PONCE MEDICAL SCHOOL FOUNDATION, INC.
PONCE RESEARCH INSTITUTE

INSTITUTIONAL REVIEW BOARD (IRB) FOR THE PROTECTION OF HUMAN SUBJECTS

STANDARD OPERATING PROCEDURES

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GLOSSARY

Regulatory and Compliance Terms

45 CFR 46 / Common Rule
Federal regulations that establish ethical standards and protections for research involving human participants, including requirements for IRB review and informed consent.

Belmont Report
A foundational document in U.S. research ethics, published in 1979, that outlines three core principles for the protection of human research participants: Respect for Persons (recognizing autonomy and protecting those with diminished autonomy), Beneficence (maximizing benefits and minimizing harms), and Justice (ensuring equitable selection and treatment of participants). The Belmont Report serves as the ethical framework for the Common Rule and IRB review.

Certificate of Confidentiality
A protection issued by the NIH or other HHS agencies that allows researchers to refuse to disclose identifiable, sensitive research information in legal proceedings, thereby protecting participant privacy.

Conflict of Interest (COI)
A situation in which a researcher's personal, financial, or professional interests could improperly influence the conduct or reporting of research.

Federalwide Assurance (FWA)
A document issued by the National Institutes of Health that helps protect researchers from being forced to disclose identifiable, sensitive information about study participants in legal proceedings or other settings.

Genetic Information Nondiscrimination Act (GINA)
A U.S. law that protects individuals from discrimination by health insurers or employers based on their genetic information, including family medical history or genetic test results.

Health Insurance Portability and Accountability Act (HIPAA)
A U.S. law that protects the privacy and security of individuals' medical and health information and sets standards for how this information can be used and shared.

Institutional Review Board (IRB)
An Institutional Review Board (IRB) is a committee that reviews and monitors research involving human subjects to ensure it adheres to ethical standards and regulations. IRBs are crucial for protecting the rights and welfare of research participants by assessing the risks and benefits of research proposals, ensuring informed consent, and overseeing research conduct.

Office for Human Research Protections (OHRP)
A U.S. federal office responsible for overseeing compliance with the Common Rule and ensuring the rights and welfare of human research participants. It provides guidance, education, and oversight to support ethical research practices.

Waiver

An IRB-approved exemption from a standard regulatory requirement, such as informed consent or documentation of consent. A waiver is granted only when specific criteria are met—for example, when the research poses minimal risk, obtaining consent is impracticable, or the waiver will not adversely affect participants' rights and welfare.

Roles and Responsibilities

Co-Principal Investigator (Co-PI)

A researcher who shares equal responsibility and authority with the Principal Investigator (PI) for the design, conduct, and oversight of a research study. A Co-PI is typically named in the grant or protocol, participates in major decisions, and is accountable for compliance with all applicable regulations, policies, and IRB requirements.

Community Member of the IRB

An IRB member who is not affiliated with the institution and is not part of the immediate family of anyone affiliated with it. The community member represents the perspective of the general public, ensuring that research reviews consider community values, participant protections, and ethical standards from outside the institution's viewpoint.

Human Protections Administrator

An institutional official or staff member responsible for managing and overseeing the organization's Human Research Protection Program (HRPP). This role typically includes ensuring IRB operations comply with federal regulations, providing guidance on ethical standards, maintaining policies and procedures, coordinating training for researchers and IRB members, and serving as a point of contact with oversight agencies such as the Office for Human Research Protections (OHRP).

IRB Administrator

A staff member who manages the day-to-day operations of the Institutional Review Board (IRB). Responsibilities typically include coordinating IRB meetings, preparing and distributing review materials, ensuring submissions are complete, communicating IRB decisions to investigators, maintaining records, monitoring deadlines for continuing review, and ensuring the IRB operates in compliance with federal regulations, institutional policies, and ethical standards.

IRB Chairperson

The leader of the Institutional Review Board, responsible for guiding IRB meetings, facilitating discussion, and ensuring reviews are thorough, fair, and compliant with regulations and ethical principles. The chairperson works closely with IRB members and staff to interpret policies, resolve review challenges, and communicate decisions to investigators. They also represent the IRB in institutional matters and may perform expedited reviews when authorized.

Key Personnel

Individuals who contribute significantly to the design, conduct, or reporting of a research study. This includes the Principal Investigator, Co-Principal Investigators, and others whose involvement is essential to the project's success, such as those responsible for participant recruitment, data analysis, or specialized procedures. Key personnel must typically be listed in the IRB application, complete required human subjects' protection training, and comply with all applicable regulations and policies.

Principal Investigator (PI)

The lead researcher responsible for the overall design, conduct, management, and reporting of a research study. The PI ensures the study complies with all applicable laws, regulations, institutional policies, and IRB requirements, and is ultimately accountable for participant safety and data integrity.

Signatory Official

An institutional leader—often the President, CEO, or designated Institutional Official—authorized to legally commit the organization to comply with federal regulations for the protection of human research participants. The signatory official signs assurances (such as the Federalwide Assurance, or FWA) and bears ultimate responsibility for the institution's Human Research Protection Program.

Human Subjects Protection Concepts

Adverse Event

Any unfavorable or unintended medical or behavioral occurrence experienced by a research participant during a study, whether it is related to the research procedures.

Serious Adverse Event

An adverse event that results in death, is life-threatening, requires hospitalization or prolongs existing hospitalization, causes significant disability or incapacity, or involves a congenital anomaly/birth defect. Serious adverse events require prompt reporting to the IRB and other relevant oversight bodies.

Assent

The affirmative agreement of a person, often a child or someone not legally able to provide full informed consent, to participate in research. Assent is obtained in addition to permission from a parent or legal guardian and ensures that the participant understands, to the extent possible, what the study involves and agrees to take part voluntarily. Mere failure to object should not be construed as assent.

Assent Form

A written document used to obtain the affirmative agreement of individuals who are not legally able to provide informed consent—such as children or those with limited decision-making capacity—to participate in research. The form is written in language appropriate to the participant's age, maturity, and comprehension level, and is used alongside the consent form signed by a parent or legally authorized representative.

Biosafety / Biosecurity

Biosafety: Practices, procedures, and containment measures designed to protect researchers, the public, and the environment from exposure to potentially hazardous biological agents or materials used in research. Biosecurity: Measures and policies implemented to prevent the loss, theft, misuse, or intentional release of hazardous biological agents or related information. Both operate under ethical and regulatory oversight to ensure safe and responsible handling of biological materials.

Community Engagement Research

A collaborative approach to research that actively involves community members, organizations, and stakeholders in the design, implementation, and dissemination of studies. This approach builds trust, ensures the research addresses community needs and priorities, and promotes mutual respect and benefit between researchers and the community.

Confidentiality

The obligation to protect participants' private information from unauthorized access, use, or disclosure. In research, confidentiality involves securing records, limiting access to identifiable data, and ensuring

that information shared in publications or reports cannot be linked to individual participants without their consent.

Consent Form

A written document that provides potential research participants with all the essential information about a study—including its purpose, procedures, risks, benefits, confidentiality protections, and the participant's rights—so they can make an informed decision about whether to participate. The consent form must be written in clear, understandable language and signed (and dated) by the participant or their legally authorized representative before participation begins.

De-Identified Data

Information that has been stripped of all direct and indirect identifiers, so individuals cannot reasonably be identified by the data alone or in combination with other available information. De-identification is done in accordance with regulatory standards (such as HIPAA) and is used to protect participants' privacy while allowing data to be analyzed or shared for research.

Emancipated Minor

An individual under the age of majority who has been granted legal independence through marriage, military service, court order, or other legal means. Emancipated minors can provide their own informed consent to participate in research without needing parental or guardian permission, in accordance with state laws and institutional policies.

Good Clinical Practice

An international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials involving human participants. GCP ensures that the rights, safety, and well-being of participants are protected, and that trial data are credible, accurate, and verifiable. Compliance with GCP is required by regulatory authorities and is a cornerstone of ethical and high-quality clinical research.

Human Subject

A living individual about whom a researcher obtains information or biospecimens through intervention or interaction and uses, studies, or analyzes them, or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. Human subjects are protected under federal regulations to ensure their rights, safety, and welfare are upheld during the research process.

Human Subjects Research

Any research activity involving living individuals from whom information is obtained through interaction/intervention or identifiable private information.

Identifiable Data

Information that can directly or indirectly identify a specific individual, either alone or when combined with other available data. Examples include names, addresses, Social Security numbers, medical record numbers, or unique personal characteristics. In research, identifiable data require heightened protections to safeguard participant privacy and confidentiality.

Information Privacy Security

The policies, procedures, and technical measures used to protect research participants' personal and sensitive information from unauthorized access, use, disclosure, alteration, or destruction. Privacy focuses on controlling access to personal data, while security ensures the confidentiality, integrity, and availability of that data through safeguards such as encryption, secure storage, access controls, and staff training.

Informed Consent

A process in which a potential research participant is given comprehensive information about a study—including its purpose, procedures, potential risks and benefits, confidentiality protections, and the voluntary nature of participation—and has the opportunity to ask questions before deciding whether to take part. Informed consent must be obtained before participation begins and documented, typically with a signed consent form, unless the IRB has approved a waiver or alteration.

Minimal Risk

The likelihood and magnitude of harm or discomfort anticipated in the research are no greater than those ordinarily encountered in daily life or during routine physical or psychological tests. This is a key threshold in determining the level of IRB review and the protections required for participants.

Privacy

An individual's right to control access to themselves and their personal information. In research, privacy refers to how investigators collect, access, and handle information about participants, as well as the settings and circumstances under which interactions or data collection occur, to ensure individuals' dignity and personal boundaries are respected.

Research

A systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. This includes studies involving humans, animals, or data, and can involve observation, surveys, experiments, or analysis of existing information. In the context of IRB oversight, research typically refers to activities involving human subjects that require review to ensure ethical conduct and participant protection.

Responsible Conduct of Research

The practice of conducting research with integrity, transparency, and adherence to ethical, professional, and regulatory standards. RCR encompasses areas such as data management, authorship, peer review, conflict of interest, human and animal subject protections, mentorship, and the reporting of research findings. Its goal is to promote credibility, accountability, and public trust in the research enterprise.

Sensitive Topic

A subject in research that may cause discomfort, distress, or potential risk to participants if discussed or disclosed. Examples include questions about sexual behavior, substance use, illegal activities, trauma, mental health, or other deeply personal matters. Research on sensitive topics requires careful design to protect participants' privacy, ensure confidentiality, and minimize potential harm.

Special Population

Groups of individuals who may require additional protection in research due to legal status, health conditions, or social circumstances. Examples include children, prisoners, pregnant women, individuals with cognitive impairments, and other groups identified in federal regulations or institutional policy. Research involving special populations must include safeguards to address their specific needs and ensure their rights and welfare are protected.

Vulnerable Population

Groups of individuals who may be at increased risk of coercion or undue influence in research due to limited autonomy, social, economic, or educational disadvantages, or medical conditions. Examples include children, prisoners, pregnant women, individuals with cognitive impairments, and economically or educationally disadvantaged persons. Extra safeguards are required to protect their rights and welfare in research studies.

IRB Review Processes and Types

CITI Certification

Training provided through the Collaborative Institutional Training Initiative (CITI Program) to educate researchers, IRB members, and research staff on topics such as human subjects' protection, Good Clinical Practice (GCP), the responsible conduct of research, and other compliance areas. CITI certification demonstrates completion of required modules and ongoing competency in ethical and regulatory standards for conducting research.

Continuing Review

A periodic evaluation conducted by the IRB to ensure that an ongoing research study continues to protect participants' rights and welfare, remains compliant with approved protocols, and adheres to federal regulations and institutional policies. Continuing review typically occurs at intervals determined by the level of risk and may involve full board, expedited, or administrative review.

Cooperative Research / Single IRB

The single Institutional Review Board designated to review and oversee a multisite research study on behalf of all participating sites. The Single IRB model streamlines the review process, reduces duplication, and ensures consistent ethical oversight across locations, while each site remains responsible for local context considerations, participant protections, and regulatory compliance.

IRB Review

An IRB review is the process by which an Institutional Review Board (IRB) evaluates a research study involving human participants to ensure it is ethical and protects participants' rights and welfare.

Exempt Review: A category of IRB review for research involving minimal risk that fits specific regulatory criteria (45 CFR 46.104). Studies under exempt review typically involve anonymous or de-identified data and require simplified oversight, as they are not subject to the full Common Rule requirements. While still reviewed by the IRB, these studies receive a streamlined evaluation to ensure ethical standards are maintained.

Expedited Review: A type of IRB review for research involving minimal risk that can be reviewed by one or a few IRB members instead of the full board.

Full Board Review: A type of IRB review conducted by the convened IRB when a study involves more than minimal risk or does not qualify for exempt or expedited review. The entire IRB committee participates in evaluating the research protocol to ensure it meets ethical standards and regulatory requirements, with particular attention to participant safety, informed consent, and risk–benefit balance.

Protocol Amendment / Modification

A formal change or addition to an approved research protocol. Amendments can involve modifications to study procedures, recruitment methods, consent documents, or other aspects of the research. All amendments must be reviewed and approved by the IRB before implementation to ensure continued compliance with ethical standards and regulatory requirements.

Protocol Closure

The formal process by which an IRB-approved research study is concluded. Protocol closure occurs when the study has ended, all participant activities are complete, and data collection is finished. The closure ensures that the IRB's oversight is officially ended, records are finalized, and any remaining regulatory or reporting obligations are met. Note that a protocol closure does not affect an investigator's

ability to write articles or publish. Should the investigator decide future contact is needed with the participants or collect additional data, they must notify the IRB.

Streamlyne

An electronic research administration platform used by institutions to manage the full lifecycle of sponsored projects. Streamlyne supports functions such as proposal development and submission, budget creation, compliance tracking (including IRB and IACUC), award management, and reporting, helping ensure efficiency, transparency, and regulatory compliance in research administration.

Additional Key Concepts

Anonymity

The condition in which research participants' identities are not known to the researchers and cannot be linked to the data collected. Anonymity protects participants' privacy by ensuring that responses or information cannot be traced back to any individual.

Compensation

A payment or other form of reimbursement provided to research participants for their time, effort, inconvenience, or expenses incurred while participating in a study. Compensation must be appropriate, not coercive, and clearly described in the informed consent process. It is not considered a research benefit.

Data Management and Sharing Plan

A structured document outlining how research data will be collected, stored, protected, and shared, in compliance with institutional and sponsor requirements.

Data and Safety Monitoring

A systematic process for overseeing the safety of participants and the integrity of data in a research study. This includes tracking adverse events, monitoring study progress, ensuring compliance with the protocol, and implementing corrective actions if risks or issues arise. The level of monitoring is proportional to the study's risk and may be conducted by the study team, an independent committee, or an external board.

Deception / Incomplete Disclosure

A research practice in which participants are intentionally misled or not fully informed about certain aspects of a study, such as its true purpose or procedures, typically to prevent bias or influence on behavior. This approach is only permissible under specific IRB-approved conditions, must be ethically justified, pose minimal risk, and include a debriefing process in which participants are fully informed about the study's true purpose as soon as possible.

Noncompliance

The failure to follow applicable laws, regulations, IRB-approved protocols, institutional policies, or ethical standards for the protection of human research participants. Noncompliance can be classified as minor or serious and may result in corrective actions, reporting requirements, or sanctions to ensure participant safety and maintain regulatory compliance.

Suspension or Termination of Research

The temporary or permanent halt of a research study by the IRB or institution due to concerns about participant safety, serious noncompliance, ethical violations, or other significant risks. Suspension is a temporary stop, often pending corrective actions or review, while termination is a permanent cessation

of all study activities. Both actions are intended to protect participants and ensure adherence to regulatory and ethical standards.

Tissue Repository / Biobank

A facility or organized collection that stores human biological specimens, such as blood, tissue, or DNA, along with associated data for use in current or future research. Biobanks ensure proper handling, storage, and documentation of samples, protect donor privacy and confidentiality, and operate under ethical and regulatory oversight. They often require consent for the collection, storage, and use of specimens in research.

Introduction

The Ponce Medical School Foundation (PMSF) Institutional Review Board (IRB) for the Protection of Human Subjects was established to ensure that PMSF complies with all federally mandated regulations which govern research involving human subjects' protection. PMSF's policy is to protect the rights and welfare of all human volunteers who participate in research activities conducted under the auspices of PMSF.

Definitions

The IRB has adopted the definitions used by the United States (U.S.) Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) and the 45 Code of Federal Regulations (CFR) 46 to guide their operating procedures:

- *45 CFR 46* – CFR Title 45 Public Welfare, Part 46 Protection of Human Subjects or the Common Rule is a federal policy that guides the conduct of research involving human subjects.

- *Federal wide Assurance (FWA)* – The FWA is documentation of an institutional commitment to comply with federal regulations and maintain adequate programs and procedures for the protection of human subjects participating in research. It is the principal mechanism for compliance oversight by OHRP.

- *Human subject* – A human subject is a living individual about whom an investigator (whether professional or student) conducting research obtains:
    - Information and/or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information and/or biospecimens; or
    - Obtains, uses, studies, analyzes, or generates identifiable private information and/or identifiable biospecimens.

- *Research* – Research is a systematic investigation, including research development, testing, and evaluations, designated to develop or contribute to generalizable knowledge production [OHRP § 46.102(d)].

- *Institutional Review Board (IRB)* – A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

Institutional Responsibilities

The PSMF IRB is certified by the Office for Human Research Protections (OHRP) with an Assurance Number ***FWA 00000345***. The PMSF IRB Registration number is ***IRB 00001027***. Research that includes identifiable clinical information must also abide by the Health Insurance Portability and Accountability Act (HIPAA) that establishes national standards for the protection of individually identifiable health information. Additionally, the PMSF IRB will comply with the laws and regulations of the Commonwealth of Puerto Rico, including Article II of the Bill of Rights that emphasizes the inviolability of human dignity, equality before the law, and the right to privacy.

A. Federal Wide Assurance (FWA)

The FWA is required for all DHHS funded research involving human subjects. It is a formal commitment made by an institution to provide for the protection of human subjects participating in research. PMSF assures that all its activities related to human subjects' research, regardless of the source of support, will be guided by the ethical principles in the Belmont Report[1].

- *Respect for Persons* – Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. individuals should be recognized as autonomous human beings, capable of making informed decisions about their participation in research. For those who do not have full autonomy—such as children, individuals with cognitive impairments, or those facing coercive circumstances, researchers must implement safeguards to ensure their rights and welfare are protected. This principle underlies the ethical requirement for informed consent, ensuring that participation in research is voluntary and based on a clear understanding of the risks, benefits, and purpose of the study.
- *Beneficence* – Persons who participate in research must be treated ethically—not only by respecting their autonomy and protecting them from harm, but also by actively promoting their wellbeing This includes adhering to the principles of *nonmaleficence* (do no harm) and *beneficence* (maximizing potential benefits while minimizing possible risks).
- *Justice* – The ethical principle that requires the equitable distribution of the burdens and benefits of research. This means that no group should bear an unfair share of the risks, and that the benefits of research should be accessible to all populations, especially those who have historically been underrepresented or disadvantaged.

PMSF ensures that whenever researchers engage in human subject research, they comply with the terms of the FWA for U.S.-based institutions (as outlined in a separate document on the OHRP website), unless the research is exempt from the Common Rule or a sponsoring department or agency has determined that the research will be governed by a separate assurance.

B. Institutional Oversight

Within the institution, a designated official must hold responsibility for the oversight of IRB functions. This individual should have the legal authority to represent the institution and must be capable of ensuring that the institution effectively fulfills its obligations in research oversight.

According to OHRP, the ***Signatory Official***, is responsible for "setting the tone for an institutional culture of respect for human subjects". The designated Signatory Official is the President of the PMSF.

The ***Human Protections Administrator*** serves as the primary contact for DHHS OHRP and holds administrative responsibility for PMSF's Human Protections Administration. This role includes ensuring that human subjects involved in research are adequately protected and that PMSF remains in full compliance with applicable regulations.

[1] ORI: The Protection of Human Subjects - Belmont Report

The ***Chairperson*** of the IRB is responsible for providing leadership and ensuring the effective operation of the IRB. Key responsibilities include presiding over IRB meetings, guiding discussions during protocol reviews, and ensuring compliance with applicable ethical standards and regulatory requirements. The Chairperson upholds the principles of respect for persons, beneficence, and justice, as outlined in federal regulations and institutional policies. In addition, the Chairperson serves as a resource for IRB members, researchers, and institutional officials, promoting a culture of integrity and ethical oversight in all research involving human subjects.

Investigator's Responsibilities

A. Principal Investigator

The **Principal Investigator (PI)** is the individual with primary responsibility for ethical conduct, regulatory compliance, and scientific oversight of a human subject research protocol. Given the level of responsibility and accountability involved, the PI must be a qualified faculty member or professional with appropriate institutional credentials. This typically includes individuals affiliated with a clinical department of a hospital, a medical school, or an academic research program who have the authority and experience to oversee human subject research.

Students and trainees may serve as Co-Principal Investigators (Co-PIs) or Key Research Personnel. They are expected to play significant roles in the design and conduct of the research, particularly when the research supports a dissertation or capstone project. While trainees (including doctoral students, residents, and postdoctoral fellows) are often referred to as "PIs" in the context of fellowship or training grants (e.g., NIH F31 or F32 awards), the responsibilities of a PI in human subject research involve ethical and regulatory oversight that requires experience and institutional authority. For this reason, PHSU students and professionals in training may not serve as PIs on IRB protocols. This policy is intended to ensure that a qualified faculty member or professional is accountable for the protection of human subjects, data integrity, and compliance with institutional and federal regulations.

B. Investigator Responsibilities

To support clarity and compliance, investigators, whether faculty or trainees—must adhere to the following:

- Submit complete and accurate IRB applications and amendments.
- Report unanticipated problems and adverse events in a timely manner (refer to bullet G).
- Maintain accurate and secure research records and informed consent documents.
- Complete required human subject protection training prior to engaging in the research

C. Training Courses

All Principal Investigators and key research personnel must complete the required human subjects' protections training prior to initiating any research activities. Proof of training in the form of a valid certificate must be supplied with the IRB application. IRB applications that do not include this documentation will be considered incomplete and returned without review. PMSF is affiliated to the "Collaborative Institutional Training Initiative (CITI Program) which provides online training for faculty, students, collaborators and staff (citiprogram.org). Other

equivalent certificates will be evaluated on a case-by-case basis. Training certificates are valid for three years.

Training courses available include:

- Human Subject Research
- Good Clinical Practice
- Good Laboratory Practice
- Biosafety-Biosecurity
- Animal Care and Use
- Information Privacy Security (Does not expire)
- Responsible Conduct of Research
- Social and Behavior Research Basic/Refresher
- Biomedical Basic Refresher/Research

Investigators can refer to the PRI website to assess which courses are applicable to their research projects: IRB CITI Program - Ponce Research Institute

D. Submitting Protocols for Approval

All investigators must obtain IRB approval for each research protocol involving human subjects prior to initiating the study (also refer to Section VI. *THE IRB Review Process)*. Protocols submitted without all the required documentation will not be reviewed. Investigators can follow the next steps presented below:

All IRB submissions must be made electronically through the Streamlyne System
Streamlyne is an efficient online system for faster review and online approval. Investigators are strongly encouraged to carefully review the submission guidelines, ensure that all the IRB questions directly related to the protocol needs are answered thoroughly and save responses frequently.

For instructions on how to log in to Streamlyne visit IRB: Streamlyne - Ponce Research Institute

If the investigator is not an employee at PHSU and would like to have access to Streamlyne, they must send their complete name, email, phone number and institution name to IT Administrative Support (Streamlyneirb@psm.edu).

For more information, visit IRB - Ponce Research Institute website.

E. PMSF IRB Rules and Regulations

- The IRB provides the required templates for consent and assent form (if applicable). All supplemental material (flyers, posters, questionnaires, interview scripts, advertisements) must be submitted in both English and Spanish. These forms must be written in simple language, at an eighth (8^{th}) grade reading level.
- Valid certificates of Human Subjects training and Information Privacy Security (IPS does not expire) must be summitted as part of the protocol. Applicable courses will vary according to each project. Visit CITI Program additional details.
- Children are defined as less than <21 years old in Puerto Rico. In the continental US, each state determines the definition of minors. Investigators are responsible for researching relevant local laws and regulations.

- In Puerto Rico, individuals between the ages of 18-21 years who are legally married are considered emancipated and may provide their own consent for participation in research. However, marriage under the age of 18 does not confer full emancipation**,** and such individuals are still considered minors for the purposes of legal consent.
- If any vulnerable population (children, prisoners, etc.) is included or excluded as subject in a study, a specific reason for their inclusion/exclusion should be stated.
- All advertisements must be approved in advance by the PRI Marketing Officer Ms. Paula Lugo, palugo@psm.edu
- Overemphasis of benefits to the subjects in the advertisement or consent form is considered coercion.
- Payment is not considered a benefit and must not be included in the Benefits section, but rather in the compensation section. Any form of payment should not be included in the promotional materials.

When using a pro-rated mechanism of payments in the case of longitudinal studies, participants may receive part of the incentives, but not the final one if they do not complete the study)

- Research activities involving institutions and agencies outside of PMSF must receive written approval from their appropriate ethical committee. The IRB protocol and letter of approval must be submitted with the IRB application.

- Justification of exclusion criteria for specific individuals or groups must be provided in the application**.** Investigators should describe the scientific, ethical, or safety reasons for excluding certain populations. For example, pregnant individuals may be excluded from a clinical drug trial due to unknown risks to the fetus, or non-English speakers may be excluded if the study materials are not yet available in other languages and accurate translation is essential to informed consent. Exclusion should never be based solely on convenience or bias and must be grounded in a valid research rationale.

- Note the difference between anonymity and confidentiality. An anonymous study does not collect any information that may identify the participant – there is no way to link data back to individual subjects. In contrast, if personal or identifiable information will be collected, the study is not anonymous, and the investigator must clearly explain the measures that will be taken to protect participant's privacy and ensure the confidentiality of their data (e.g., secure data storage, limited access, coding or de-identification procedures).

F. Amendments/Changes to Protocol already approved

The Principal Investigator must promptly report any proposed modifications to approved studies by submitting an amendment to the IRB. This must include a cover letter summarizing the proposed changes, the revised consent forms, new letters of support, and new CITI Certificates (if new personnel are added). No changes to the study may be initiated prior to IRB review and approval of the amendment. Certain modifications—such as changes to study design, risk level, or participant population— may require full IRB review.[2]

Visit the IRB - Ponce Research Institute webpage for instructions on how to submit amendments.

[2] Streamlyne Website

G. Continuing Review (protocols already approved)

All protocols approved by the IRB must undergo continuing review **at least once per year** to maintain approval. At the time of renewal, investigators are required to log in to Streamlyne, select renewal, complete the questionnaire and submit the following information:

- A letter requesting renewal with or without amendment, and significant changes.

Visit the IRB - Ponce Research Institute for instructions on how to submit a Continuing review. These reviews are evaluated by the IRB Chairperson and referred to the committee as needed.

H. Safety Mailing Reports Submission:

The IRB is responsible for reviewing all reports of adverse events or unanticipated problems involving risks to subjects or others. These events must be reported promptly, within seven calendar days of the investigator becoming aware of the issue. However, if a protocol deviation was made to eliminate an immediate hazard to a participant, it must be reported within 24 hours:

A summary page with the Serious Adverse Event must include:

- Patient's coded ID number
- Date of report
- Kind of report (i.e. Initial, follow-up 1, etc.)
- Adverse event description
- Opinion of Investigator whether the adverse event is protocol related. It is very important to write an opinion about the adverse events that are probably or possibly related to the study drugs/intervention and what steps being taken to minimize risks to patients.

Visit the IRB - Ponce Research Institute for instructions on how to submit a Serious Adverse Event Report.

I. Processing Fees

Protocols supported by private entities or pharmaceutical companies, the PMSF IRB will collect a processing fee from the Principal Investigator or the sponsoring entity (at the time of submission). The ultimate responsibility for payment relies on the PI.

IRB fee per protocol submitted:

Full review	$2,500.00
Fast-track review	$3,500.00
Full review Renewal fee	$1,200.00
Expedited review	$1,500.00
Exemption review	$500.00
Expedited review renewal	$750.00
Amendments	$500.00

J. Informed Consents

Investigators must provide a copy of the IRB-approved informed consent form each participant at the time of consent. All documentation must be stored as outlined in the IRB application in a secure location (paper documents, file cabinets with restricted access, secure cloud platforms) for at least three years after the completion of the study.

The Institutional Review Board (IRB) for the Protection of Human Rights

A. IRB Authority/Jurisdiction

In accordance with federal guidelines, the IRB has the authority to approve, request modification, or reject proposed human research studies and authority to modify or disapprove of ongoing studies.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head *(45 CFR 46.113).*

B. Composition

According to federal policy, *45 CFR 46.107,* the IRB committee must include at least five members with diverse backgrounds regarding race, gender, cultural background, professional expertise, and representation of different communities. The committee must include:

- **At least one member with a primarily scientific background**
- **At least one member with a primarily non-scientific background**
- **At least one member unaffiliated with PMSF**, and not an immediate family member of someone affiliated with the institution

This diversity is intended to promote balanced, unbiased reviews of research protocols and ensure representation of varied perspectives in the decision-making process. A list of current IRB members must be submitted to OHRP and kept with the IRB's records *(45 CFR 46.103(b)(3) & 46.115 (a)(5).* **The list must identify members by name, earned degrees, representative capacity, indications of experience (such as board certifications and licenses) sufficient to describe each member's chief's anticipated contributions to IRB deliberations,** and any employment or other relationship between each member and the institution (i.e., full-time employee, stockholder, unpaid consultant, or board member). Any changes in the IRB membership must be reported to the head of the department or agency supporting or conducting the research unless the department or agency has accepted the existence of a DHHS-approved Assurance *(45 CFR 46.103(a)).* In the latter case, changes in membership are to be reported to OHRP *(45 CFR 46.103(b)(3) and 46.115(a)(5).* The composition of the PMSF IRB committee is available at the IRB - Ponce Research Institute webpage.

C. IRB Member Considerations

The IRB can have as many members as necessary for it to perform its duties effectively. Care should be taken, however, to ensure that it does not become so large that its management becomes cumbersome.

The nonaffiliated (community) members of the IRB should be drawn from the local community-at-large. The persons selected should be knowledgeable about the local community. The nonaffiliated member(s) should not be vulnerable to intimidation by the other members of the IRB, and their services should be fully utilized by the IRB.

An investigator can be a member of the IRB; however, without exception, the investigator-member cannot participate in the review and approval process of any project for which there is a present, potential or perceived conflict of interest. Where there is a conflicting interest, the investigator-member should be present only to provide information requested by the IRB. The investigator-member should be absent from the meeting room during the discussion and voting phases of the review and approval process. IRB minutes should reflect whether these requirements have been met.

If the IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, the IRB must consider the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues, which require expertise beyond or in addition to that available on the IRB. **These individuals will not vote**.

D. Member Appointment

IRB members are appointed by the President of Ponce Medical School Foundation, Inc.. Appointments are made on a yearly basis. IRB members must complete required Human Subject Research training (e.g., CITI Certification for IRB members) and must report any conflict of interest (COI) on an annual basis, following institutional guidelines.

E. IRB Member Responsibilities

IRB Members shall:

- Complete all the required human subject protection educational trainings before beginning their appointment.
- Attend workshops and other educational opportunities focused on IRB functions should be encouraged and supported to the extent possible.
- Keep updated with an understanding of the ethical principles of human participant research, federal regulations, applicable state laws, PMSF FWA and institutional policies and procedures for the protection of human participants.
- Review and criticize each proposal submitted and present a summary critique at the IRB meeting.
- Should be absent from the meeting room (or videoconference) during discussion, voting or continuing review of a study when he/she has a conflict of interest (COI). The IRB member may be required, however, to provide information to the IRB about such projects as necessary.

- Keep all information always related to the discussions of specific research studies in strict confidence.
- Notify the IRB Chair when he/she will not attend an upcoming IRB meeting in a timely manner.
- Maintain a good attendance record. Three consecutive unexcused absences or less than 50% attendance/year will disqualify the person's membership. Members may also be removed by the President of PMSF at any time, given written notice, for due cause (i.e. failure to meet IRB responsibilities, failure to meet educational requirements for human participant research, ethical misconduct, disregard for federal regulations or PMSF policies).

F. Selection/Responsibilities of the Chairperson

One of the most important actions to be taken in establishing the IRB is selecting the individual who will function as a chair. The IRB chairperson should be a highly respected individual from within or outside the institution, fully capable of managing the IRB and the matters brought before it with fairness and impartiality.

The task of making the IRB a respected part of the institutional community will fall primarily on the shoulders of this individual. The IRB must be perceived to be fair and impartial, immune from pressure either by the institution's administration, the investigators whose protocols are brought before it, or other professional and nonprofessional sources.

Duties of the chair:

- Ensures the PMSF and Federal and Commonwealth of Puerto Rico rules are being considered as the committee reviews the planned research proposals.
- Be familiar with every protocol that comes before the committee and have a thorough knowledge of policy.
- Be responsible for directing the IRB committee meetings to ensure that the meetings proceed as planned on the agenda.
- Decide if a protocol is "exempt" from full board review.
- Review & approve (with the input of two other IRB members) research that can be identified within federal guidelines as "expedited" because it involves "no more than minimal risk" to a person who may consent to participate or if there is a small change in a previously approved protocol.
- Review and approve or disapprove of any resubmissions of protocols deemed "approval pending clarification/modification" by the full IRB only when the convened IRB has stipulated specific revisions requiring simple consensus by the investigator.
- Identify and assign lead reviewers for protocols to be reviewed by the full board.

G. IRB Administrator Responsibilities

The IRB Administrator will work closely with the IRB Chair in matters of developing policy for IRB Committee meetings. The Administrator must have a thorough understanding of federal policy and must work daily to ensure that the PMSF remains in compliance with all applicable federal regulations. A major responsibility is to triage the proposals received into the categories of IRB review (exempt, expedited, or full committee review).

Record Keeping: The office of the IRB Administrator must prepare and maintain adequate documentation of IRB activities. In addition to the written IRB procedures and membership

lists required by assurance process, such documentation must include copies of all research proposals, reviewed, minutes of the IRB meetings, records of continuing review activities, copies of all correspondence between the IRB and investigators, and statement of significant new findings provided to subjects.

H. Alternate Members

From time to time, as needed, alternate members may be appointed as regular voting members(s). The appointment of an alternate member shall be based on expertise like that of the regular voting member(s). An alternate member may vote only when the regular voting member is absent.

I. IRB Meetings

The IRB will meet once a month in person or by video conference (secure platform), as needed, to review, discuss, and vote on submitted protocols. If there are no protocols to review in any given month, the IRB is not required to meet. From time to time, if there are no protocols to review, the IRB may decide to meet to keep updated on the expedited and exempt protocols that were received. One week prior to each meeting, members will receive submitted protocols for preliminary review. In addition, each IRB member will receive the location, time, and date of the meeting.

During the convened meeting, a majority (>50%) of the members of the IRB must be present including at least one scientist, one nonscientist, and one community member. If the required number of members is lost during a meeting, no further action may be taken until it is restored. For research to be approved, it must receive the approval of a majority of the voting members present at the meeting.

Minutes of IRB meetings will include attendance, actions taken by the IRB, voting on these actions including the number of members voting for, against, and abstaining, the basis for requiring changes in or disapproving research, and a written summary of the discussion of controverted issues and their resolution. Voting is conducted independently and anonymously on the Streamlyne platform. If a conflict of interest (COI) exists for IRB members, the platform blocks access to the voting system.

The IRB will make one of the following determinations regarding an application:

- **Approved as is,** without questions, concerns or requests for modifications
- **Specific minor concerns –** Clarification and/or modification of minor or substantial specific points of components of the application is needed. The research activity may not be undertaken until the IRB's concerns are addressed and submitted to the designated IRB member or review by full committee, according to the level of risk, and approval after clarifications are evaluated.
- **Substantive concerns –** This indicates approval by the IRB has been withheld as substantive concerns or significant requests for clarification have been raised and/or the proposed research does not meet PMSF or federal or Puerto Rico guidelines for the protection of human participants. The research activity may not be undertaken until the IRB's concerns are addressed and submitted to the full IRB for review and approval.
- **Not approved –** The IRB may disapprove of a proposed activity with serious and substantive problems and/or that fails to meet PMSF, Federal, or Puerto Rico guidelines for the protection of human participants.

IRB approval of a research protocol is usually granted for one year starting from the date of the convened meeting of the IRB at which the protocol was reviewed and approved. However, based on the degree of risk to human participants, the IRB may impose special conditions such as a shorter approval period or a requirement for progress at specified intervals. Continuation of projects beyond its approval period requires project continuation review and approval by the IRB chair or designee.

The IRB Review Process

A. Review Requirements

The IRB chair or his/her designees will determine whether a given study/protocol can be considered human participants' research based on the federal definition of "research".

The IRB Chair or his/her designees will also determine if certain categories of research involving minimal risk to participants meet one of the federal categories for expedited review. In these cases, the IRB chair or his/her designee will review the study through expedited review procedures, and the entire board need not review the study.

Minimal risk – Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

The three basic ethical principles – Respect for Persons, Beneficence, and Justice – set forth in the Common Rule (45CFR46) and *The Belmont Report*, shall guide the IRB in its review.

1. Respect for Persons

- Where appropriate, the IRB should require adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

- In accordance with *45 CFR 46.111(b)*, when some or all the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, the IRB shall determine whether additional safeguards have been included in the research to protect the right and welfare of these participants.

- The investigator shall seek informed consent from each prospective participant or the participant's legally authorized representative in accordance with and to the extent required by *45 CFR 46.116*, and such consent shall be appropriately documented, in accordance with, and to the extent required by *45 CFR 46.117* and retained as a matter of record.

- When research involves more than minimal risk or substantial stress or discomfort, such risk, stress or discomfort shall be carefully explained to the participant before his or her participation and justified by the expected benefits of the research.

- A participant shall have the right to withdraw from a research project at any time or to refuse to participate without loss of benefits to which the individual would otherwise be entitled. In addition, a participant shall have the right to appropriate professional

care, to privacy and confidentiality in the use of personal information, and to freedom from undue embarrassment, discomfort, anxiety, and harassment.

2. Beneficence

- Direct or potential benefits to the participant or the importance of knowledge to be gained shall not preclude the consideration of the inherent risks to the individual.

- The IRB will consider the qualifications of the investigator, his or her professional development, and experience when assessing the degree of risk to participants in the research project. This assessment applies to research that may fall within all categories of IRB review.

- Research plans should make adequate provision for monitoring the data collected to ensure the safety of participants, where necessary.

- Risks to participants shall be minimized by using procedures that are consistent with sound research design.

- Risks to participants shall be reasonable in relation to the anticipated benefits, if any, and the importance of knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits participants would receive even if they were not participating in the research). The IRB shall not consider the long-range effects of applying knowledge gained in the research as among those research risks that fall within the purview of its responsibilities.

3. Justice

- Selection of participants should be equitable. When appropriate, every effort shall be made to include participants of diverse ages, race, gender, and ethnicity.

- The IRB shall ensure that compensation or inducement offered for participation in a study is made appropriately, with participants fairly recruited and adequately informed rather than unduly influenced by promised compensation. Financial incentives should not be so great as to be coercive to potential participants and should constitute reasonable compensation for the inconvenience of participating. Information related to compensation shall be included in the informed consent form.

- Involvement of human participants in research will not be permitted until the IRB has reviewed and approved the IRB protocol and documents (informed consent forms, flyers, etc.).

- It is the principal investigator's responsibility to obtain approval from the IRB prior to the initiation of any research activity, including pilot or pre-test studies, involving the use of human participants.

- The investigator should ensure that consent for participation is sought prior to any research activity, and only under circumstances that minimize the possibility of coercion or undue influence. Subject participation must be voluntary, and the subject should be able to withdraw from the study at any time without penalty.

- A copy of the signed consent form, in hard copy or electronic, must be provided to participants.

B. Criteria for IRB Approval of Research

(45 CFR 46.111) (a) to approve research covered by this policy the IRB shall determine that all the following requirements are satisfied:

- Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design, and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

- Selection of subjects is equitable. In making this assessment the IRB should consider the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by *45 CFR 46.116*.

- Informed consent will be appropriately documented, in accordance with, and to the extent required by *45 CFR 46.117*.

- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain confidentiality of data.

C. Levels of Review

1. Exempt Review

The following research activities are considered exempt from federal regulations as stated in *45 CFR 46.104:* Unless otherwise required by law or by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques curricula, or classroom management methods.

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, **unless**:

    - Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; or

    - Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

    - The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by *46.111.*

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is **not exempt under paragraph if:**

    - The human subjects are elected or appointed public officials or candidates for public office; or

    - Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

- Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

- Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

- Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

- Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food and Inspection Service of the U.S Department of Agriculture.

2. Expedited Review

Expedited review categories of research shall comply with "Categories of Research That May be Reviewed by the IRB through an Expedited Review Procedure" *45 CFR 46.110*.

- Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture follows:
    - From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
    - From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period, and collection may not occur more frequently than 2 times per week.

- Prospective collection of biological specimens for research purposes by noninvasive means.

- Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).

- Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

- Collection of data from voice, video, digital, or image recordings made for research purposes.

- Research on individual or group, characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, or oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

- Continuing review of research previously approved by the convenient IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

- Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

The IRB may use the expedited review procedures to review minor changes in previously approved research during the period for which approval is authorized.

The expedited review procedure is carried out by the IRB chair and his/her designees.

In reviewing the research, reviewers may exercise all the authorities of the IRB except the reviewers may not disapprove of the research. Disapproval of a research application requires most of the full IRB.

At a convened IRB meeting, members may request that certain protocols be approved by the IRB in accordance with full board review procedures. A vote of the members shall be taken concerning the request, and the majority shall decide the issue. A PI may also request that an application receive full board review.

The IRB Chair shall review amendments for previously approved research which can be approved under an expedited review procedure.

3. Full Board Review

All proposed research deemed by the IRB chair based on federal regulations (Common Rule) to fit neither the exempt nor expedited review must be reviewed by the full IRB. In addition, the IRB may require full review of any research submitted or approved under expedited review and any research not approved by expedited review.

The primary criteria for full board review are the risk to participants during the procedures and interactions between participants and researchers.

Examples of research activities that must be reviewed by the full IRB include:

- Research in which potential participants may not be given sufficient information to make decisions about whether to participate and accept potential risks. This may include research in which outright deception or incomplete disclosure of the purpose of the study might reasonably affect a person's decision to participate in the study.

- Research involving more than minimal risk, where defined as "the probability and magnitude of harm or discomfort are not greater in and of themselves than those ordinarily encountered in the daily life or during the performance of routine physical psychological examinations or tests."

- Non-curricular, interactive research in primary and secondary schools.

- Research in which participation per se in the study constitutes a risk (i.e. identification as a participant in a drug-use survey). This would include research in which researchers have applied for a waiver of documentation of consent, which can be used as a method of reducing risks to participants who may be placed at a risk simply by being involved in the study.

- Research on special populations, i.e., minors, prisoners, pregnant women, and mentally incompetent persons.

- Research involving potential risks to participants' right to privacy and/or threats to confidentiality.

4. Continuing Review

For studies that need extended time (>1 year after approval) the investigators are required to submit a continuing review questionnaire to the IRB before the expiration date of the study. This questionnaire will be used to re-evaluate IRB protocols at appropriate intervals, not less than **once a year.** The approval period is generally one year from the date of the approval letter.

An original protocol may have received an expedited review, but the continuing review may go to the full IRB, as deemed necessary by the IRB Chair or a designee.

Continuing review is required for continued analysis of identifiable information but is <u>not required</u> if the data have been de-identified.

- For new analysis of previously collected identifiable data, a new IRB protocol is required.
- For a new analysis of previously collected de-identified data, no IRB review is required.

5. Case Studies

A ***Case Study*** is understood to mean the collection and presentation of detailed information about a particular participant or small group, frequently including the accounts of subjects themselves. A form of qualitative descriptive research, the case study looks intensely at an individual or small participant pool, drawing conclusions only about that participant or

group and only in that specific context. It may involve collecting data about participants using participant and direct observations, interviews, protocols, tests, examinations of records, and collections of writing samples. Case studies may also involve either retrospective or prospective studies. A *retrospective case study* looks backwards looks backwards and examines the incidence of certain factors in relation to an established outcome. A *prospective case study* looks forward to and examines a particular individual or case for a particular outcome that may be associated with the presence/absence of relevant factors.

IRB Review of Case Studies: Case studies generally fail to meet the federal definition of research because there is no intent to test a hypothesis via systematic analysis. As a result, case studies generally qualify for exempt review by the IRB provided that the study (a) does not involve a sensitive topic, (b) is conducted in a manner that protects subjects' identity, and (c) does not involve at risk or special populations. A listing of privacy issues and special populations is provided below. Case studies that include (a), (b) or (c), will be evaluated by the committee.

Subject private and/or medical identifiers: Exempt studies may not include any of the following identifiers (see Privacy Rule [45 CFR46.514(B)(2)]).

- Names
- All elements of dates (except year) for dates related to an individual, including birth date, admission date, discharge date, or date of death.
- All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes.
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social security number
- Medical record numbers
- Health Plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic or code

Special populations: Exempt studies may not include participants from any of the following protected groups:

- Pregnant women, human fetuses, and neonates [45 CFR 46 Subpart B]
- Prisoners [45 CFR 46 Subpart C]
- Children [45 CFR 46 Subpart D]

IRB Review of "N of one" Studies and Case Series with Data Manipulation: It is noted, however, that an "N of one" trial that uses an experimental treatment on a single subject, or a case series that incorporates levels of data manipulation (statistics) to allow possible

extrapolation of the results to a larger population, would satisfy the federal definition of research. As such, these studies must be submitted to the IRB for expedited or full board review.

Community Engagement in Research (CEnR)

Investigators are encouraged to engage community stakeholders in the design, implementation, dissemination, and interpretation of research, particularly when the research involves underrepresented or vulnerable populations. Community engagement can take many forms, including stakeholder interviews, town halls, focus groups, or advisory panels.

Use of Community Advisory Boards (CABs)

For studies involving significant interaction with the community or public health interventions, the IRB recommends the formation of a Community Advisory Board (CAB) to:

- Review and advise on study design, recruitment, and consent procedures.
- Help ensure cultural relevance and respect for community norms.
- Serve as a liaison between researchers and participants.

Ethical Considerations for CEnR

- Informed consent documents should explain the role of the community and any CAB oversight.
- Investigators should demonstrate how community input influenced study design and identify plans for returning results to the community.
- Compensation or acknowledgment for CAB members must be fair and transparent.

IRB Review of CEnR Projects

The IRB will evaluate CEnR proposals for:

- Evidence of equitable community engagement.
- CAB involvement, if appropriate.
- Adequate protections for community members participating in research.
- Mechanisms to ensure community feedback informs study conduct and dissemination.

D. Informed Consent Process

Informed consent must be sought from each prospective participant or participant's legally authorized representative before research begins. Consent is a continuing process, and participants always retain the right to withdraw from participating in a research project. Federal policy requires that investigators inform participants of any important new information that might affect their willingness to continue participating in the research.

1. The basic elements of informed consent as stated in *45 CFR 46.116* are:
   - A statement that the study involves research
   - An explanation of the purpose of the research
   - The expected duration of the subjects' participation

- A description of the procedures to be followed and, if appropriate, identification of any procedures that are experimental (i.e., therapies that are being tested).
- A description of any reasonable risks or discomforts to the subject.
- A description of any benefits to the participants or to others which may reasonably be expected from the research and how that will contribute to the field of study or may benefit others.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to the participant.
- A statement describing the extent, if there is any, to which confidentiality of records identifying the participant is maintained. This includes the matter and place of data storage.
- For research involving more than minimal risk, and explanation as to whether any compensation is available, and explanation as to whether any medical treatments are available if injury occurs and what they consist of or where further information may be obtained.
- An explanation of whom to contact for answers to pertinent questions about the research and research participant's rights, and whom to contact in the event of a research-related injury. PMSF consent forms should include the address, phone number, and e-mail addresses of the PI and the PMSF IRB.
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
- Research that involves collection of identifiers in data or biospecimens must explain the measures taken to protect the confidentiality of participants if data are shared with other researchers, uploaded to public databases, or used in future studies. This statement must include steps to use ID codes, remove identifiers in shared data and measures to restrict access to the data and minimize breaches of confidentiality via encryption and firewalls.
- If genetic data is obtained,
    - The risk of a potential data breach must be stated in the Consent form. This includes the risk of others knowing about current or potential genetic conditions, risk of loss of privacy or discrimination by insurers or employers.
    - The federal law entitled Genetic Information Nondiscrimination Act (GINA) must be referenced as added protection against use of data in the case of data breaches. GINA generally makes it illegal for health insurance companies and most employers to discriminate against human subjects based on genetic information. This law generally will protect participants in the following ways:
        - Health insurance companies and group health plans may not request genetic information obtained through research.
        - Health insurance companies and group health plans may not use genetic information when making decisions regarding eligibility or premiums.
        - Employers with 15 or more employees may not use genetic information obtained from this research when deciding to hire, promote, or fire or when setting the terms of employment.

        - All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.
        - This new Federal law does not protect participants against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.
    - Any other measures to protect the confidentiality of the participants must be described, including obtaining a Certificate of Confidentiality from the US DHHS. With this Certificate, investigators cannot be forced (for example by court order or subpoena) to disclose information that may identify the subject in any federal, state, local, civil, criminal, legislative, administrative, or other proceedings

2. Additional requirements may include:

- A statement that the treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable.
- Anticipated circumstances under which participation may be terminated by the investigator without regard to the participant's content.
- Any additional costs to the participant that may result from participation in the research.
- The consequences of a participant's decision to withdraw from the research and procedures for orderly closure of participation by the participant.
- A statement that significant new findings developed during research, which may relate to the participants' willingness to continue participation, will be provided to the participants.
- The approximate number of participants involved in the study
- Information regarding storage, maintenance, and secondary research use of identifiable private information/identifiable biospecimens.

The IRB may waive written documentation of informed consent if *(45 CFR 46.116 c. & d)*.

- The research represents no more than a minimal risk of harm to participants
- The waiver or alteration will not adversely affect the rights and welfare of the participant
- The research could not be carried out without the waiver or alteration, and
- Where informed consent constitutes the only threat to anonymity, and
- Whenever appropriate, the participant will be debriefed.
- Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

The waiver of documentation will be on a case-by-case basis. When consent is waived, the IRB may require the investigator to offer participants written information about the study.

Consent forms should avoid jargon and should be written in the second person (e.g., If you agree to the research…) in a language and at a level that is understandable to the participant. Informed consent will not be accomplished unless the requirement is met so that the participant understands the components of the consent form. The person who signs the consent form must be given a signed copy as a reference and reminder of the information conveyed by the researcher. Non-written methods of administering consent are also possible (e.g., appropriately documented oral consent).

3. Informed consent for Minors

Children (minors) are defined as people who have not attained the legal age for consent to procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. In Puerto Rico, residents under 21 years of age are considered minors unless they are "emancipated" by court order. In the U.S., each state determines the legal age of adulthood, which is generally 18 years old. For international studies, the investigator must follow the laws of the country where the study is taking place.

Assent is the child's affirmative agreement to participate in research. A child's legal guardian or parent must sign an informed consent form in order for a child to participate in a research study. Where appropriate, the child should assent to participating in the research. Both consent and assent forms must be submitted to the IRB for approval. If assent is not used, an explanation for not including this component should be included in the application. According to OHRP, to assent the minor must actively demonstrate a continued willingness to participate in the research and not just comply with participation directions.

The HHS regulations do not require documentation of assent. The Institutional Review Board (IRB) has the discretion to determine the appropriate manner, if any, of documenting child assent. Based on such considerations as the child's age, maturity, and degree of literacy, the IRB should decide what form of documentation, if any, is most appropriate. If adolescents are involved in research where a consent form would have been used if the subjects were adults, it would generally be appropriate to use a similar form to document an adolescent's assent.
If young children are involved who are as yet unable to read, documentation should take a form that is appropriate for the purpose of recording that assent took place. The IRB may also decide that documentation of assent is not warranted.[3]

4. Informed Consent for Non-English-Speaking Subjects

DHHS regulations for the protection of human participants require that informed consent information be presented "in language understandable to the subject" and, in most situations, that informed consent be documented in writing.

The written consent document should embody, in language understandable to the participant, all the elements necessary for legally effective informed consent. Participants who do not speak English should be presented with a consent document written in a language they understand. The IRB must receive a copy of the document.

[3] HHS | Office for Human Research Protections: Research with Children

In the case of the PMSF IRB, Informed Consent Documents (ICD) must be written in both Spanish and English. If the ICD's come from the states, the translated Spanish ICD must be accompanied with a translation certificate.

E. Modifications

All modifications/amendments to currently approved research must be reviewed and approved by the IRB before implementation. The PI must submit all changes to the IRB. Changes that do not increase the risk to research participants may receive an expedited review. Modifications to approved research projects that are more than minimal risk and do not qualify for expedited review must be forwarded to the full IRB for review and, if appropriate, to those participating in the study by way of a revised informed consent.

The PI shall incorporate each approved modification to a research protocol or consent document into the approved protocol to ensure that there is only one complete protocol, with the revision dates noted. The PI will send a copy to the IRB.

F. Adverse Events and Serious Adverse Events (SAE)

Adverse events and serious adverse events involving risks to participants or others are events or problems that are undesirable, unintended, and harmful or detrimental to the welfare of study participants or other individuals involved with research study. Reportable events are not limited to physical injury, but include psychological, social, and emotional harm or injury.

All adverse events and unanticipated problems involving risks to participants and others must be reported by the investigator immediately to the IRB. In addition, the investigator is responsible for reporting the event as required by Federal regulation, grant requirements, or contract.

The IRB is responsible for reviewing reports of any adverse events or unanticipated problems involving risks to subjects or others. Upon receipt of the report, the IRB will determine whether the study should be modified to reduce the level of risk to participants, or whether the consent form should be modified to include a description of the event. In addition, the project could be suspended or terminated.

G. Noncompliance

The IRB shall be responsible for reviewing and determining all issues of serious or continuing noncompliance with 45 CFR 46, IRB requirements or PMSF requirements. Any serious or continuing noncompliance will be reported to the Human Protections Administrator and the IRB Chair who together will investigate all credible reports of alleged noncompliance and inappropriate involvement of human participants in research.

Noncompliance includes Conducting research without IRB review, not obtaining consent; using the wrong consent form, failing to report adverse events or serious adverse events or other problems, failure to maintain adequate records, failure to follow the IRB approved protocol, modifying an approved protocol without IRB approval, inadequate supervision, or inadequate training, or research misconduct (e.g., data fabrication, falsification, plagiarism). The IRB will follow PHSU policies on misconduct in research.

When a report of alleged noncompliance is received by the IRB or Office of Human Subject Protection (OHSP), a preliminary investigation will be undertaken, and a determination will be made as to whether participants are at risk or can be allowed to continue in the research while the investigation continues. If subjects are deemed to be at risk the IRB or Human Protection Administrator and any other PMSF administrator that is deemed necessary.

Actions the IRB may take include:

- The IRB may determine that the research study is following federal regulations and IRB policy, and no further action is necessary.
- The IRB may decide that the PI found in noncompliance should not be allowed to process new protocols or renew current projects until all concerns have been addressed.
- The IRB may determine whether the research study under review is substantially in compliance with federal regulations and IRB policy but may make specific recommendations to improve or enhance protections for the study's human participants or increase oversight of the project.
- The IRB may suspend or terminate the project following guidelines described in Section H.

H. Suspension or Termination of Research

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected harm to participants (*45 CFR 46.113*). The PI will receive a written notice with the reasons for terminating/suspending their study. In this case, the investigator must acknowledge in writing the receipt of the IRB decision and inform the IRB the steps taken to resolve the issues.

The IRB has the authority to re-open terminated projects if it deems this action is necessary and in the best interest of the participants.

I. Appealing an IRB Decision

If the IRB decides that an investigator believes it to be unfair or unsubstantiated about his or her proposed research, the investigator should first discuss the matter with the IRB Chair. The investigator should be prepared to present reason that he or she believes that the proposed research is following PMSF policy, Federal Regulations and Puerto Rican Law for the protection of human participants.

If the issue cannot be resolved satisfactorily by negotiation, the PI may appeal the decision, in writing, to the full IRB. The results of any negotiations that require approval by the full IRB. The results of any negotiations needing full IRB approval will be presented at the next meeting for decision and vote.

The investigator may appear before the IRB to present his or her appeal and any supportive material or documentation obtained through consultation, but the investigator cannot be present during the vote on the IRB's final recommendation.

J. Closure of Approved Research

If an investigator decides to terminate a study, or if the study has concluded because enrollment has ended and only data analysis and dissemination remain, they must notify the IRB by submitting the request through the "Protocol Actions" tab in Streamlyne. They will navigate the "Protocol Actions" tab, then select "Request an Action" and choose "Request to Close." The submission must include:

- A justification letter uploaded to the protocol file, and
- A brief comment entered in the system summarizing the reason for termination.

Special Categories

A. Cooperative Research

PMSF will ensure that any of its collaborating entities also possesses mechanisms to protect human participants that are at least equivalent to those procedures provided for in the ethical principles to which PMSF is committed.

PMSF may enter a joint review arrangement called an *IRB Authorization Agreement,* where it relies upon the review of another qualified IRB with similar standards of human participants' protection or make similar arrangements to meet IRB review requirements and eliminate duplication of effort (Single IRB[4]). Such arrangements must be (a) in writing, (b) approved and signed by the Signatory Official of the school, which is the President/Dean of PMSF, and (c) approved and signed by correlative officials of the cooperating institutions. These arrangements may be entered into on a case-by-case basis.

B. International Research

OHRP works to ensure that human subjects outside of the United States who participate in research projects conducted or funded by DHHS receive the same level of protections as research participants inside the United States. To that end, the OHRP International Activities program offers consultation services, disseminates pertinent reports, and provides research ethics training.

The International Compilation of Human Subjects Protections is a listing of 1,000 laws, regulations, and guidelines on human subjects' protections in over 100 countries and from several international organizations. Many of the listings embed hyperlinks to the source document. These laws, regulations, and guidelines are classified into six categories:

- General
- Drugs and Devices
- Privacy/Data Protection
- Human Biological Materials
- Genetic Issues
- Embryos, Stem Cells, and Cloning

[4] HHS: Single IRB Exception Determinations

C. Internet Research

Internet research can include recruiting participants over the internet and gathering data over the internet.

- *Recruiting over the WEB.* Unsolicited email messages to multiple users are prohibited by PMSF without prior approval. The IRB must review the text of the recruitment script to be presented to participants and the context in which the recruitment takes place.
- *Gathering Data.* This type of research involves having participants submit data (i.e., survey data) over the internet and presents the most serious human participants' concerns (i.e., obtaining consent, particularly assent from minors) due to the potential limits to confidentiality. The investigator must inform the IRB of how he/she intends to obtain consent.

D. Community Engagement in Research

Investigators are encouraged to engage community stakeholders in the design, implementation, dissemination, and interpretation of research, particularly when the research involves underrepresented or vulnerable populations.
Community engagement can take many forms, including stakeholder interviews, town halls, focus groups, or advisory panels.

Use of Community Advisory Boards (CABs)
For studies involving significant interaction with the community or public health interventions, the IRB recommends the formation of a Community Advisory Board (CAB) to:

- Review and advise on study design, recruitment, and consent procedures.
- Help ensure cultural relevance and respect for community norms.
- Serve as a liaison between researchers and participants.

Ethical Considerations for CEnR

- Informed consent documents should explain the role of the community and any CAB oversight.
- Investigators should demonstrate how community input influenced study design and identify plans for returning results to the community.
- Compensation or acknowledgment for CAB members must be fair and transparent.

IRB Review of CEnR Projects
The IRB will evaluate CEnR proposals for:

- Evidence of equitable community engagement.
- CAB involvement, if appropriate.
- Adequate protections for community members participating in research.
- Mechanisms to ensure community feedback informs study conduct and dissemination.

E. Incomplete Disclosure and Deception in Research

Deception is a method used in social science research that can improve the internal validity of a research study. The intention of deception is to produce a false belief in the participants during the study. Incomplete disclosure of information may also be used in research were telling the subject about some aspects of the study in detail might interfere with the ability to measure the outcome of interest. The use of deception and incomplete disclosure in human subjects'

research raises special problems for the IRB to consider regarding informed consent and analysis of risks and benefits. Unethical uses of deception in research can cause distress to those being deceived and may undermine public trust in the research enterprise.

When studies use deception or incomplete disclosure in their procedures, the IRB needs to determine whether the deception/incomplete disclosure is necessary to make the research scientifically valid and feasible. The IRB will consider whether the study population is appropriate for the study procedures that involve deception or incomplete disclosure of information and will consider potential harms of these methods. The IRB never allows deception/incomplete disclosure that might affect the subject's willingness to participate in the study.

F. Privacy Protection

Regarding protections of privacy, "*Certificates of Confidentiality*" are issued by the Department of Health and Human Services to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies and assuring confidentiality and privacy to participants. The Office for Human Subject Protection (OHRP) has clear guidelines for the application process.

Examples of research that can be considered sensitive include:

- Information relating to sexual attitudes, preferences, or practices
- Information relating to the use of alcohol, drugs, or other addictive products
- Information pertaining to illegal conduct
- Information that if released could reasonably be damaging to an individual's financial standing, employability, or reputation
- Information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination
- Information obtaining to an individual's psychological well-being or mental health
- Genetic information

G. Research involving collection of biospecimens (biobanks)

Ethical issues to consider in the research use of stored data and/or tissues:

- **Human Tissue Repositories** collect, store, and distribute human tissue materials for research purposes. Repository activities involve three components: (i) the **collectors** of tissue samples; (ii) the **repository** storage and data management center; and (iii) the **recipient** investigators.
- If supported by the DHHS, each component must satisfy certain **regulatory requirements.**
- Operation of the Repository and its data management center should be subject to **oversight by an IRB**. The IRB should review and approve a protocol specifying the

conditions under which data and specimens may be accepted and shared and ensure adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.

- The IRB should also review and approve a sample collection protocol and informed consent document for distribution to tissue collectors and their local IRBs.
- It is recommended that **Certificate of Confidentiality** is obtained to protect confidentiality of repository specimens and data.
- Research using tissues or data that is identifiable is considered human subjects research. Research with tissues or data that are "deidentified" or "anonymized" is not considered human subjects research and therefore can be conducted without oversight from an institutional review board (IRB).
- Consent forms must be explicit about the intended use of the tissues. It is ethically problematic to use the tissues for other purposes, even if the risk to the tissue donor is minimal or nonexistent.
- Federal regulations permit a waiver of consent if four criteria are met: (1) the research is deemed to carry minimal risk, (2) the waiver would not adversely affect the rights and welfare of the participants, (3) the research would not be practicable without a waiver, and (4) the research participants will be informed later of the research, when appropriate

H. Data Sharing / Data Management Plan

Studies involving data sharing must submit a plan for ethical data management and sharing.

Data Sharing Requirements include:

- Explain any institutional or sponsor requirements for sharing research data, particularly for studies funded by agencies that mandate data sharing (e.g., NIH, NSF).
- Clarify the types of data that must be shared and the permitted repositories or platforms for data sharing.

A Data Management Plan includes:

- Require investigators to submit a data management plan as part of their protocol submission, outlining how research data will be collected, organized, documented, stored, and preserved.
- Provide guidelines or templates for developing a comprehensive data management plan.

Data Security and Confidentiality

- Outline the expected measures for protecting the confidentiality and security of research data, particularly for studies involving sensitive or identifiable information.
- Address issues such as data encryption, access controls, and secure storage and transmission of data.

Data Retention and Disposal

- Specify the required duration for retaining research data and associated documentation.
- Provide guidance on proper methods for disposing of or destroying data securely after the retention period.

Data Monitoring and Oversight

- Clarify the IRB's role in reviewing and monitoring data management practices, particularly for studies involving greater than minimal risk.

- Address the potential need for data monitoring committees or external oversight, depending on the study's risk level and complexity.

Data Transfer and Collaboration

- Provide guidance on the procedures and safeguards required for transferring or sharing data with collaborators or other institutions, including the use of data transfer agreements or data use agreements.

Certificate of Confidentiality

Eligibility for a Certificate

Any investigator conducting research in which sensitive information is gathered from human research participants (or any Investigator who intends to engage in such research) may apply for a Certificate of Confidentiality[5]. Note there are other eligibility requirements (see **FAQ Section C. Eligibility for a Certificate**).

Generally, any research project that collects personally identifiable, sensitive information and that has been approved by an IRB operating under either an approved Federal-Wide Assurance issued by the Office of Human Research Protections or the approval of the Food and Drug Administration is eligible for a Certificate. Federal funding is not a prerequisite for an NIH-issued Certificate, but the subject matter of the study must fall within a mission area of the National Institutes of Health or the Department of Health and Human Services.

1. **Can you give some examples of research projects that are eligible for a Certificate?**

   The following is an illustrative but not exhaustive list of research areas eligible for a Certificate:

   - Research on HIV, AIDS, and other STDs.
   - Studies that collect information on sexual attitudes, preferences, or practices.
   - Studies on the use of alcohol, drugs, or other addictive products.
   - Studies that collect information on illegal conduct.
   - Studies that gather information that if released could be damaging to a participant's financial standing, employability, or reputation within the community.
   - Research involving information that might lead to social stigmatization or discrimination if it were disclosed.
   - Research on participants' psychological well-being or mental health.
   - Genetic studies, including those that collect and store biological samples for future use.
   - Research on behavioral interventions and epidemiologic studies.

2. **What studies would NOT be eligible?**

   Ineligible studies include projects that are
   - Not research based,
   - Not approved by an IRB operating under either an approved Federal-Wide Assurance issued by the Office of Human Research Protections or the approval of the Food and Drug administration,

[5] HHS Office of Human Research Protections: Certificates of Confidentiality

- Not collecting sensitive information or information that, if released publicly, might harm the research participants,
- Not collecting personally identifiable information, or
- Not involving a subject matter that is within a mission area of the National Institutes of Health or the Department of Health and Human Services.

Certificate of Confidentiality vs Other Privacy and Data Protections

NIH Certificate of Confidentiality offer important protection for the privacy of research study participants by protecting identifiable health information from forced disclosure (e.g., by court order). While the Privacy Rule does establish protection for covered entities' use and disclosure of PHI, it permits use or disclosure in response to certain judicial or administrative orders. Therefore, researchers/contractors may obtain Certificates of Confidentiality to protect them from being forced to disclose information that would have to be disclosed under the Privacy Rule.

I. Quality Assurance/Quality Improvement (QA/QI) vs. Research: Do I Need to Submit for an Exemption or IRB Approval?

There is often confusion in determining whether Quality Assurance (QA) or Quality Improvement (QI) activities fall within the category of research and require submission for an exemption from IRB review or IRB review and approval or do not.

What is QA/QI?
Quality Assurance is defined as a program for systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that standards of quality are being met.

Quality Improvement is a formal approach to the analysis of performance and systematic efforts to improve it.

Key Concepts

- Quality assurance (QA) and quality improvement (QI) projects may be considered research when there is a hypothesis or question being answered and the information being collected is designed to contribute to generalizable knowledge (i.e. beyond the context of the specific institution(s) conducting project).
- Whether these projects are research is determined by the IRB on a case-by-case basis.
- The IRB makes this determination by evaluating a group of factors including the purpose and intention of the project, level of risk, and methodology.
- Publishing or presenting QA/QI findings does not automatically mean that the project is research.

How the IRB Makes a Determination regarding QA/QI?

The IRB assesses whether the project meets the **definition of research.** Then we determine if the project involves **human subjects.** Research is systematic investigation, including research development, testing and evaluation designed to contribute to generalizable knowledge. QA/QI activities **are likely not** considered human subject research when:

- The project is undertaken by or for NIH; and

- The goal of the project is immediate improvement in NIH patient safety or care or other internal NIH practices or processes, and
- The project involves an intervention, and it has been established in other settings; and
- The project will be adapted over time to accommodate NIH initiatives.

Some questions you can ask to help with these decisions:

- Does the analytical or evaluative component of the activity change the way that clinical care or other activities will be delivered in such a way that introduces or heightens risks to participants (may include randomization)?
- Are participants randomized into different intervention groups in order to enhance confidence in differences that might be obscured by other selection methods?
- Does the project seek to test interventions that are beyond the scope of current science and experience, such as new treatments?
- Does the project involve practices, interventions, or treatments that are not standard (neither consensus-based, nor evidence-based)?

If the answer to ANY of the above is yes, the project is research and should be submitted for an exemption or IRB review and approval

Publication of findings, methodological design, selection of subjects and hypothesis testing and generating do not necessarily differentiate research from QA/QI activities because these attributes can be shared by both research and non-research activities. Below are elements that are common to QA/QI and research projects. This list is not intended to be comprehensive. Rather, this list of elements can be used to assist staff in determining whether an activity involves research requiring an exemption or IRB review and approval.

Common Elements	QA/QI	Research
Purpose	To assess or improve a process, program, or system in terms of quality, performance, safety, or efficiency within a local setting as judged by established/accepted standards	To test a hypothesis and to contribute to and/or generate new knowledge that can be generalized
Starting Point	To improve performance	To answer a question or test a hypothesis
Benefits	Knowledge sought directly benefits a process/program/system, and may or may not directly benefit individuals (e.g. patients, families, or staff)	Knowledge sought may or may not benefit clinicians, the scientific community and current subjects, but may benefit future individuals
Scope of Interest	Specific unit or patient population within an organization	Generalize to populations beyond organization
Risks/Burdens	Does not increase risk to patients or other participants, with exception of possible privacy/confidentiality concerns	May put subjects at risk
Data Collection	Systematic data collection	Systematic data collection

End Point	Improve a program/process/system	Answer a research question
Testing/Analysis	Compare a program/process/system to an established set of standards	Statistically prove or disprove hypothesis

Additionally, here are examples of several types of QA/QI projects and whether or not they would also be considered research.

QA/QI Activities that ARE NOT Research:

- A QA/QI initiative (with or without presentation/publication of results) that is conducted within your institution/department only, and that serves to measure or improve your institution/department's ability to meet or exceed an existing national standard of care or benchmark.
- Submission of data to a national or state registry/database that is mandated at the state or federal level with the primary purpose of improving the delivery of clinical care.
- Submission of data to a national or state registry/database that directly impacts reimbursements and funding available from the State, Department of Health, or Federal Centers for Medicare & Medicaid services (CMS) based on performance and/or clinical or quality outcomes.

QA/QI Activities that ARE Research:

- QA/QI initiatives designed to develop a standard of care or benchmark.
- An activity that proposes comparisons of one or more prospective interventions that are deliberately administered or made available (through a randomization or other process) to some patients or providers or some hospitals (if part of a consortium or organizational effort)

What if I want to Publish the Results of my QA/QI Project?

If is entirely appropriate to disseminate and replicate QA/QI successes, including through channels that are external to an organization such as conferences or publication. This may include presentations at meetings and publications in professional journals. Therefore, the mere intent to publish the findings or a QA/QI project does not obligate submitting for an exemption or IRB review and approval if the publication makes it clear the publication is the result of quality assurance or quality improvement activity as defined above.

If the project is research involving human subjects, submission for an exemption or IRB review and approval is required.

Human Subject Regulations Decision Charts

The Office for Human Research Protections (OHRP) provides the following graphic aids as a guide for institutional review boards (IRBs), investigators and others who decide if an activity is research involving human subjects that must be reviewed by an IRB under the requirements of the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46.

OHRP welcomes comments on these decision charts. The charts address decisions on the following:

- Whether an activity **is research** that must be reviewed by an IRB
- Whether the review may be performed by **expedited procedures**, and
- Whether **informed consent** or its documentation may be waived.

Considerations

The charts are intended to assist IRBs, institutions, and investigators in their decision-making process and should not be used as substitutes for consulting the regulations. OHRP cautions that the full text of applicable regulatory provisions should be considered in making final decisions.

These charts are necessary generalizations and may not be specific enough for particular situations. Other guidance documents are available related to specific topics, at OHRP Policy Guidance by Topic. OHRP invites inquiries for additional information.

The charts do not address requirements that may be imposed by other organizations, such as the Food and Drug Administration, National Institutes of Health, other sponsors, or state or local governments. [6]

Chart 1: Is an Activity Human Subjects Research Covered by 45 CFR Part 46?

Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.104(d)?

Chart 3: Does Exemption 45 CFR 46.104(d) (1) for Educational Practices Apply?

Chart 4: Does Exemption 45 CFR 46.104(d) (2) for Educational Tests, Surveys, Interviews, or Observation of Public Behavior Apply?

Chart 5: Does Exemption 45 CFR 46.104(d) (3) for Benign Behavioral Interventions Apply?

Chart 6: Does Exemption 45 CFR 46.104(d) (4) for Secondary Research that Does Not Require Consent Apply?

Chart 7: Does Exemption 45 CFR 46.104(d) (5) for Public Benefit or Service Programs Apply?

Chart 8: Does Exemption 45 CFR 46.104(d) (6) for Food Taste and Acceptance Studies Apply?

Chart 9: Does Exemption 45 CFR 46.104(d) (7) Storage for Secondary Research for Which Broad Consent Is Required, Apply?

Chart 10: Does Exemption 45 CFR 46.104(d) (8) for Secondary Research for Which Broad Consent is Required Apply?

Chart 11: Is Continuing Review Required Under 45 CFR 46.109(f)?

[6] Human Subject Regulations Decision Charts: 2018 Requirements | HHS.gov

APPENDIX

The templates found in this appendix could also be accessed by visiting the following website: https://www.ponceresearch.com/regulatory-compliance/irb/templates/

- IRB Committee Concerns Template
- Informed Consent Template English and Spanish versions
- Assent Form English and Spanish versions
- Streamlyne Questionnaire

The decision charts found in this appendix could also be accessed by visiting the following website: Human Subject Regulations Decision Charts: 2018 Requirements | HHS.gov

Dr. SimonCarlo
IRB Chair
Ponce Health Sciences University
388 Zona Industrial Reparada 2
Ponce, Puerto Rico 00716

Dear Dr. Carlo,

I am submitting the following corrections for your revision and consideration concerning the research proposal entitled "***Title and number of protocol here***". Below you will find our written response to the revisions the board proposed:

IRB Notes	Researcher Response
Concern #1	Response #1
Concern #2	Response #2
Concern #3	Response #3
Concern #4	Response #4
Concern #5	Response #5
Concern #6	Response #6
Concern #7	Response #7

This document should be accompanied by any other changes that need to be submitted (mergedin a single pdf file) and use highlighter (yellow) to emphasize changes made. – ***THIS CAN BE DELETED AFTER CAREFULLY READING.***

****Remember that changes done in the online Streamlyne questionnaire must be followed by the letter "R" (as in Revised) and the date (MM/DD/YYYY). We require this informationas the platform does not allow highlighting revised text.**

General Informed Consent Template

** Do not use for collection of biospecimens or research involving genetic/genomic analyses**

Informed consent is required to provide potential participants or their legally authorized representatives with the information necessary for a **"reasonable person"** to make a decision about participating in research.

Information in the consent document must be **organized** to facilitate comprehension. Consent documents should be written in plain language, generally at the **8th grade reading level.** The reading level can be higher if the target population tends to have a higher literacy rate than the general population. For child assent documents, the reading level and complexity of the information provided should be appropriate for the age of the child.

The PRI IRB strongly recommends the use of this template to create the informed consent document(s) for your study, particularly for federally-sponsored clinical trials that will be required to post a consent document on a public website. Please note:

1. **As of January 21, 2019**, federal regulations require that the informed consent contain a concise and focused presentation of the key information that is most likely to help potential participants understand why they might or might not want to participate in the study. The key information must be presented first and should include the following:
    a. Identification of the project as a research study
    b. Purpose of the research, duration of participation, and a description of research procedures
    c. Foreseeable risks or discomforts, if any
    d. Expected benefits to participants or others, if any
    e. Statement that participation is voluntary

    Many studies have brief consent documents (2 or 3 pages) that meet this new requirement without the need for a separate Key Information section. However, if your project is complex or involves numerous research procedures, the Key Information section (Section 1.1) is required for federally-sponsored projects and strongly recommended for all others.
2. Text that is not highlighted is required information; text in **[brackets]** represents information about your study that you must add.
3. A backslash indicates that you must make a selection depending on the procedures for your study (e.g., "will/will not" or "I/we").
4. Additional instructions and sample text are highlighted in light grey.
5. Before you upload your consent document to Streamlyne, **delete this cover page**, **backslashes, brackets, and highlighted text**. The finished document should reflect what you will give to the participant.
6. Use a file name for each consent document that clearly identifies the type of consent and for which participants it is intended (e.g. child assent, parental permission, adult consent, etc.).

For questions about informed consent, please contact the PMSF IRB at 787-840-2575 x 4748 or mcruz@psm.edu.

For more information on plain language go to http://www.plainlanguage.gov/.

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:
Principal Investigator: [Name, credentials, institutional affiliation]
Co-Investigator(s): [Name, credentials, institutional affiliation] Delete if this does not apply.
Faculty Advisor: [Name, credentials, institutional affiliation] Required for projects with a student PI, otherwise delete.
Study Sponsor: [Name or None] Delete if this does not apply.

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study. If this document will be used to obtain parental permission for their child to participate in research, replace **"you"** with **"your child"** throughout.

The revised Common Rule requires a **concise and focused description** of the research project to be included at the beginning of the consent document. This section is required for complex research projects such as those involving multiple study procedures and those posing more than minimal risk to participants.

1.1 Key Information

Things you should know:

- The purpose of the study is to [provide a brief, simple, non-technical description of the project].
- If you choose to participate, you will be asked to [do what, when, where, and how]. This will take approximately [period of time].
- Risks or discomforts from this research include [briefly describe].
- The direct benefits of your participation are [description of potential direct benefits to participants – or state that there are no direct benefits].

Taking part in this research project is voluntary. You do not have to participate and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

2. PURPOSE OF THIS STUDY

Briefly, in one paragraph, explain in simple, non-technical language, the scientific reason for doing this study. Do not describe the details of the protocol here – protocol details should be described in Section 4 "Information about Study Participation."

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study? List important eligibility criteria (e.g., age, gender, language, health condition, etc.) in simple, non-technical language. Also, include a discussion of any important exclusion criteria, if applicable.

3.2 How many people are expected to take part in this study? This question is **optional**. Some participants may wish to know how many others will be taking part. Delete this section if you will not provide this information.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Explain in lay terms, typically in chronological order, what will happen to participants during the study. List all research/experimental procedures in this section. The following should always be

included, if applicable:

- The location where research activities/procedures will take place
- Description of all research interactions/experimental activities or interventions
- Data collection procedures (surveys, interviews, audio-visual recording, observation, etc.)
- Identification of which procedures are standard and which are experimental
- Randomization procedures
- Use of medical records
- Linking of data collected or created as part of the research to other information, such as protected health information, administrative data such as from the U.S. Census or state agencies, or publicly available information
- For projects involving the collection of sensitive information or questions that might be upsetting, include examples of the types of questions asked or describe the sensitive topics involved.

4.2 How much of my time will be needed to take part in this study? Explain as needed, describing time in hours, number of interactions or study visits, and duration of the research. For example, "Participants will be asked to take one survey each month for a period of six months. Each survey is expected to take about one hour." Be liberal in the estimation of how much time is required and ensure that it is consistent with what you have described in the Streamlyne application. If this is a longitudinal project, tell participants that you may contact them again in the future and provide the interval if known.
.

4.2.1 When will my participation in the study be over? Necessary only if not addressed in 4.2 above, otherwise delete this section.

4.3 If I decide not to take part in this study, what other options do I have?
For projects that involve an **intervention** that might improve a condition or disease, describe alternatives to participating in the research. These could include an intervention or treatment available outside the research context. Required only for studies that treat a condition or disease. Delete this section if not applicable.
There may be other ways of treating your condition if you do not want to be in this research study. Check with your health care provider to discuss other options.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
Describe the known or expected risks of the study. These may be physical, psychological, legal or informational. Breach of confidentiality (i.e., informational risks) is a potential risk in all research that collects or maintains personally identifiable information and may be the only risk in some studies.

The researchers will try to minimize these risks by [describe what you will do to protect participants against risks.] For example, psychological risks could be mitigated by providing participants with counseling resources.

For projects that involve **surveys/interviews/focus groups**, include the statement: You do not have to answer any questions you do not want to answer.

For informational risks state: Because this study collects information about you, [one of the risks/the primary risk] of this research is a loss of confidentiality. See Section 8 of this document for more information on how the study team will protect your confidentiality and privacy.

5.1.1 What happens if I get hurt, become sick, or have other problems because of this research? For **more than minimal risk** projects only - delete section 5.1.1 for minimal risk projects (most projects reviewed by our IRB do not require this section).
The researchers have taken steps to minimize the risks of this study. Please tell the researchers if you have any injuries or problems related to your participation in the study. For health-related research involving **treatment**, include: You should also tell your regular doctors. The University may be able to assist you with obtaining emergency treatment, if appropriate, but you or your insurance company will be responsible for the cost. By signing this form, you do not give up your right to seek payment if you are harmed because of being in this study.

5.2 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. **or** You might benefit from being in the study [describe direct benefits]. Note: Compensation for research participation is not considered a benefit of the research. Information about compensation should be described in Section 7.

5.3 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study? Include this section for health-related research involving an **intervention**, otherwise delete. Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 9 “Contact Information”. If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study? You will receive [type and total amount of compensation] for your participation in the study. Describe how compensation will be distributed if the participant withdraws from the research before the end of the study.

7.1.1 Will I need to pay anything to be part of the study? To be part of the study, you will need to pay for [indicate what costs, if any, participants will have to pay (such as parking)]. Delete this section if there are no costs to participants.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information? Describe procedures that will be followed to keep participant information secure and confidential. Note: any research data that

will be linked to individual identifiers is considered identifiable.

8.1.1 Special Protections (Delete this section if not applicable)

We will disclose your information for any purpose to which you have consented, as described in this informed consent document. This includes [Briefly summarize. For example, "This includes placement of your research information into your medical record, and sharing your de-identified data with other researchers."]

[If you are not required by law to report to authorities in specific cases but plan to do so, include a statement here. For example, "We may also disclose your information to the appropriate authorities if we suspect or learn about cases of child or elder abuse or neglect, or that you may harm yourself or others, or if we learn that you have [condition/disease]." [***NOTE:*** where reporting **is** required by law, do not discuss here. Discuss in the next paragraph.]

[*Use this paragraph only as applicable*] If required by local or state law, we will report to the appropriate authorities in specific cases, such as if we learn of [Describe as required by law. For example, "…such as if we learn of abuse, neglect or endangerment of any vulnerable person"]. [***NOTE:*** where reporting **is not** required by law but the researchers want to report such situations, do not discuss here. Discuss in the preceding paragraph.]

[*Use this paragraph only as applicable]* We will disclose your information if the [enter name of federal or state sponsor], the agency funding this research, requests information to audit or evaluate our procedures.

8.2 Who will have access to my research records?
There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- University, government officials, study sponsors or funders, auditors, and/or the Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.
- If applicable, state: Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

8.3 What will happen to the information collected in this study?
We will keep the information we collect about you during the research [for future research projects/for study recordkeeping or other purposes (describe)]. Your name and other information that can directly identify you will be stored securely and separately from the research information we collected from you. Note: any research data that will be linked to individual identifiers is considered identifiable. Linking of data to individual identifiers, length of time data will be linked to identifiers, and whether destruction of identifiers will occur should be described here.

For longitudinal research: The researchers [plan to/may] contact you again as part of this project.

Or: We will not keep your name or other information that can identify you directly.

The results of this study could be published in an article or presentation, but will not include any information that would let others know who you are.

If the investigator wishes to identify a participant in a presentation or article, state: The results of this study could be published in an article or presentation, but would not include any information that would let others know who you are without your permission.

8.4 Will my information be used for future research or shared with others?
The Common Rule requires that investigators tell participants whether their data will be stored and shared for future research, even if de-identified.

We may use or share your research information for future research studies. If we share your information with other researchers it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

If you plan to retain and share identifiable information for unspecified future research, state: We would like to share your identifiable information with other researchers for future research. We will ask for your consent to do so at the end of this form. You can be a part of this current research project without agreeing to this future use of your identifiable information.

or We will not store your research information or share it with other researchers. The IRB does not recommend the use of this statement, as it will preclude the secondary use of these data in the future.

8.4.1 Special Requirements (Delete this section if not applicable.)
If your project meets the definition of an NIH clinical trial, include the following required language: A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by the National Institutes of Health (NIH). This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

If you will register your project on ClinicalTrials.gov voluntarily or in order to meet journal or other requirements, include the following: This trial will be registered and may report results on www.clinicaltrials.gov. This site will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

For projects that will contribute research data to a repository, use the following language: We will put the information we collect from you into a repository. The repository contains information about many people. Your information will be [de-identified –or- labeled with a code, instead of your name or other information that could be used to directly identify you.] Add additional information regarding data protections provided by the repository.

9. CONTACT INFORMATION

Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures

- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:
Email:
Phone:

Co-Investigator:
Email:
Phone:

Co-Investigator:
Email:
Phone:

If you have any questions about your rights as a participant in this research, you may contact Dr. Simon Carlo, Director of the Institutional Review Board (IRB) of the Ponce Medical School Foundation (PMSF), Inc. at **(787) 840-2575, ext. 4758 or emailing him at scarlo@psm.edu**

10. YOUR CONSENT

Consent/Assent to Participate in the Research Study

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records and I/we will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information in Section 9 provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

IDENTIFYING FIELDS: If your protocol is NOT anonymous, use these fields and delete the ANONYMOUS FIELDS.

Print Legal Name: _____

Signature: _____
Date of Signature (mm/dd/yy): _____

Principal Investigator Signature: _____

ANONYMOUS FIELDS: If your protocol is ANONYMOUS, use these fields and delete the IDENTIFYING FIELDS.

□ Yes, I accept being part of this study.
□ No, I do not accept being part of this study.

Principal Investigator Signature: _____

Investigators are reminded that they should give a copy to the participant and retain a full copy of the consent including a copy of the signature page as part of your research records. Participants must complete all of the required information (printed name, signature and date).

Parent or Legally Authorized Representative Permission (delete this section if it does not apply)

By signing this document, you are agreeing to [your child's] **or** [the person's named below] participation in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records. I/We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I understand what the study is about and my questions so far have been answered. I agree for [my child] **or** [the person named below] to take part in this study.*

_____
Print Participant Name

_____
Print Parent/Legally Authorized Representative Name
Relationship to participant: ϒ Parent ϒ Spouse ϒ Child ϒ Sibling ϒ Legal guardian ϒ Other

_____
Signature Date

Principal Investigator Signature: _____

_____
Printed Parent/Legally Authorized Representative Name (when two parent signatures are required) Two signatures are required for more than minimal risk research with no direct benefit to the child.
Relationship to participant: ϒ Parent ϒ Sibling ϒ Legal guardian ϒ Other

_____
Signature Date

Principal Investigator Signature: _____

Reason second parent permission was not collected:
ϒ Parent is unknown
ϒ Parent is deceased
ϒ Parent is incompetent
ϒ Only one parent has legal responsibility for care and custody
ϒ Parent is not reasonably available*; explain:

** Note: "Not reasonably available" means the other parent cannot to be contacted by phone, mail, email, or fax, or his or her whereabouts are unknown. It does not mean that the other parent is at work or home, or that he or she lives in another city, state, or country.*

11. OPTIONAL CONSENT (IF YOUR PROTOCOL IS EXEMPT, DELETE ALL OF THESE CONSENT FORMS)

Separate signatures should be obtained for specific activities when those activities are optional. Whether an activity is required or optional must be clearly described in the main body of the consent document. Some common optional research activities are included below. Delete this section or any of the following consent statements that do not apply to your research. Participants must complete all of the required information (printed name, signature and date) if an optional consent section is offered.

Consent to use [video recordings/audio recordings/photography] for purposes of this research. (Use this ONLY if recording is not required to participate in the research.)

This study involves [video recordings/audio recordings/photography]. If you do not agree to be [video recorded/audio recorded/photographed], you can still take part in the study.

_____ Yes, I agree to be [video recorded/audio recorded/photographed].

_____ No, I do not agree to be [video recorded/audio recorded/photographed].

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Principal Investigator Signature: _____

Consent to use of video recordings, audio recordings or photographs for publications, presentations or for educational purposes.

I give permission for audio recordings/video recordings/photographs made of me as part the research to be used in publications, presentations or for educational purposes.

_____

_____ Yes

_____ No

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Consent to use and/or share your identifiable information for future research
The researchers would like to use your identifiable information for future research that may be similar to or completely different from this research project. Identifiable means that the data will contain information that can be used to directly identify you. The study team will not contact you for additional consent to this future research. We may also share your identifiable information with other researchers. You can contact us at any time to ask us to stop using your information. However, we will not be able to take back your information from research projects that have already used it.

Note: This separate consent is not necessary if you will only store and share de-identified data or biospecimens.

_____ Yes, I agree to let the researcher(s) use or share my personally identifiable information for future research.

_____ No, I do not agree to let the researcher(s) use or share my personally identifiable information for future research.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Principal Investigator Signature: _____

Consent to be Contacted for Participation in Future Research
Researchers may wish to keep your contact information to invite you to be in future research projects that may be similar to or completely different from this research project.

_____ Yes, I agree for the researchers to contact me for future research projects.

_____ No, I do not agree for the researchers to contact me for future research projects.

Versión en español de la hoja de consentimiento informado

Modelo de Consentimiento Informado (General)

No utilizar para la colección de muestras biológicas o investigaciones que involucren análisis de genética / genómica

Se requiere el consentimiento informado para proporcionar a los posibles participantes o sus representantes legalmente autorizados la información necesaria para que una **persona con capacidad de tomar decisiones** sobre su participación en una investigación.

La información en el documento de consentimiento debe estar **organizada** para facilitar la comprensión. El consentimiento debe estar escrito en lenguaje sencillo, generalmente en el nivel de **lectura de 8vo grado**. El nivel de lectura puede ser más alto si la población a quien va dirigida tiende a tener destrezas de alfabetización más alta que la población general. Para el documento de asentimiento del menor, el nivel de lectura y la complejidad de la información proporcionada deben ser apropiados para la edad del menor (ej. niños de edad escolar y adolescentes).

El IRB de Ponce Medical School Foundation (PMSF)) recomienda el uso de este modelo para crear el documento de consentimiento informado para su estudio. Tenga en cuenta que:

A partir del **21 de enero de 2019**, las regulaciones federales requieren que el consentimiento informado contenga una presentación concisa de la información clave que ayude a los posibles participantes a comprender por qué podrían o no querer participar en el estudio. La información clave debe presentarse primero y debe incluir lo siguiente:

- **a.** Identificación del proyecto como un estudio de investigación.
- **b.** Propósito de la investigación, duración de la participación y una descripción de los procedimientos de investigación y lugar.
- **c.** Riesgos o molestias esperados, si los hay y cómo minimizar los mismos.
- **d.** Beneficios esperados para los participantes u otros, si los hay; compensación.
- **e**. Declaración de que la participación es voluntaria.

1. Muchos estudios tienen consentimientos breves (2 o 3 páginas) que cumplen con este nuevo requisito sin la necesidad de una sección separada de Información Clave. Sin embargo, si su proyecto es complejo o involucra múltiples procedimientos de investigación, la sección Información Clave (Sección 1.1) se requiere para proyectos patrocinados por el gobierno federal y se recomienda encarecidamente para todos los demás.
2. El texto que no está resaltado es información requerida; el texto entre **[corchetes]** representa información sobre su estudio que debe añadir.
3. Una barra diagonal inversa indica que debe realizar una selección según los procedimientos para su estudio (por ejemplo, "será / no será" o "Yo / nosotros").
4. Las instrucciones adicionales y el texto que se presenta como modelo se resaltan en gris claro.
5. Antes de incorporar su documento de consentimiento a Streamlyne, **elimine esta portada**, las **barras diagonales inversas, los corchetes y el texto resaltado**. El documento final debe reflejar lo que le dará al participante.
6. Utilice un nombre de archivo para cada documento de consentimiento que identifique claramente el tipo de consentimiento y para qué participante está destinado (por ejemplo, asentimiento de los niños, permiso de los padres, consentimiento de un adulto, etc.).

Para preguntas sobre el consentimiento informado, comuníquese con el IRB de PMSF al 787-840-2575 x 4758 o mcruz@psm.edu. Para obtener más información sobre el uso de lenguaje sencillo, visite http://www.plainlanguage.gov/.

CONSENTIMIENTO PARA SER PARTE DE UN ESTUDIO DE INVESTIGACIÓN

1. INFORMACION CLAVE SOBRE LOS INVESTIGADORES Y ESTE ESTUDIO

Título del Estudio:

Investigador Principal: [Nombre, credenciales, institución afiliada]

Co-Investigador(es): [Nombre, credenciales, institución afiliada] Borrar si no le aplica

Patrocinador del estudio: [Nombre o Ninguno] Borrar si no le aplica

Estás invitado a participar en un estudio de investigación. Este formulario contiene información que le ayudará a decidir si desea unirse al estudio. Si este documento se utilizará para obtener el permiso de los padres para que su hijo participe en la investigación, reemplace **"usted"** por **"su hijo"** en todo momento.

La Regla Común (Common Rule) revisada requiere que se incluya una **descripción concisa** del proyecto de investigación al comienzo del documento de consentimiento. Esta sección es necesaria para proyectos de investigación complejos como los que involucran múltiples procedimientos de estudio y aquellos que presentan un riesgo más que mínimo para los participantes.

1.1 Información clave - Cosas que debes saber:

- El propósito del estudio es [proporcionar una descripción breve, simple, no técnica del proyecto].
- Si elige participar, se le pedirá que haga [qué, cuándo, dónde y cómo]. Esto tomará aproximadamente [período de tiempo].
- Los riesgos o molestias de esta investigación incluyen [describir brevemente].
- Los beneficios directos de su participación son [descripción de posibles beneficios directos para los participantes, o indique que no hay beneficios directos].

La participación en este proyecto de investigación es voluntaria. Usted no tiene que participar y puede terminar su participación en cualquier momento. Tómese el tiempo para leer este formulario completo y hacer preguntas antes de decidir si participará en este proyecto de investigación.

2. PROPOSITO DEL ESTUDIO

Brevemente, en un párrafo, explique en un lenguaje simple (no técnico), la razón científica para hacer este estudio. No describa los detalles del protocolo aquí; los detalles del protocolo deben describirse en la Sección 4 “Información sobre la participación en el estudio”.

3. ¿QUIEN PUEDE PARTICIPAR EN EL ESTUDIO?

3.1 ¿Quién puede participar en este estudio? Enumere los criterios de elegibilidad importantes (por ejemplo, edad, género, idioma, condición de salud, etc.) en un lenguaje simple y no técnico. También, incluya una discusión sobre cualquier criterio de exclusión importante, si aplica.

3.2 ¿Cuántas personas se espera que participen en este estudio? Esta pregunta es

opcional. Algunos participantes pueden desear saber cuántas personas participarán. Elimine esta sección si no proporcionará esta información.

4. INFORMACIÓN SOBRE LA PARTICIPACIÓN DEL ESTUDIO

4.1 ¿Qué me pasará en este estudio?

Explique en términos simples, en orden cronológico, lo que sucederá con los participantes durante el estudio. Enumere todos los procedimientos de investigación / experimentales en esta sección. Siempre se debe incluir lo siguiente, si corresponde:

- El lugar donde se llevarán a cabo las actividades / procedimientos de investigación.
- Descripción de todas las interacciones de investigación / actividades experimentales o intervenciones.
- Procedimientos de recopilación de datos (encuestas, entrevistas, grabación audiovisual, observación, etc.)
- Identificación de qué procedimientos son estándar (comúnmente realizados como parte del cuidado médico) y cuáles son experimentales.
- Procedimientos de aleatorización.
- Uso de expedientes médicos.
- Vinculación de los datos recopilados o creados como parte de la investigación con otra información, como información de salud protegida, datos administrativos como el del Censo de Estados Unidos o agencias estatales, o información disponible públicamente.
- Para proyectos que involucren la recopilación de información sensible o preguntas que puedan causar molestia, incluya ejemplos de los tipos de preguntas formuladas o describa los temas sensibles involucrados.

4.2 ¿Cuánto tiempo necesitaré para participar en este estudio? Explique según sea necesario, describiendo el tiempo en horas, el número de interacciones o visitas de estudio y la duración de la investigación. Por ejemplo, “Se les pedirá a los participantes que respondan una encuesta cada mes durante un período de seis meses. Se espera que cada encuesta tome aproximadamente una hora." Sea generoso en la estimación de cuánto tiempo se requiere y asegúrese de que sea coherente con lo que ha descrito en la aplicación de Streamlyne. Si se trata de un proyecto longitudinal, informe a los participantes que puede contactarlos nuevamente en el futuro y proporcione el intérvalo si lo conoce.

4.2.1 ¿Cuándo terminará mi participación en el estudio? Necesario solo si no se atiende en el encasillado 4.2, de lo contrario, elimine esta sección.

4.3 Si decido no participar en este estudio, ¿qué otras opciones tengo?

Para proyectos que involucran una **intervención** que podría mejorar una condición o enfermedad, describa alternativas para participar en la investigación. Estos podrían incluir una intervención o tratamiento disponible fuera del contexto de investigación. Requerido solo para estudios que tratan una condición o enfermedad. Elimine esta sección si no corresponde.

Puede haber otras formas de tratar su condición si no desea participar en este estudio de investigación. Consulte con su proveedor de atención médica para analizar otras opciones.

5. INFORMACIÓN SOBRE RIESGOS Y BENEFICIOS DEL ESTUDIO

5.1 ¿Qué riesgos enfrentaré al participar en el estudio? ¿Qué harán los investigadores para protegerme contra estos riesgos?
Describa los riesgos conocidos o esperados del estudio. Estos pueden ser físicos, psicológicos, legales o informativos. La violación de la confidencialidad (es decir, riesgos asociados a la información) es un riesgo potencial en toda investigación que recopile o mantenga información de identificación personal y puede ser el único riesgo en algunos estudios.

Los investigadores tratarán de minimizar estos riesgos [describa lo que hará para proteger a los participantes contra los riesgos]. Por ejemplo, los riesgos psicológicos podrían mitigarse proporcionando a los participantes recursos terapéuticos.

Para proyectos que involucren **encuestas / entrevistas / grupos focales**, incluya la declaración: No tiene que responder ninguna pregunta que no quiera responder.

Para los riesgos relacionados a la información: Debido a que este estudio recopila información sobre usted, [uno de los riesgos / el riesgo primario] de esta investigación es una pérdida de confidencialidad. Consulte la Sección 8 de este documento para obtener más información sobre cómo el equipo de investigación protegerá su confidencialidad y privacidad.

5.1.1 ¿Qué sucede si me lastimo, me enfermo o tengo otros problemas debido a esta investigación? Solo para proyectos de **riesgo más que mínimo**: elimine la sección 5.1.1 para proyectos de riesgo mínimo (la mayoría de los proyectos revisados por nuestro IRB no requieren esta sección).
Los investigadores han tomado medidas para minimizar los riesgos de este estudio. Informe a los investigadores si tiene alguna lesión o problema relacionado con su participación en el estudio. Para la investigación relacionada con la salud que involucra **tratamiento**, incluya: Usted también debe informar a su médico. El investigador puede referirlo para obtener tratamiento de emergencia, si corresponde; pero usted o su compañía de seguros serán responsables del costo. Al firmar este formulario, no renuncia a sus derechos legales.

5.2 ¿Cómo podría beneficiarme si participo en este estudio? ¿Cómo podrían beneficiarse los demás?
Es posible que no reciba ningún beneficio personal por participar en este estudio. Sin embargo, otros pueden beneficiarse del conocimiento obtenido de este estudio. **o** Podría beneficiarse de participar en el estudio [describa los beneficios directos]. Nota: La compensación por la participación en la investigación no se considera un beneficio de la investigación. La información sobre compensación debe describirse en la Sección 7.

5.3 ¿Me dirán los investigadores si se enteran de nueva información que podría cambiar mi disposición a permanecer en este estudio? Incluya esta sección para la investigación relacionada con la salud que implique una intervención, de lo contrario elimínela. Sí, los investigadores le dirán si se enteran de nueva información importante que puede cambiar su disposición a permanecer en este estudio.

6. ABANDONAR EL ESTUDIO

6.1 Si quiero dejar de participar en el estudio, ¿qué debo hacer? Si usted decide terminar su participación en el estudio antes de que culmine, no conlleva ninguna consecuencia. Si decide terminar el estudio antes de que finalice, informe a una de las personas enumeradas en la Sección 9 "Información de contacto". Si elige decirle a los investigadores por qué está terminando el estudio, sus razones pueden mantenerse como parte del registro del estudio. Los investigadores mantendrán la información recopilada sobre usted en la investigación a menos que nos solicite que la eliminemos de nuestros registros. Si los investigadores ya han utilizado su información en un análisis de investigación, no será posible eliminarla.

7. COMPENSACIÓN POR PARTICIPACIÓN

7.1 ¿Se me pagará o recibiré algo por participar en este estudio? Recibirá [tipo y monto total de compensación] por su participación en el estudio. Describa cómo se distribuirá la compensación si el participante se retira de la investigación antes del final del estudio.
7.1.1 ¿Tendré que pagar algo para ser parte del estudio? Para ser parte del estudio, deberá pagar [indique qué costos, si corresponde, los participantes deberán pagar (como el estacionamiento)].

8. PROTEGIENDO Y COMPARTIENDO LA INFORMACIÓN DE INVESTIGACIÓN

8.1 ¿Cómo protegerán los investigadores mi información? Describa los procedimientos que se seguirán para mantener la información de los participantes segura y confidencial o indicar que el estudio es anónimo. Nota: cualquier dato de investigación que se vinculará con identificadores individuales se considera identificable.

8.1.1 Protecciones especiales (Elimine esta sección si no aplica)
Divulgaremos su información para cualquier propósito para el que haya dado su consentimiento, como se describe en este documento de consentimiento informado. Esto incluye [Resumir brevemente. Por ejemplo, "Esto incluye compartir los datos de la investigación con su médico y con otros investigadores".]
[Si la ley no le exige que informe a las autoridades en casos específicos, pero considera hacerlo, incluya una declaración aquí. Por ejemplo, "También podemos divulgar su información a las autoridades correspondientes si sospechamos o conocemos casos de abuso o negligencia de niños o ancianos, o si puede lastimarse a sí mismo u otros, o si descubrimos que tiene [condición / enfermedad] . " [**NOTA**: cuando la ley **exige** la presentación de informes, no discuta aquí. Discuta en el siguiente párrafo.]
[Use este párrafo solo según corresponda] Si así lo requiere la ley local o estatal, informaremos a las autoridades correspondientes en casos específicos, como por ejemplo si nos enteramos de [Describa según lo exija la ley. Por ejemplo, "... como si descubrimos que hay abuso, negligencia o peligro de cualquier persona vulnerable"]. [**NOTA:** cuando la ley **no** exige la presentación de informes, pero los investigadores desean informar sobre tales situaciones, no lo discuta aquí. Discuta en el párrafo anterior.]
[Utilice este párrafo solo según corresponda]. Divulgaremos su información si el [ingrese el nombre del patrocinador federal o estatal], la agencia que financia esta investigación, solicita información para auditar o evaluar nuestros procedimientos.

8.2 ¿Quién tendrá acceso a mis registros de investigación?

Existen razones por las cuales los investigadores u otras personas pueden usar o ver información sobre usted durante o después de este estudio. Ejemplos incluyen:

- La universidad, los funcionarios gubernamentales, los patrocinadores del estudio, los auditores y / o la Junta de Revisión Institucional (IRB) pueden necesitar la información para asegurarse de que el estudio se realice de manera segura y adecuada.
- Si aplica, estado: La ley federal o estatal puede requerir que el equipo de investigación provea información a las agencias gubernamentales. Por ejemplo, para evitar daños a usted u otros, o por razones de salud pública.

8.3 ¿Qué pasará con la información recopilada en este estudio?
Mantendremos la información que recopilamos sobre usted durante la investigación [para futuros proyectos de investigación / para el mantenimiento de registros de estudio u otros fines (describir)]. Su nombre y otra información que pueda identificarlo directamente se almacenarán de forma segura y por separado de la información de investigación que recopilamos de usted. Nota: cualquier dato de investigación que contenga identificadores se considera información identificable. Describa el tiempo que se van a guardar los datos y cómo se van a destruir.

Para investigación longitudinal: Los investigadores [planean / pueden] contactarlo nuevamente como parte de este proyecto.

O: No guardaremos su nombre u otra información que pueda identificarlo directamente.

Los resultados de este estudio podrían publicarse en un artículo o presentación, pero no incluirán ninguna información que permita que otros sepan quién es usted.

Si el investigador desea identificar a un participante en una presentación o artículo, diga: Los resultados de este estudio podrían publicarse en un artículo o presentación, pero no incluirían ninguna información que les permitiera saber a otros quién es usted sin su permiso.

8.4 ¿Se usará mi información para futuras investigaciones o se compartirá con otros? (elimine esta sección si no corresponde). La Regla Común (Common Rule) requiere que los investigadores les digan a los participantes si sus datos serán almacenados y compartidos para futuras investigaciones, incluso si no se identifican.

Podemos usar o compartir su información de investigación para futuros estudios de investigación. Si compartimos su información con otros investigadores, será de-identificada, lo que significa que no contendrá su nombre u otra información que pueda identificarlo directamente. Esta investigación puede ser similar a este estudio o completamente diferente. No le pediremos un consentimiento informado adicional para estos estudios.

Si planea retener y compartir información identificable para futuras investigaciones no especificadas, indique:

Nos gustaría compartir su información identificable con otros investigadores para futuras investigaciones. Le pediremos su consentimiento para hacerlo al final de este formulario. Usted puede ser parte de este proyecto de investigación actual y no aceptar que en el futuro se use su información identificable.

o No almacenaremos su información de investigación ni la compartiremos con otros investigadores. El IRB no recomienda el uso de esta declaración, ya que impedirá el uso secundario de estos datos en el futuro.

8.4.1 Requisitos especiales (elimine esta sección si no aplica).
Si su proyecto cumple con la definición de un estudio clínico de NIH, incluya el siguiente lenguaje requerido: Una descripción de este estudio clínico estará disponible en www.ClinicalTrials.gov, según lo requerido por los Institutos Nacionales de Salud (NIH). Este sitio web no incluirá información que pueda identificarlo. Como máximo, el sitio web incluirá un resumen de los resultados. Puede visitar este sitio web en cualquier momento.
Si va a registrar su proyecto en ClinicalTrials.gov voluntariamente o para cumplir con los requisitos de la revista u otros, incluya lo siguiente: Este estudio clínico se registrará para reportar los resultados en www.ClinicalTrials.gov. Este sitio no incluirá información que pueda identificarlo. Como máximo, el sitio web incluirá un resumen de los resultados. Puede visitar este sitio web en cualquier momento.

Para proyectos que aportarán datos de investigación a un repositorio, use el siguiente lenguaje: Pondremos la información que recopilamos de usted en un repositorio que contiene información sobre muchas personas. Su información será [de-identificada ó etiquetada con un código, en lugar de su nombre u otra información que pueda usarse para identificarlo directamente.] Agregue información adicional con respecto a las protecciones de datos proporcionadas por el repositorio.

9. INFORMACIÓN DE CONTACTO

¿A quién puedo contactar para saber más de este estudio?
Please contact the researchers listed below to: Puede contactar los investigadores mencionados abajo para:

- Obtener más información sobre el estudio.
- Preguntar sobre los procedimientos del estudio.
- Reportar si tiene malestar, una lesión u otro problema (Puede que también necesite contactar a su médico general).
- Dejar el estudio antes de que culmine.
- Expresar su preocupación sobre el estudio.

Investigador principal:
Correo Electrónico:
Teléfono: (si va a proveer el teléfono de la institución, recuerde de también debe proveer el número de extensión)

Co-Investigador:
Correo Electrónico:
Teléfono:

Co-Investigador:
Correo Electrónico:
Teléfono:

Si tiene alguna pregunta sobre sus derechos como participante en esta investigación,

puede comunicarse con el Dr. Simón Carlo, Director de la Junta de Revisión Institucional (IRB) de Ponce Medical School Foundation (PMSF), Inc., llamando al **(787) 840-2575, ext. 4758 o vía correo electrónico: scarlo@psm.edu**

10. Su Consentimiento

Consentimiento / asentimiento para participar en el Estudio de Investigación
Al firmar este documento, usted acepta participar en este estudio. Asegúrese de comprender de qué se trata el estudio antes de firmar. Yo/Nosotros le daré/le daremos una copia de este documento para sus registros y yo/nosotros guardaré/guardaremos una copia con los registros del estudio. Si tiene alguna pregunta sobre el estudio después de firmar este documento, puede comunicarse con el equipo de investigación utilizando la información de la Sección 9 proporcionada anteriormente.

Entiendo de qué trata el estudio y mis preguntas hasta ahora han sido respondidas. Acepto participar en este estudio.

CAMPOS IDENFICADORES: Si su protocolo NO es anónimo, utilice estos campos y borre los campos ANÓNIMOS.

Nombre legal (en letra de molde): _____
Firma: _____
Fecha de Firma (mm/dd/yy): _____

Firma del Investigador Principal: _____

CAMPOS ANÓNIMOS: Si su protocolo es ANÓNIMO, utilice estos campos y borre los campos IDENTIFICADORES.

□ Sí, acepto ser parte de este estudio.
□ No, no acepto ser parte de este estudio.

Firma del Investigador Principal: _____

Se recuerda a los investigadores que deben entregar una copia al participante y conservar una copia completa del consentimiento, incluyendo una copia de la página de firmas como parte de sus registros de investigación. Los participantes deben completar toda la información requerida (nombre impreso, firma y fecha).

Permiso de los padres o representantes legalmente autorizados (elimine esta sección si no aplica)

Al firmar este documento, usted acepta la participación [de su hijo] o [la persona nombrada a continuación] en este estudio. Asegúrese de entender de qué se trata el estudio antes de firmar. Yo/Nosotros le daré/le daremos una copia de este documento para sus registros. Yo/Nosotros guardaré/guardaremos una copia con los registros del estudio. Si tiene alguna pregunta sobre el estudio después de firmar este documento, puede comunicarse con el equipo de investigación utilizando la información proporcionada anteriormente. Entiendo de qué trata el estudio y mis preguntas hasta ahora han sido respondidas.
Estoy de acuerdo en [que mi hijo] o [la persona nombrada a continuación] participar/participe en

este estudio.

_____
Nombre del Participante en letra de molde

_____
Escriba el nombre del padre / representante legalmente autorizado
Relación con el participante: □ Padre □ Cónyuge □ Hijo □ Hermano □ Tutor legal □ Otro

_____
Firma Fecha

_____
Nombre en letra de molde del padre / representante legalmente autorizado (cuando se requieren las firmas de dos padres) Se requieren dos firmas para una investigación de riesgo más que mínima sin beneficio directo para el niño.
Relación con el participante: □ Padre □ Hermano □ Tutor legal □ Otro

_____
Firma Fecha

Motivo por el que no se obtuvo el permiso del segundo padre:
□ El padre es desconocido
□ Padre fallecido
□ El padre es incompetente
□ Solo uno de los padres tiene responsabilidad legal por el cuidado y la custodia
□ El padre no está razonablemente disponible *; explique:

**Nota: "No está razonablemente disponible" significa que no se puede contactar al otro padre por teléfono, correo, correo electrónico o fax, o se desconoce su paradero. No significa que el otro padre esté en el trabajo o en el hogar, o que él o ella viva en otra ciudad, estado o país.*

11. CONSENTIMIENTO OPCIONAL (SI SU PROTOCOLO ES EXEMPTO, BORRE TODOS ESTOS CONSENTIMIENTOS)

Se deben obtener firmas separadas para actividades específicas cuando esas actividades son opcionales. Si una actividad es obligatoria u opcional debe describirse claramente en el cuerpo principal del documento de consentimiento. Algunas actividades de investigación opcionales comunes se incluyen a continuación. Elimine esta sección o cualquiera de las siguientes declaraciones de consentimiento que no se aplican a su investigación. Los participantes deben completar toda la información requerida (nombre impreso, firma y fecha) si se ofrece una sección de consentimiento opcional.

Consentimiento para usar [grabaciones de video / grabaciones de audio / fotografía] para los propósitos de esta investigación. (Úselo SOLO si no es necesario grabar para participar en la investigación).
Este estudio involucra [grabaciones de video / grabaciones de audio / fotografía]. Si no acepta

ser [video grabado / audio grabado / fotografiado], aún puede participar en el estudio.

_____ Sí, acepto ser [video grabado / audio grabado / fotografiado].
_____ No, no estoy de acuerdo con ser [video grabado / audio grabado / fotografiado].

Nombre legal impreso: _____

Firma: _____

Fecha de firma (mm/dd/yy): _____

Firma del Investigador Principal: _____

Consentimiento para el uso de grabaciones de video, grabaciones de audio o fotografías para publicaciones, presentaciones o con fines educativos.
Doy permiso para grabaciones de audio / grabaciones de video / fotografías hechas de mí como parte de la investigación para ser utilizadas en publicaciones, presentaciones o con fines educativos.

_____ Sí

_____ No

Nombre legal impreso: _____
Firma: _____
Fecha de firma: (mm/dd/yy): _____

Firma del Investigador Principal: _____

Consentimiento para usar y / o compartir su información identificable para futuras investigaciones
Los investigadores desean utilizar su información identificable para futuras investigaciones que pueden ser similares o completamente diferentes a este proyecto de investigación. Identificable significa que los datos contendrán información que puede usarse para identificarlo directamente. El equipo de investigación no se comunicará con usted para obtener un consentimiento adicional para esta investigación futura. También podemos compartir su información identificable con otros investigadores. Puede contactarnos en cualquier momento para solicitarnos que dejemos de usar su información. Sin embargo, no podremos recuperar su información de proyectos de investigación que ya la hayan utilizado.

Nota: Este consentimiento por separado no es necesario si solo almacenará y compartirá datos o muestras biológicas no identificados.

_____ Sí, estoy de acuerdo en dejar que los investigadores usen o compartan mi información de identificación personal para futuras investigaciones.

_____ No, no estoy de acuerdo en dejar que los investigadores usen o compartan mi información de identificación personal para futuras investigaciones.

Nombre legal en letra de molde:

_____

Firma: _____

Fecha de firma (mm/dd/yy): _____

Firma del Investigador Principal: _____

Consentimiento para ser contactado para participar en investigaciones futuras

Los investigadores desearían mantener su información de contacto para invitarlo a participar en futuros proyectos de investigación que pueden ser similares o completamente diferentes a este proyecto de investigación.

_____ Sí, acepto que los investigadores me contacten para futuros proyectos de investigación.

_____ No, no estoy de acuerdo con que los investigadores me contacten para futuros proyectos de investigación.

Nombre del Participante: _____

Firma del Participante: _____

Firma del Investigador: _____

Nombre del Investigador: _____

Fecha: _____

IRB FORM 5

Template

ASSENT FORM FOR CHILDREN/MINORS IN A RESEARCH STUDY

[This should all be on one page and should be read to child/minor if necessary]

You are being asked to be in a research study. *[Describe the study as if you were telling a story.]*

[Explain who will know about the child's participation in the study. If information will be released to a third party i.e. therapist or family physician, this must be disclosed. If there is a possibility of uncovering a reportable event, this must also be disclosed. Sample language = "If we find out someone has hurt you, we must report this to a responsible adult, but not to the person who hurt you.]

Child's Assent: I have been told about this study and know why it is being done and what to do. I also know what I do not have to do it if I do not want to. If I have any questions, I can ask _____. I can stop at any time.

My parents/guardians know what I am being asked to be in this study.

Child's Signature _____

Parent's Signature _____

Principal Investigator Signature:_____

FORMULARIO DE CONSENTIMIENTO PARA NIÑOS/MENORES EN UN ESTUDIO DE INVESTIGACIÓN

[*Todo esto debe estar en una página y debe leerse al niño o menor si es necesario*].

Se le pide que participe en un estudio de investigación. [*Describa el estudio como si estuviera contando una historia*].

[*Explique quién conocerá la participación del menor en el estudio. Si se va a revelar información a terceros, por ejemplo, al terapeuta o al médico de cabecera, debe indicarse. Si existe la posibilidad de que se descubra un suceso de notificación obligatoria, también debe indicarse. Ejemplo de texto = «Si descubrimos que alguien te ha hecho daño, debemos informar de ello a un adulto responsable, pero no a la persona que te hizo daño*»].

Consentimiento del niño: Me han informado sobre este estudio y sé por qué se realiza y qué debo hacer. También sé que no tengo que hacerlo si no quiero. Si tengo alguna duda puedo preguntar a _____. Puedo dejarlo en cualquier momento.

Mis padres/tutores saben lo que se me pide para participar en este estudio.

Firma del menor: _____

Firma del padre/madre: _____

Firma del Investigador Principal: _____

Streamlyne: IRB Protocol

Questionnaire

A. Protocol Summary Interview (Complete)

What are your study's objectives? Please state each objective in a separate manner and, after each objective, present a simple rationale for the proposed objective.

What are the possible benefits to your study? Please present, in a separate manner, the study benefits as they correspond to each study objective presented above.

What site(s) will be used in your study? Note that you must upload a Study Site Approval Letter in the Protocol Attachments section for each study site that you identify.

What is the proposed time period for the study? Please state in years and/or months.

Please describe your recruitment procedures. Note that all Recruitment Documentation, such as advertisements, flyers, posters, etc., must be uploaded to the Protocol Attachments section.

Please describe the characteristics of the subject population. Include information on gender, age, ethnic background, and health status.

Please describe the Subject Inclusion Criteria. Please be as specific as possible.

Please describe the Subject Exclusion Criteria. Please be as specific as possible. Remember that Exclusion Criteria are related to any subject that fulfills all Inclusion Criteria but has a characteristic -- that could be a confounding variable, for instance -- that makes him/her not suitable for the research. If one study criteria is, "to be Hispanic and able to consent," for instance, please do not state, as Exclusion Criteria, "to be not Hispanic and unable to consent."

Please describe investigational methods and procedures. Your description MUST include details about the study design, independent and dependent variables, instruments, statistical plan per objective, quality control methods, limitations, biases, and methods to minimize bias. Note that copies of each instrument (surveys, scales, etc.) must be uploaded in the Protocol Attachments section. Additionally, if your description of the statistical plan exceeds half a page, please upload a copy of the statistical plan to the Protocol Attachments section in addition to the description provided here.

What are the possible risks and discomforts to subjects, as described on the consent form? Please include expected frequency and severity of adverse reactions or risks. Be sure to state if the research activities involve no more than 'Minimal Risk.' If so, state each one separately. Submissions stating 'this study implies no risk' are not acceptable.

Please describe the special precautions to minimize risks or hazards. Please state, in a separate manner, the special precautions as they apply to each possible risk or discomfort stated above. Please take into consideration that discomfort can be influenced by factors such as study content and participant time commitment. Investigators must consider consequences to participants' mental/emotional state, level of fatigue, etc.

Please describe the measures taken to protect confidentiality. Please address the following questions

in your response: Who is responsible for each component of each protocol? When will data be shared and how? How will you protect the data? How long will the data be stored once the study is finished? How will you dispose of data once the study is finished?

B. PI Submission Interview (Complete)

Is this study generalized or non-generalized? (Yes/No)

If non-generalized, is the study a pilot study or an exploratory study? (If the study is generalized, type 'N/A'.)

What is your sample size?

How did you calculate your sample size? Include alpha/beta values, errors or differences, confidence intervals, baseline values such as incidence, prevalence, and median values as they apply to the study, including a percentage of margin of error, etc.

What is the age range of your subjects?

What is the source of your subjects?

Does your study propose remuneration for participants by test and/or study? (Yes/No)

In your judgement, might the procedures place the subject at more than minimal risk? (Yes/No)

In your judgement, are the proposed research procedures apart from and beyond the diagnostic and therapeutic needs of the subject? (Yes/No)

Will the procedures involve administration of new drugs, which have not been approved formerly? (Yes/No)

Will the procedures involve an Investigational Device? (Yes/No)

Does the study include questionnaires with sensitive areas, for example alcohol/drug abuse, sexual behavior, HIV status, etc.? (Yes/No)

Does the protocol involve Biohazard risk? (Yes/No)

I agree to use procedures with respect to safeguard human subjects involved in this research. (Yes/No)

If changes in investigative procedures involving human subjects are called for during the research program covered by this application, I shall seek prior approval for the changes from the IRB and I shall agree to follow their recommendations. (Yes/No)

I further agree to report to the IRB, if applicable, any complications or unanticipated or adverse events with respect to human subjects. (Yes/No)

I also understand that I must submit a renewal application annually. (Yes/No)

C. Data Sharing (Complete)

Will this application include Data Sharing? (Yes/No)

How will you be sharing the data? Describe the method of data transfer.

HUMAN SUBJECT REGULATIONS DECISION CHARTS: 2018 REQUIREMENTS

OHRP
Office for Human Research Protections

NOTE: This guidance is consistent with the 2018 Requirements (i.e., the revised Common Rule).

For use after January 20, 2019

SCOPE: The following graphic charts are intended to aid those who need to decide if an activity is research involving human subjects that must be reviewed by an institutional review board (IRB) and whether informed consent or the documentation of informed consent can be waived under the 2018 Requirements found for the U.S. Department of Health and Human Services (HHS) at 45 CFR part 46, Subpart A.

TARGET AUDIENCE: IRBs, institutions, investigators, and others

CONSIDERATIONS: These charts are necessarily generalizations and may not be specific enough for particular situations. Other guidance documents are available related to specific topics at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/index.html. OHRP cautions that the full text of an applicable regulatory provision should be considered in making final decisions. The charts do not address requirements that may be imposed by other organizations, such as the Food and Drug Administration, the National Institutes of Health, other sponsors, or state or local governments.

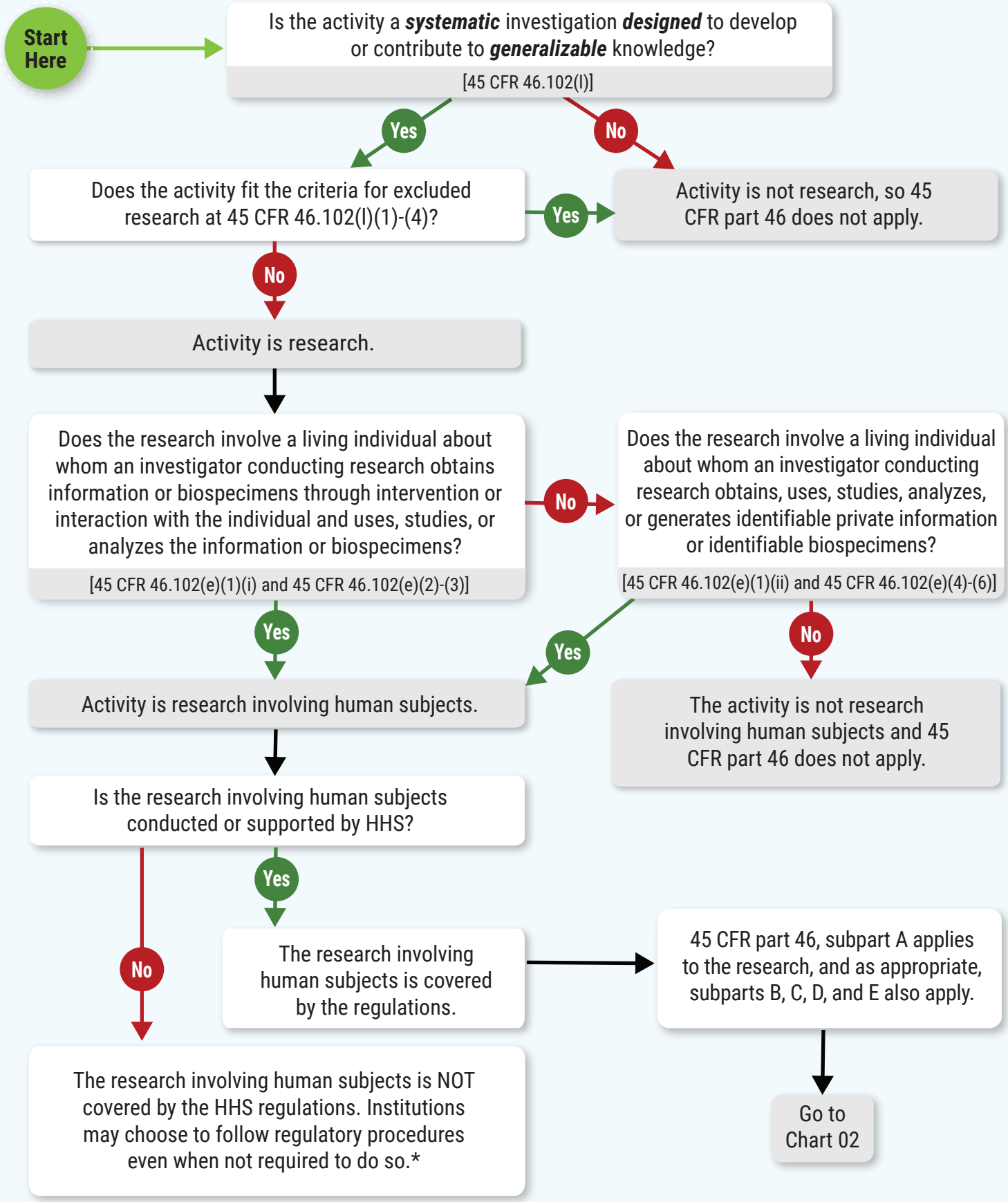
CHART 01

IS AN ACTIVITY HUMAN SUBJECTS RESEARCH COVERED BY 45 CFR PART 46?

NOTE: This chart is consistent with the 2018 Requirements (i.e., the revised Common Rule)

OHRP Office for Human Research Protections

For use after January 20, 2019



*For information on whether an institution needs to revise its FWA because of the 2018 Requirements, see, https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html

CHART 02

IS THE RESEARCH INVOLVING HUMAN SUBJECTS ELIGIBLE FOR EXEMPTION UNDER 45 CFR 46.104(d)?

NOTE: This chart is consistent with the 2018 Requirements (i.e., the revised Common Rule)

OHRP Office for Human Research Protections

For use after January 20, 2019

Has HHS ***prohibited*** exemption of the human subjects research? (Most research involving prisoners, some research involving children.)

[45 CFR 46.104(b)]

Yes → No exemptions to 45 CFR part 46 apply. Provisions of 45 CFR part 46, subpart A apply, and subparts B, C, and D also apply if subjects are members of populations covered in those subparts.

No

Will the ***only**** involvement of human subjects be in one or more of the following categories?

Research conducted in ***established or commonly accepted*** educational settings, involving ***normal education practices***?

Yes → Exemption 45 CFR 46.104(d)(1) may apply. → Go to Chart 03

Or

Research only including interactions involving ***educational tests***, ***survey procedures***, ***interview procedures***, or ***observation of public behavior***?

Yes → Exemption 45 CFR 46.104(d)(2) may apply. → Go to Chart 04

Or

Research involving benign ***behavioral interventions*** and collection of information from ***adults*** with their agreement?

Yes → Exemption 45 CFR 46.104(d)(3) may apply. → Go to Chart 05

Or

Secondary research use of identifiable private information or identifiable biospecmens?

Yes → Exemption 45 CFR 46.104(d)(4) or (d)(8) may apply. → Go to Chart 06 & Chart 10

Or

Research studying, evaluating, or examining ***public benefit*** or ***service programs***?

Yes → Exemption 45 CFR 46.104(d)(5) may apply. → Go to Chart 07

Or

Research involving ***taste and food quality evaluation*** of ***consumer acceptance studies***?

Yes → Exemption 45 CFR 46.104(d)(6) may apply. → Go to Chart 08

Or

Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research use?

Yes → Exemption 45 CFR 46.104(d)(7) may apply. → Go to Chart 09

Only** means that no nonexempt activities are involved. Research that excludes both exempt and nonexempt activities is ***not exempt. Research may involve activities exempt under more than one exemption category.

CHART 03

DOES EXEMPTION 45 CFR 46.104(d)(1) FOR EDUCATIONAL PRACTICES APPLY?

NOTE: This chart is consistent with the 2018 Requirements (i.e., the revised Common Rule)

OHRP Office for Human Research Protections

For use after January 20, 2019

TO BE EXEMPT, NO NONEXEMPT ACTIVITIES CAN BE INVOLVED. RESEARCH THAT INCLUDES BOTH EXEMPT AND NONEXEMPT ACTIVITIES IS NOT EXEMPT. RESEARCH MAY INVOLVE ACTIVITIES EXEMPT UNDER MORE THAN ONE EXEMPTION CATEGORY.

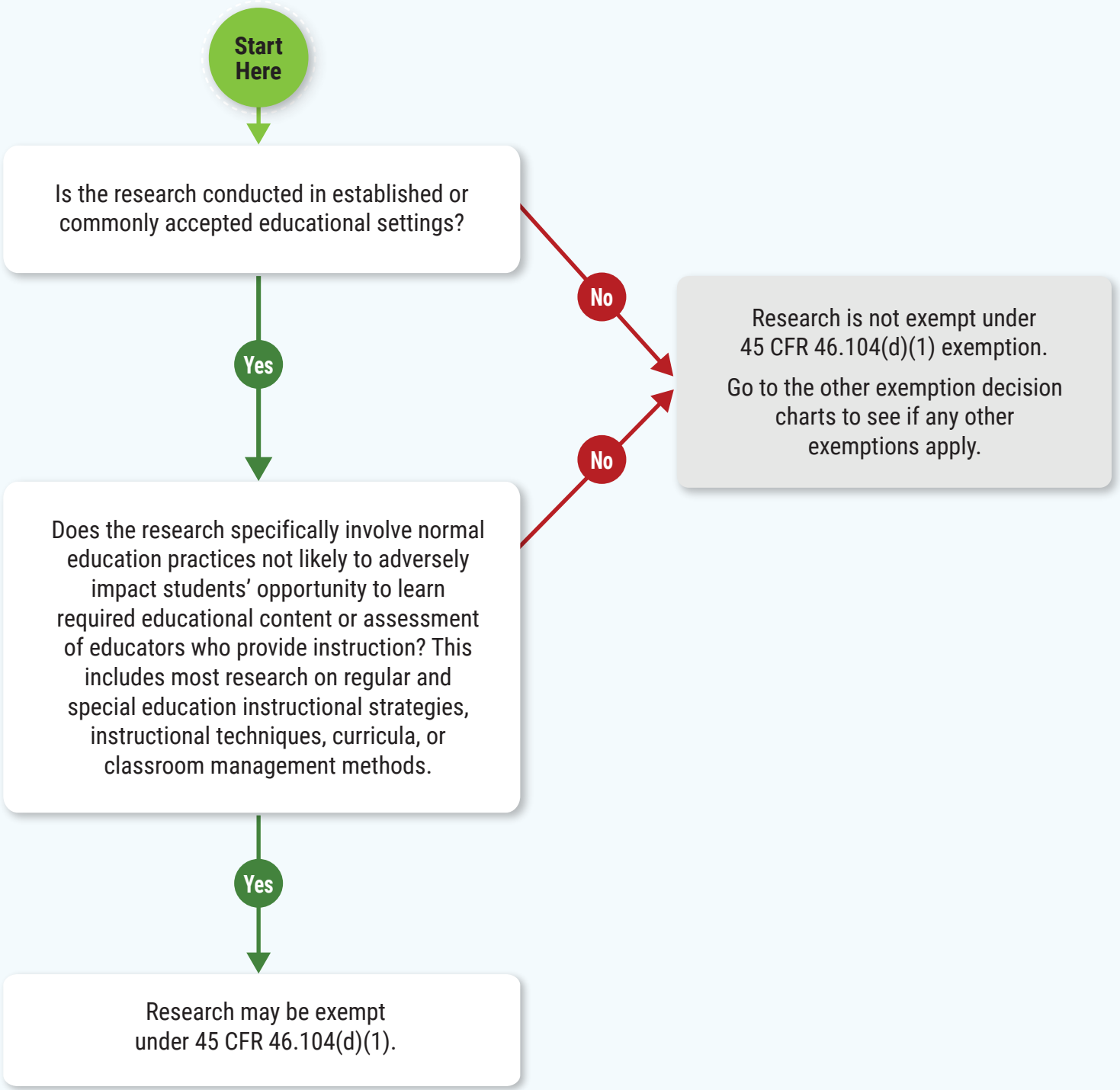


CHART 04

DOES EXEMPTION 45 CFR 46.104(d)(2) FOR EDUCATIONAL TESTS, SURVEYS, INTERVIEWS, OR OBSERVATION OF PUBLIC BEHAVIOR APPLY?

NOTE: This chart is consistent with the 2018 Requirements (i.e., the revised Common Rule)

OHRP Office for Human Research Protections

For use after January 20, 2019

TO BE EXEMPT, NO NONEXEMPT ACTIVITIES CAN BE INVOLVED. RESEARCH THAT INCLUDES BOTH EXEMPT AND NONEXEMPT ACTIVITIES IS NOT EXEMPT. RESEARCH MAY INVOLVE ACTIVITIES EXEMPT UNDER MORE THAN ONE EXEMPTION CATEGORY.

Start Here

Does the research only include interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recordings)?

No → The research is not exempt under 45 CFR 46.104(d)(2). Go to the other exemption decision charts to see if any other exemptions apply.

Yes

Is the information obtained recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects?

[45 CFR 46.104(d)(2)(i)]

Yes → The exemption may apply. However, when the subjects are children, this may only apply to research involving educational tests or the observation of public behavior when the investigator ***does not participate*** in the activities being observed.

[45 CFR 46.104(b)(3)]

Or

Is it the case that any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation?

[45 CFR 46.104(d)(2)(ii)]

Yes → The exemption may apply. However, when the subjects are children, this may only apply to research involving educational tests or the observation of public behavior when the investigator ***does not participate*** in the activities being observed.

[45 CFR 46.104(b)(3)]

Or

Is the information obtained recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and has an IRB conducted a limited review to make the determination required by 45 CFR 46.111(a)(7)?

[45 CFR 46.104(d)(2)(iii)]

No → The research is not exempt under 45 CFR 46.104(d)(2). Go to the other exemption decision charts to see if any other exemptions apply.

Yes → The exemption may apply unless the research involves children. This condition ***does not apply*** to research subject to Subpart D.

[45 CFR 46.104(b)(3)]

CHART 05

DOES EXEMPTION 45 CFR 46.104(d)(3) FOR BENIGN BEHAVIORAL INTERVENTIONS APPLY?

NOTE: This chart is consistent with the 2018 Requirements (i.e., the revised Common Rule)

OHRP Office for Human Research Protections

For use after January 20, 2019

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Start Here

Does the research involve ***benign behavioral interventions**** in conjunction with collection of information from adults through verbal or written responses (including data entry) or audiovisual recording?

Yes → Have the subjects prospectively agreed to the intervention and information collection?

Yes → Is the information obtained ***recorded*** in such a manner that human ***subjects can be readily identified***, directly or through identifiers linked to the subjects?

Yes → Has an IRB conducted a limited review to make the determinations required by 45 CFR 46.111(a)(7); that, when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data?

No → Could ***any disclosure*** of the human subjects' responses outside the research reasonably ***place the subjects at risk*** of criminal or civil liability ***or be damaging*** to the subjects' financial standing, employability, educational advancement, or reputation?

No → Research may be exempt under 45 CFR 46.104(d)(3).

Yes → The research is not exempt under 45 CFR 46.104(d)(3). Go to the other exemption decision charts to see if any other exemptions apply.

No → The research is not exempt under 45 CFR 46.104(d)(3). Go to the other exemption decision charts to see if any other exemptions apply.

Yes → The research is not exempt under 45 CFR 46.104(d)(3). Go to the other exemption decision charts to see if any other exemptions apply.

No → The research is not exempt under 45 CFR 46.104(d)(3). Go to the other exemption decision charts to see if any other exemptions apply.

Exemption 45 CFR 46.104(d)(3) does not apply if the research involves deceiving subjects regarding the nature or purposes of the research unless the subject authorizes the deception through prospective agreement to be unaware of or misled regarding the nature or purposes of the research.

***Benign behavioral interventions** are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

CHART 06

DOES EXEMPTION 45 CFR 46.104(d)(4) FOR SECONDARY RESEARCH THAT DOES NOT REQUIRE CONSENT APPLY?

NOTE: This chart is consistent with the 2018 Requirements (i.e., the revised Common Rule)

OHRP Office for Human Research Protections

For use after January 20, 2019

TO BE EXEMPT, NO NONEXEMPT ACTIVITIES CAN BE INVOLVED. RESEARCH THAT INCLUDES BOTH EXEMPT AND NONEXEMPT ACTIVITIES IS NOT EXEMPT. RESEARCH MAY INVOLVE ACTIVITIES EXEMPT UNDER MORE THAN ONE EXEMPTION CATEGORY.

Start Here

Does the research involve ***secondary uses*** of identifiable private information or identifiable biospecimens? *

Yes

Is the identifiable private information or are the identifiable biospecimens publicly available?

[45 CFR 46.104(d)(4)(i)]

Yes

Or

Is the information, which may include information about biospecimens, recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects?

[45 CFR 46.104(d)(4)(ii)]

Yes

Or

Does the research involve only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for purposes of "healthcare operations" or "research" as defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b)?

[45 CFR 46.104(d)(4)(iii)]

Yes

Or

Is the research conducted or supported by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, and the research generates identifiable private information that is or will be maintained on information technology subject to and in compliance with section 208(b) of the E-Government Act of 2002, and all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995?

[45 CFR 46.104(d)(4)(iv)]

Yes

Yes

No

No

The research is not exempt under 45 CFR 46.104(d)(4).

Go to the other exemption decision charts to see if any other exemptions apply.

Research may be exempt under 45 CFR 46.104(d)(4).

*Research use of identifiable private information or identifiable biospecimens collected for either research studies other than the proposed research, or for nonresearch purposes.

CHART 07

DOES EXEMPTION 45 CFR 46.104(d)(5) FOR PUBLIC BENEFIT OR SERVICE PROGRAMS APPLY?

NOTE: This chart is consistent with the 2018 Requirements (i.e., the revised Common Rule)

OHRP Office for Human Research Protections

For use after January 20, 2019

TO BE EXEMPT, NO NONEXEMPT ACTIVITIES CAN BE INVOLVED. RESEARCH THAT INCLUDES BOTH EXEMPT AND NONEXEMPT ACTIVITIES IS NOT EXEMPT. RESEARCH MAY INVOLVE ACTIVITIES EXEMPT UNDER MORE THAN ONE EXEMPTION CATEGORY.

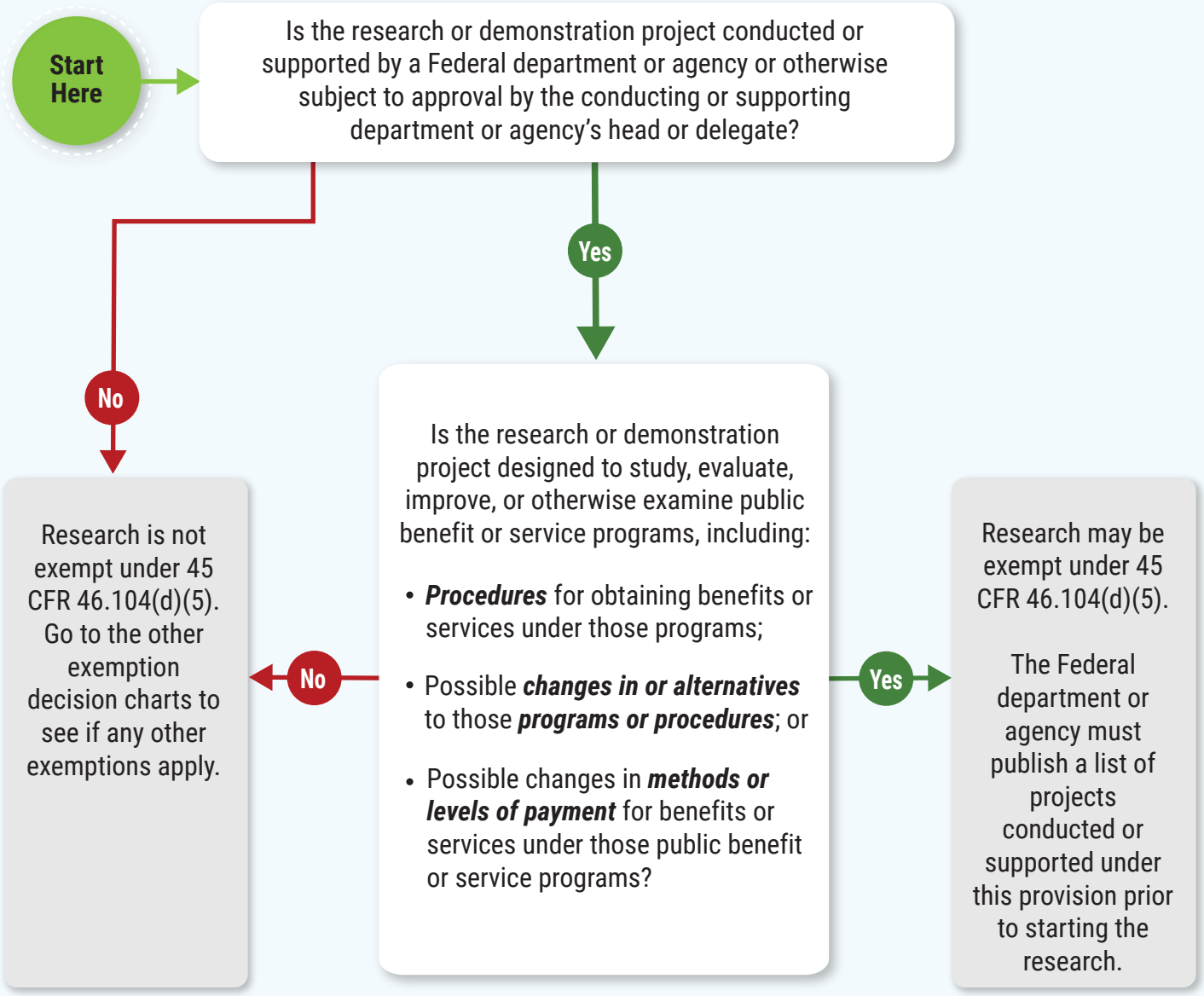

CHART 08

DOES EXEMPTION 45 CFR 46.104(d)(6) FOR FOOD, TASTE, AND ACCEPTANCE STUDIES APPLY?

NOTE: This chart is consistent with the 2018 Requirements (i.e., the revised Common Rule)

OHRP Office for Human Research Protections

For use after January 20, 2019

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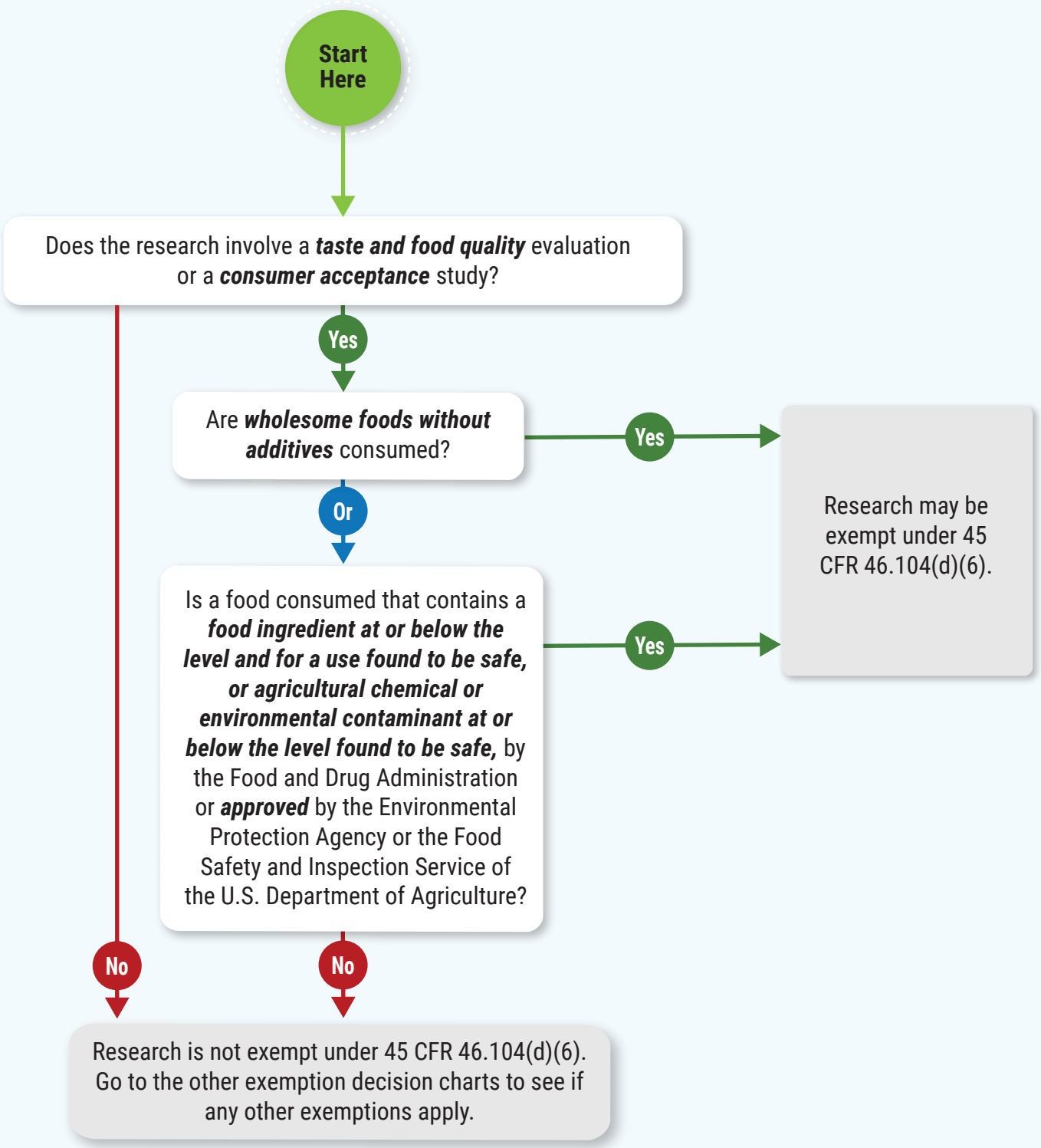


CHART 09

DOES EXEMPTION 45 CFR 46.104(d)(7), STORAGE FOR SECONDARY RESEARCH FOR WHICH BROAD CONSENT IS REQUIRED, APPLY?

OHRP Office for Human Research Protections

NOTE: This chart is consistent with the 2018 Requirements (i.e., the revised Common Rule)

For use after January 20, 2019

TO BE EXEMPT, NO NONEXEMPT ACTIVITIES CAN BE INVOLVED. RESEARCH THAT INCLUDES BOTH EXEMPT AND NONEXEMPT ACTIVITIES IS NOT EXEMPT. RESEARCH MAY INVOLVE ACTIVITIES EXEMPT UNDER MORE THAN ONE EXEMPTION CATEGORY.

Start Here

Does the research involve storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research?*

Yes

Has an IRB conducted a limited review and made the determinations required by 45 CFR 46.111(a)(8) that:

broad consent for storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens is obtained in accordance with 45 CFR 46.116(a)(1)-(4), (a)(6), and (d);

And

broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with 45 CFR 46.117;

And

if a change is made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data?

Yes → Research may be exempt under 45 CFR 46.104(d)(7).

No

No → Research is not exempt under 45 CFR 46.104(d)(7).
Go to the other exemption decision charts to see if any other exemptions apply.

Secondary research involving storage or maintenance of private information or biospecimens that are not identifiable does not involve human subjects and 45 CFR part 46 does not apply.

*Research use of identifiable private information or identifiable biospecimens collected for either research studies other than the proposed research, or for nonresearch purposes.

CHART 10

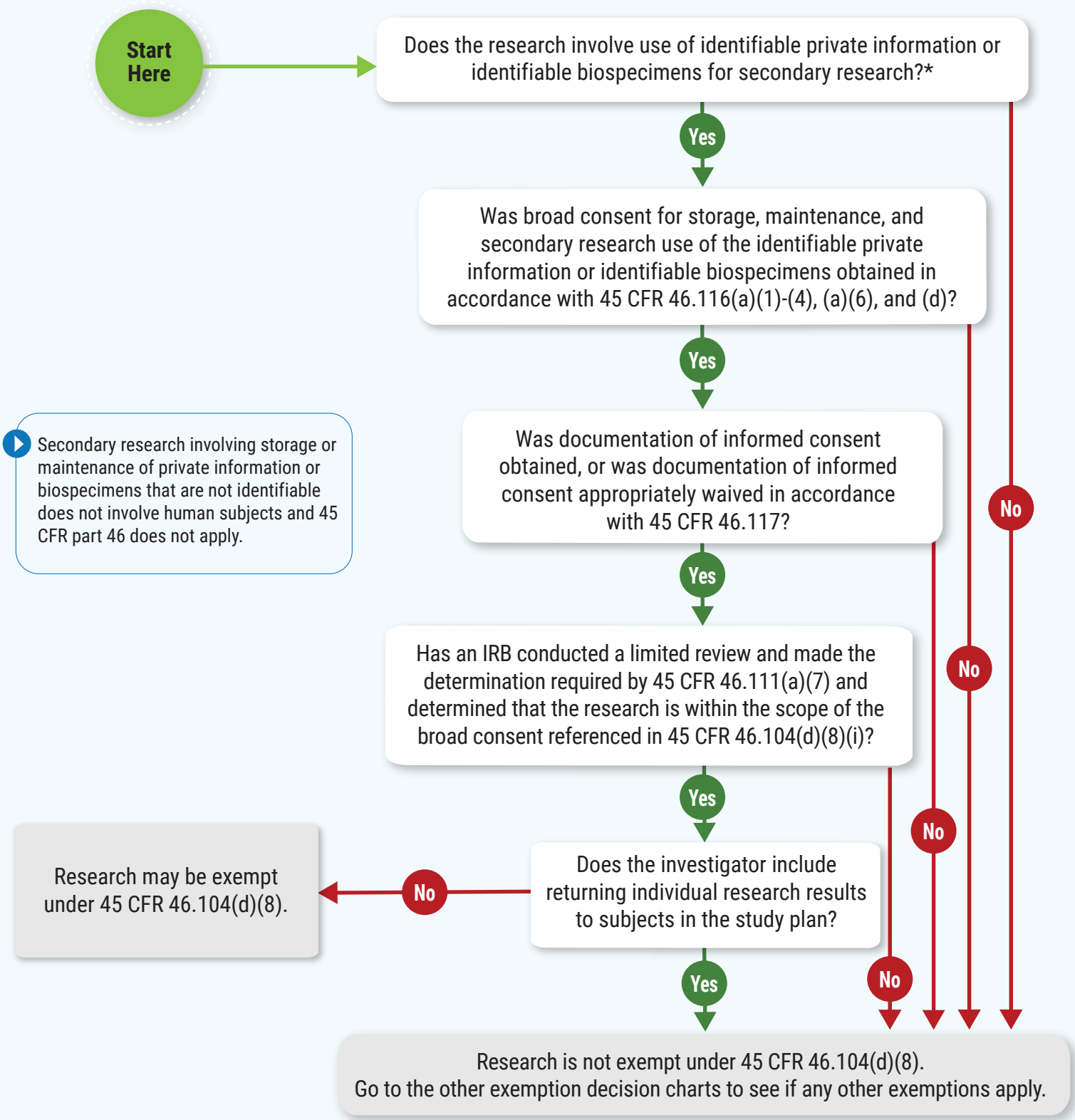
DOES EXEMPTION 45 CFR 46.104(d)(8) FOR SECONDARY RESEARCH FOR WHICH BROAD CONSENT IS REQUIRED APPLY?

NOTE: This chart is consistent with the 2018 Requirements (i.e., the revised Common Rule)

OHRP Office for Human Research Protections

For use after January 20, 2019

TO BE EXEMPT, NO NONEXEMPT ACTIVITIES CAN BE INVOLVED. RESEARCH THAT INCLUDES BOTH EXEMPT AND NONEXEMPT ACTIVITIES IS NOT EXEMPT. RESEARCH MAY INVOLVE ACTIVITIES EXEMPT UNDER MORE THAN ONE EXEMPTION CATEGORY.



Secondary research involving storage or maintenance of private information or biospecimens that are not identifiable does not involve human subjects and 45 CFR part 46 does not apply.

*Research use of identifiable private information or identifiable biospecimens collected for either research studies other than the proposed research, or for nonresearch purposes.

CHART 11

IS CONTINUING REVIEW REQUIRED UNDER 45 CFR 46.109(f)?

NOTE: This chart is consistent with the 2018 Requirements (i.e., the revised Common Rule)

OHRP Office for Human Research Protections

For use after January 20, 2019

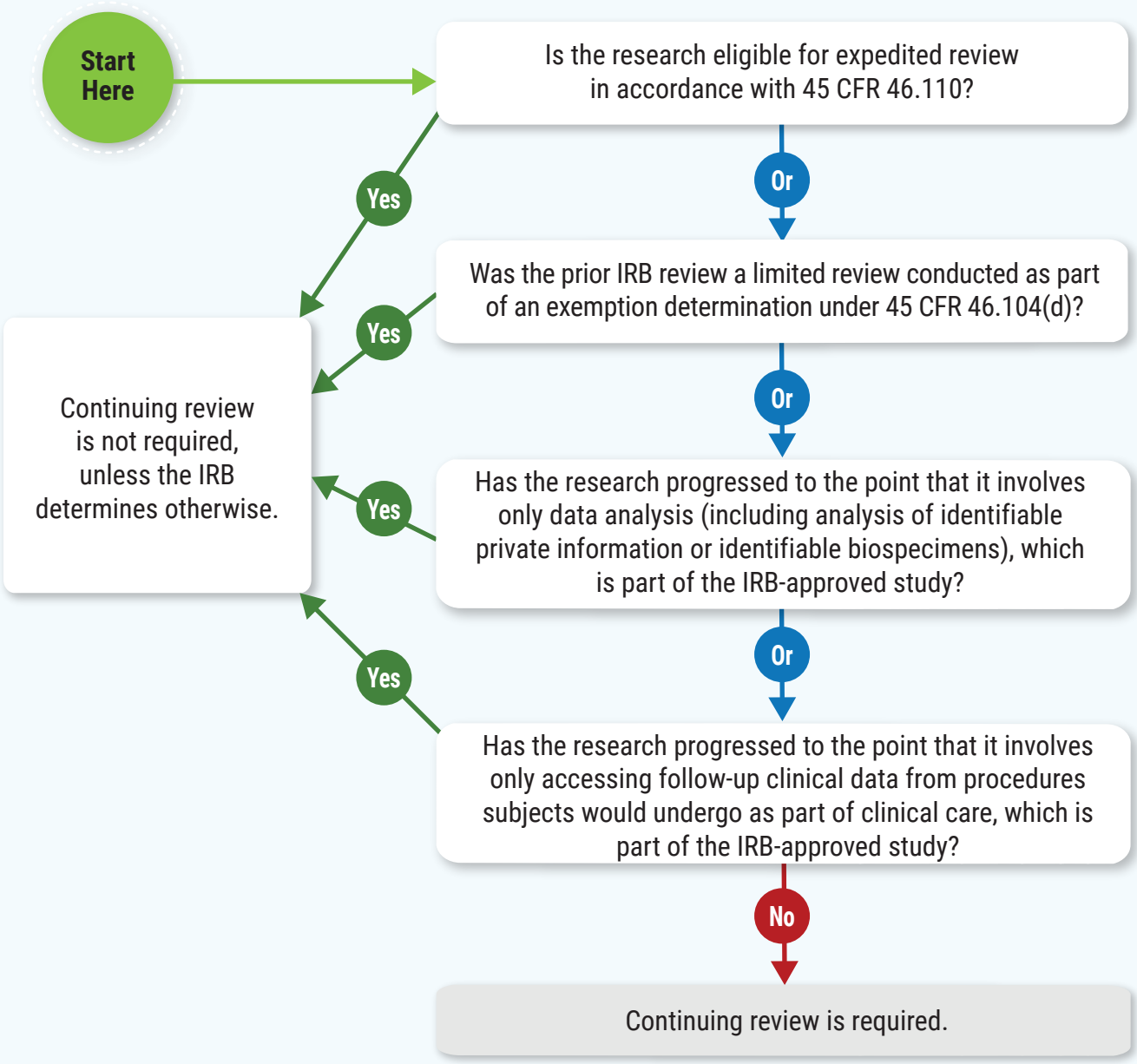


CHART 12

WAIVER OR ALTERATION OF INFORMED CONSENT IN RESEARCH INVOLVING PUBLIC BENEFIT AND SERVICE PROGRAMS CONDUCTED BY OR SUBJECT TO THE APPROVAL OF STATE OR LOCAL GOVERNMENT OFFICIALS (45 CFR 46.116(e))

OHRP Office for Human Research Protections

NOTE: This chart is consistent with the 2018 Requirements (i.e., the revised Common Rule)

For use after January 20, 2019

Start Here

Has an IRB found and documented that the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine any of the following:

- Public benefit or service programs;
- Procedures for obtaining benefits or services under those programs;
- Possible changes in or alternatives to those programs or procedures; or
- Possible changes in methods or levels of payment for benefits or services under those programs?

[45 CFR 46.116(e)(3)(i)]

No → No waiver or alteration of informed consent is allowed.

Yes

Has an IRB found and documented that the research could not practicably be carried out without the waiver or alteration?

[45 CFR 46.116(e)(3)(ii)]

No → No waiver or alteration of informed consent is allowed.

Yes

Waiver: An IRB may waive the requirement to obtain informed consent, provided the IRB satisfies the requirements for waiver at 45 CFR 46.116(e). However, if an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at 45 CFR 46.116(d), and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

[45 CFR 46.116(e)(1)]

Or

Alteration: An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent found at 45 CFR 46.116(b) and (c) provided the IRB satisfies the requirements at 45 CFR 46.116(e). However, an IRB may not omit or alter any of the requirements described at 45 CFR 46.116(a). If a broad consent procedure is used, an IRB may not omit or alter any of the elements required at 45 CFR 46.116(d) as stipulated under 45 CFR 46.116(e)(2).

[45 CFR 46.116(e)(2),(3)]

CHART 13

WHEN CAN INFORMED CONSENT BE WAIVED OR ALTERED UNDER 45 CFR 46.116(f)?

OHRP Office for Human Research Protections

NOTE: This chart is consistent with the 2018 Requirements (i.e., the revised Common Rule)

For use after January 20, 2019

Start Here

Has an IRB found and documented that ***all*** of the following conditions have been met?

- The research involves no more than minimal risk to the subjects;
- The research could not practicably be carried out without the requested waiver or alteration;
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

[45 CFR 46.116(f)(3)]

No → No waiver or alteration of informed consent is allowed.

Yes

Waiver: An IRB may waive the requirement to obtain informed consent for research provided the IRB satisfies this requirement. However, if an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at 45 CFR 46.116(d), and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

[45 CFR 46.116(f)(1)]

Or

Alteration: An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in 45 CFR 46.116(b) and (c) provided the IRB satisfies this requirement. However, an IRB may not omit or alter any of the requirements described at 45 CFR 46.116(a). If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under 45 CFR 46.116(d).

[45 CFR 46.116(f)(2)]

CHART 14

CAN DOCUMENTATION OF INFORMED CONSENT BE WAIVED UNDER 45 CFR 46.117(c)?

NOTE: This chart is consistent with the 2018 Requirements (i.e., the revised Common Rule)

OHRP Office for Human Research Protections

For use after January 20, 2019