

COMMUNITY UPDATE

ALL ABOUT CITI PROGRAM CERTIFICATES IN STREAMLYNE FOR IRB

If a subject is involved in any type of investigation, all study components must have CITI certificates. But the big question is: Which certificate do I need? This chart will help you determine the required certification based on your department.

		Information Privacy Security (IPS)	Biomedical Research	Social and Behavioral Research	Public health Research
Departments	Public Health	✓			✓
Dental	✓	✓			
Behavioral and Brain Sciences	✓		✓		
Medicine	✓	✓			



If your study involves a
clinical lab, add:
Good Laboratory Practice.



If your study is in a
clinic/medical office add:
Good Clinical Practice



For taking biopsies/blood
samples add:
Biosafety/Biosecurity

Administrators' advice:

- Make sure that all CITI certificates are up to date before uploading to Streamlyne. Expired CITI certificates will get your protocol returned.
- While not required, uploading all your CITI certificates to Streamlyne as a single PDF file will help accelerate your review process.
- If you require a Biosafety/Biosecurity Certificate, you will also need an authorization letter from Dr. Grissell Tirado (gtirado@psm.edu).
- CITI Certificates are meant to be uploaded under each protocol personnel, please upload your CITI Certificates in the designated section (personnel), not in protocol attachments.



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STREAMLYNE ADMINISTRATOR'S

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WORKING WITH ANIMALS? (MICE OR RATS) -GET YOUR CITI CERTIFICATES

The Institutional Animal Care and Use Committee (IACUC) is a regulatory body responsible for overseeing and ensuring the ethical treatment and welfare of animals used in research, testing, and education.

IACUC ensures that studies comply with federal, state, and institutional guidelines, including the Animal Welfare Act and Public Health Service (PHS) Policy. It reviews research protocols, inspects animal facilities, and ensures that alternatives to animal use are considered whenever possible. Ponce School of Medicine has an approved Animal Welfare Assurance D16-00392

Every investigation requires training, and study personnel involved in animal research must complete specific CITI Certificates. These certificates must be uploaded to Streamlyne to ensure compliance with research regulations.



Required by the Institution for handling private or confidential data : Information Privacy Security (IPS) CITI Certificate.

Animal TECHNICIANS add:
Laboratory Animal
Research-Animal
Technicians CITI Certificate.

OR

RESEARCHERS add:
Laboratory Animal
Research -Researchers
CITI Certificate.

Students working with
Animals add: Students
working with Animals CITI
Certificate.

OR

Students NOT working with
animals (but are part of the
study) add: Students NOT
working with animals CITI
Certificate.

Working with MICE in
Research add: Family:
Muridea Cricetidae CITI
Certificate.

OR

Working with RATS in
Research Setting add:
Genus: Rattus CITI
Certificate.

Administrators' advice:

- Make sure that all CITI certificates are up to date before uploading to Streamlyne. Expired CITI certificates will get your protocol returned.
- While not required, uploading all your CITI certificates (per personnel) to Streamlyne as a single PDF file will help accelerate your review process.
- If you require a Biosafety/Biosecurity Certificate, you will also need an authorization letter from Dr. Grissell Tirado (gtirado@psm.edu).
- CITI Certificates are meant to be uploaded under each protocol personnel, please upload your CITI Certificates in the designated section (personnel), not in protocol attachments.
- Ensure protocol is written at 8th grade level reader and include timelines to facilitate reviews.

For more Information
scan this QR Code



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(IACUC ADMINISTRATOR)



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ext. 4752 (IACUC)



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I RECEIVED A "RETURN TO PI" IN STREAMLYNE, NOW WHAT?

You could receive a "Return to PI" (Principal Investigator) in your protocol submission if the IRB reviewer finds that your submission is incomplete, contains errors, or requires clarification or changes before it can move forward in the review process.

To avoid receiving a "Return to PI" notification, make sure to follow IRB guidelines carefully. All necessary information and instructions can be found at:

<https://www.ponceresearch.com/regulatory-compliance/irb/>



Don't worry if you receive a 'Return to PI'—simply review the feedback, make the necessary updates, and resubmit your protocol!

To learn how to resubmit a protocol, scan the QR code below.



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These are the MOST Common reasons for a "Return to PI":

- Missing information – Required sections are not filled out or attachments (like abstract, consent forms or instruments in both English and Spanish) are not included.
- Inconsistencies – Details in your application don't match (e.g., participant numbers, procedures, or timelines vary between sections).
- Incorrect selections – Submission or review type, categories for exemption or expedited review, or checkboxes do not align with your actual protocol.
- Formatting issues – Documents aren't properly uploaded in the correct format (PDF).
- Ethical concerns – Inadequate explanation of how you will protect participants' confidentiality, minimize risk, or obtain informed consent.

When your protocol is returned, review the comments provided though email. These will tell you exactly what needs to be fixed or clarified. In this stage, no other document is required. (Do not use "Answer to critiques" document).

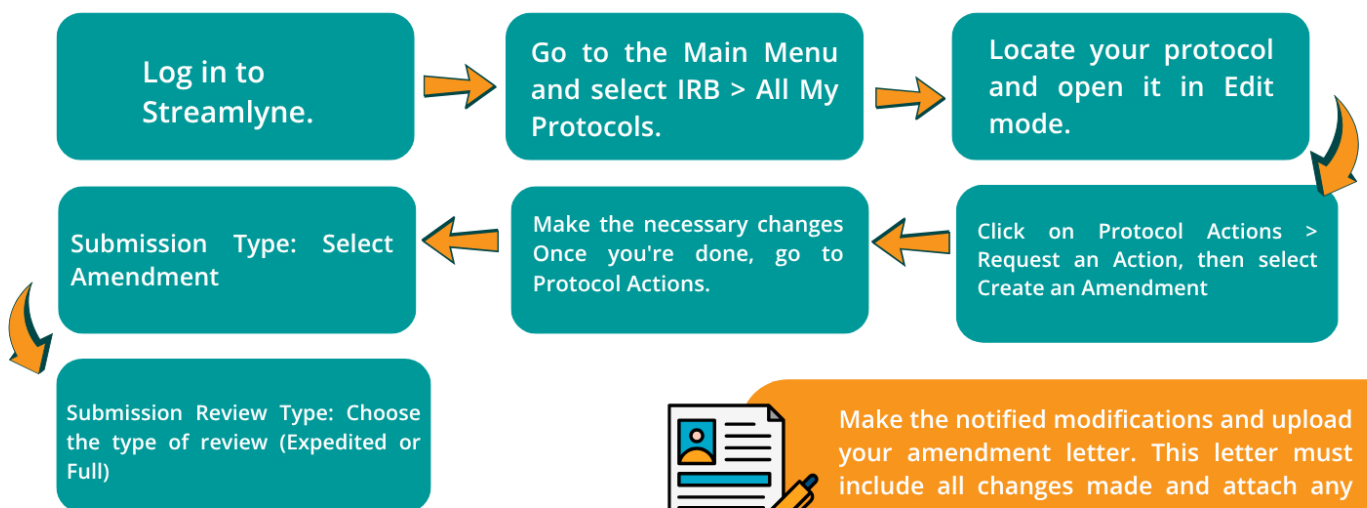
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I NEED TO MAKE AN AMENDMENT TO MY PROTOCOL - THIS IS HOW.

Once a protocol is active, it's perfectly normal to catch errors or make adjustments—whether it's updating documents to address challenges or improving the process for participants. However, all of these changes must be reviewed and approved by the IRB before they are implemented.

Need to make a change to your IRB-approved protocol? Here's how to submit an amendment in seven simple steps:



Make the notified modifications and upload your amendment letter. This letter must include all changes made and attach any documents that changed, remember to have consistency. If you do not upload your amendment letter, your protocol will be returned to you.

Common reasons to resubmit an Amendment:

- Adding or modifying study documents
- Changing study procedures or methodology
- Updating compensation or incentive (e.g., changing payment method, amount, or frequency)
- Correcting errors or clarifying information (e.g., clarifying procedures that caused confusion)
- Including new study personnel
- Changing the study population
- Adding new sites or locations



For a more detailed explanation access this QR code

<https://prezi.com/view/nFZ45ruwsGJfYac8EVyI/>



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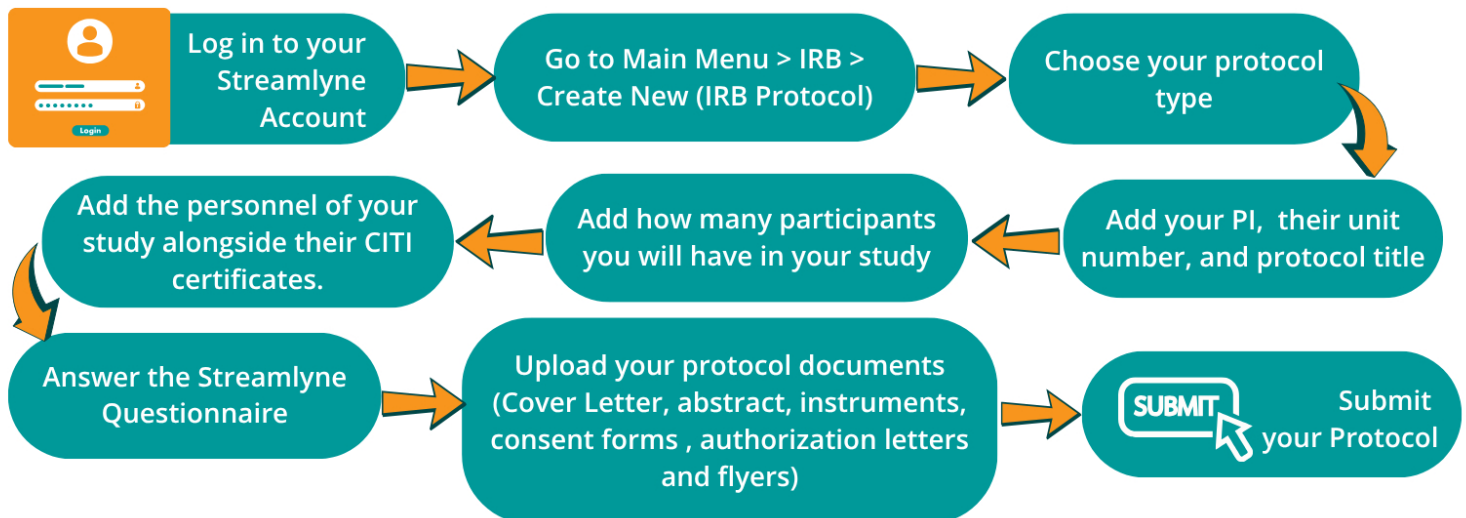
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NEED IRB APPROVAL? SUBMIT WITH CONFIDENCE IN STREAMLYNE

Streamlyne is the official platform for managing research protocols, amendments, and compliance submissions at PHSU. It offers a centralized, secure way to track research documents, supports electronic signatures, and provides real-time status updates. Be sure to complete all required documents before submission to avoid delays.

Submitting a Protocol is a simple process! Below you will see a summarized version of the protocol submission process. To get a more detailed view, scan the QR code!



Administrators' Advice:

- You will need a Streamlyne account to log in. If you do not have an account, please request one at: <http://j.mp/2Atz5pC>
- When completing the Streamlyne questionnaire, ensure your responses are in complete sentences. N/A is not a valid answer.
- Some questions contain multiple parts or embedded sub-questions. Be sure to address all components of each question.
- Before submitting, confirm that you have included all required documents for the IRB.



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DON'T FORGET THESE! MUST-HAVE ATTACHMENTS FOR YOUR PROTOCOL

When submitting a research protocol to an Institutional Review Board (IRB), it's essential to include all required supporting documents to ensure a thorough and efficient review process. Below is a list of key documents typically required, please upload in this order:



Cover Letter

A professional summary that introduces your study, outlines key details, lists included documents, and highlights any special considerations to help the IRB review your protocol more efficiently.



Abstract

An abstract is a brief summary of a research study that includes the background, objective, methods, key results, and hypothesis or expected results.



IRB APPROVED Consent Forms*

Use the IRB-approved consent forms and only adapt them as allowed—don't remove required content. Informed consent ensures ethical standards and protects participants.



Data Extraction Tools*

Submit all surveys, questionnaires, interview guides, and data collection tools, and include permission for use of any copyrighted instruments so the IRB can review content and confirm legal and ethical compliance.



Site Approval Letter(s)*

Include a separate site approval letter for each location where research will be conducted, confirming permission to carry out the study at that site.



Institutional or Biohazard Approval*

Include institutional approval letter provided by Elizabeth Rivera (erivera@psm.edu) when an institutional email is used for recruitment or the research is conducted within the institution. Obtain biohazard approval when collecting any type of human biological sample with Grissell Tirado (biosafety@psm.edu)



Promotional Flyers*

Submit all promotional flyers or recruitment materials at palugo@psm.edu along with Paula Lugo's approval email, so the IRB can ensure the content is accurate, ethically appropriate, and institutionally approved.

Documents marked with an asterisk may not be required for every submission. However, if they are needed, they must be prepared and uploaded in both English and Spanish.

This flyer is accompanied by a helpful Q&A section that addresses common questions and provides additional guidance.



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MOST COMMON QUESTIONS:

Q: Is there a template available for my cover letter?

A: No, the IRB does not provide a specific template for cover letters. However, you are encouraged to follow standard professional formatting and clearly outline the purpose of your submission.

Q: Is there a template for the study abstract?

A: No, there is no specific template for the study abstract. You should provide a clear and concise summary of your study in your own words.

Q: Can I submit a concept paper instead of an abstract?

A: Yes, if you already have a concept paper, you may upload it. However, the IRB prefers a formal abstract as it offers a more concise overview of your study.

Q: Is there a template for the consent form?

A: Yes, the IRB provides a consent form template. You can download it through Ponce Research Institute webpage: <https://www.ponceresearch.com/regulatory-compliance/irb/templates/>

Q: Can the consent form template be adapted?

A: Yes, the template can be adapted to fit the specifics of your study. However, it includes clear instructions that must be followed strictly to ensure compliance with IRB requirements. All required elements must remain in place, and the language should be clear and understandable (8th grade level) for participants.

Q: Does the consent form need to be in both English and Spanish?

A: Yes, the consent form must be provided in both English and Spanish to ensure all participants can fully understand the information, unless the study population exclusively speaks only one language.

Q: Do all documents submitted with the protocol need to be in both English and Spanish?

A: Yes, all documents intended for participant use—such as consent forms, recruitment materials, and questionnaires—must be submitted in both English and Spanish languages due to audit purposes. However, this requirement does not apply to the abstract, cover letter, or approval letters.

Q: Do I need approval to use copyrighted questionnaires in my study?

A: Yes, if you plan to use copyrighted questionnaires, you must obtain written permission from the copyright holder before including them in your study materials. Proof of permission should be submitted with your IRB application. It could be attached right after the copyrighted questionnaire.

Q: Do I need a site approval letter?

A: Yes, if your study will take place at an external institution or any location outside of PHSU, you must provide a site approval letter from the appropriate authority at that site.

Q: What site approvals are required for studies conducted within PHSU?

A: For studies conducted within PHSU, site approval must be obtained from Elizabeth Rivera. If your study involves the Wellness Center, you must obtain specific approval from Juliette Rivera.

Q: Is there a required template for flyers, and how do I get it approved?

A: Yes, there is a flyer template, which you can request by emailing Paula Lugo at palugo@psm.edu. Once your flyer is created, it must be approved by Paula Lugo. Be sure to include both final flyers and her approval email with your IRB protocol documents.



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STREAMLYNE ADMINISTRATOR'S

COMMUNITY UPDATE

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CATCH ATTENTION, KEEP THE BRAND: RECRUITMENT FLYER BASICS

A well-designed flyer that follows branding guidelines not only grabs attention but also builds trust and recognition—showing your audience that your message is clear, professional, and aligned with your organization's identity.

What does a Flyer needs to include?

Study title, as it is in your protocol.

Study objectives summarized in a 8th grade level vocabulary.

All study Inclusion and exclusion criteria summarized in bullets.

Contact Information (PI and Co-I) include email, phone numbers and extensions.

Ponce Health Science University
New logo and IRB protocol number.



How to request flyer Templates:

WE HAVE MULTIPLE TEMPLATES FOR YOUR STUDY FLYERS!

- To obtain access to these templates, please contact Paula Lugo at palugo@psm.edu and request them.
- She will send you a Canva Link. This link is unique for everyone.
- When you click on the link you will see multiple templates that could be adapted.
- After you finish your Flyer you will send back to Paula Lugo your finished Flyer.
- Once approved by Paula (she will reply to your email "approved")
- Screenshot this email and attach it in your protocol right after your flyers.

Extras that could be included:



- Including a QR code on a recruitment flyer makes it easy for people to access more information or sign up quickly, helps track engagement, and keeps the design clean and mobile-friendly.
- You might choose not to include compensation on a recruitment flyer because it can risk coercing vulnerable populations, may violate IRB guidelines, attract unqualified participants, raise privacy concerns, or conflict with the intended message or purpose of the project.
- Including an image on a recruitment flyer helps catch attention, communicates your message quickly, and makes the flyer more visually appealing and engaging.

Scan for Prezi presentation with more information



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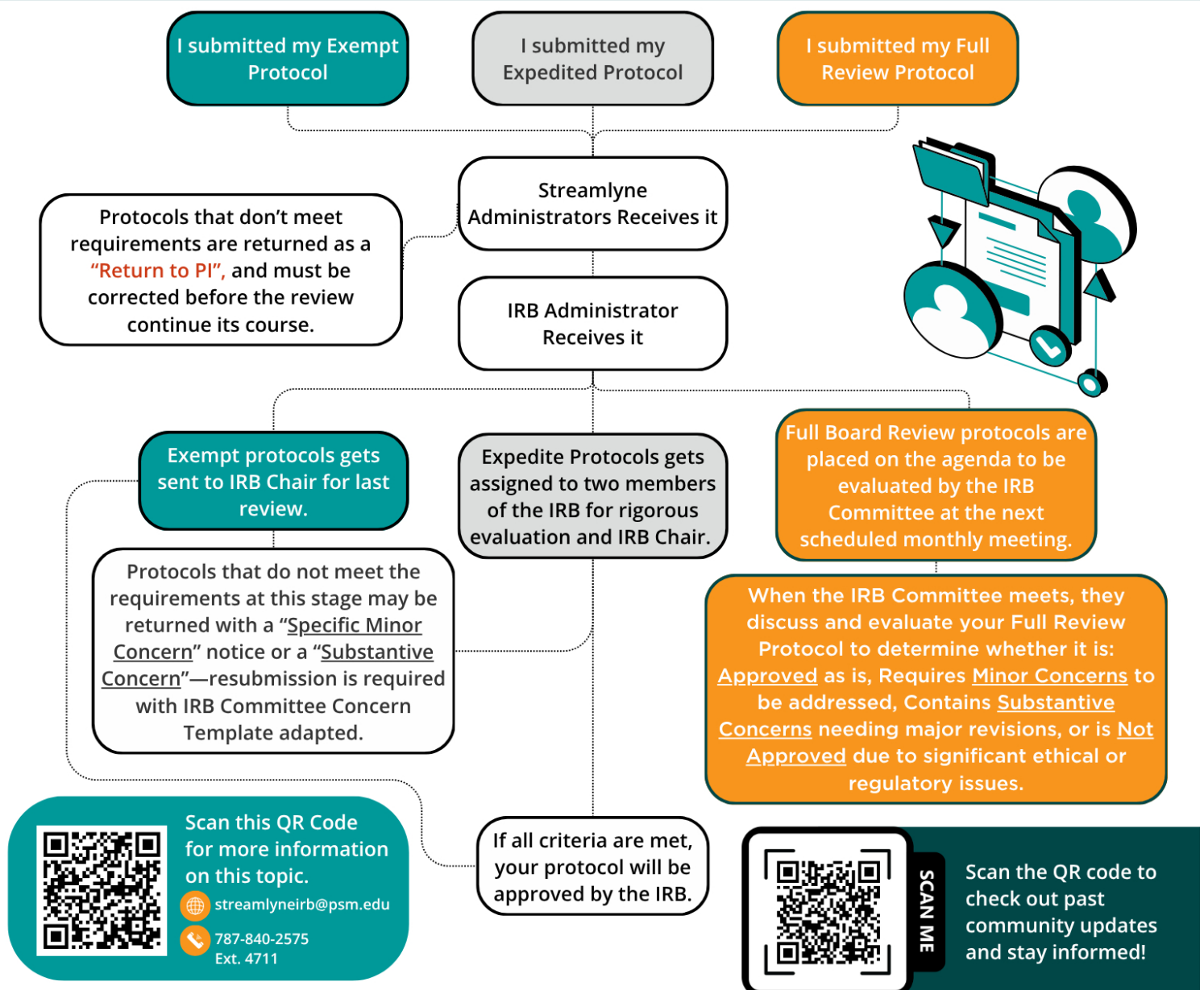
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SUBMITTING YOUR PROTOCOL... IT DOESN'T END THERE!

Submitting your protocol sparks a carefully managed journey where your study undergoes administrative checks, ethical reviews, and necessary revisions—ensuring that when you get the green light, your research is ready to make a real impact with integrity and confidence.



COMMUNITY UPDATE

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BUILDING A CONSENT FORM THAT INFORMS AND PROTECTS

A well-crafted consent form ensures that participants are fully informed about the study's purpose, procedures, risks, benefits, and their rights—including the right to withdraw—while protecting both the participant's autonomy and the researcher's ethical responsibilities.

Mission of a Consent Form



Ensures voluntary participation

Clearly communicates study
procedures, risks, and benefits

Protects both participants and
researchers

TIPS

Use plain, easy-to-understand language (8th grade reading level)

Avoid technical or legal jargon
Be honest and transparent—
don't hide risks

Translate into
participants' native
language when necessary

Review with your IRB
(Institutional Review Board)
before use

Key Elements Every Consent Form Must Include:

- Study Title
- Principal Investigator's name, credentials, and affiliation
- Purpose of the Study
- Procedures (what participants will do)
- Duration of Participation
- Risks and Discomforts
- Benefits
- Confidentiality & Data Protection
- Voluntary Participation & Right to Withdraw
- Contact Information for Questions
- Signature Section (Participant & Investigator)

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Scan the QR code to learn more
about IRB already approved Consent
Form with a Prezi presentation.



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STRATEGIC RECRUITMENT: FINDING FIT, NOT JUST FILLING SEATS

A correct recruitment approach ensures the right person is hired for the right role, saving time and resources while building strong, high-performing teams. It reduces turnover, boosts morale, and lays the foundation for long-term success.



Correct recruitment in the context of research means attracting and enrolling participants in a way that is:

Ethical

Respectful

Compliant with
IRB guidelines

Transparent and
non-coercive



When submitting a protocol for IRB approval, you must include:

Recruitment Plan:

- Where and how you will find participants.
- Who will approach them and how.

Justification of Inclusion/Exclusion Criteria:

- Avoid discrimination or unfair targeting.
- Clearly state why certain groups are included or excluded.

Recruitment Materials to be submitted:

- Flyers, posters, social media posts
- Email or phone scripts
- Text or visual content for ads
- Recruitment letters or brochures

Informed Consent Process:

- Description of how and when consent will be obtained.
- Ensuring participants understand they are volunteering.



Confidentiality and Privacy:

- Explain how you'll protect personal information during recruitment.
- Especially important if reviewing medical records to identify potential participants.



Scan the QR code to learn
all about recruitment on
a Prezi presentation.



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STREAMLYNE ADMINISTRATOR'S

COMMUNITY UPDATE

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IS YOUR STUDY LOW-RISK OR HIGH-RISK? LEARN YOUR IRB REVIEW TYPE!

The IRB reviews research based on the level of risk and participant vulnerability. Studies may be Exempt (low-risk, routine activities), Expedited (minimal risk, specific low-risk procedures), or require Full Board Review (greater than minimal risk, sensitive populations, or ethically complex procedures). Understanding the review type helps researchers plan and conduct studies safely and ethically. Under federal regulations, an investigator's application to conduct a research project involving human subjects can be processed by the IRBs in the next three categories:

Category	Exempt Review	Expedited Review	Full Board Review
Risk level	Minimal risk, routine practices	Minimal risk, but may involve minor procedures	Greater than minimal risk (beyond daily life or routine exams)
Participants	General population, classroom settings, public officials	Healthy adults, non-vulnerable populations	Vulnerable or special populations; minors, patients, etc.
Data Type	Public or de-identified data; anonymous surveys/tests, taste/foods studies	Existing data, records, specimens; bodily materials	Sensitive data, private information, or situations threatening confidentiality
Methods	Normal educational practices, anonymous surveys/tests, taste/food studies	Non-invasive procedures, small blood draws, voice recordings, moderate exercise, low -stress behavioral studies	Use of deception, incomplete disclosure, risky surveys, non-curricular school research
Regulatory Concerns	Legally protected confidentiality, government-approved services research	Non-FDA regulated drug/device studies; routine clinical techniques	Deception, waiver of consent documentation, privacy/confidentiality

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COMMUNITY UPDATE

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ANONYMOUS VS. CONFIDENTIAL: DETERMINING YOUR RESEARCH PROTOCOL'S DATA PROTECTION LEVEL



Make a decision:

When deciding between confidential and anonymous, consider whether you need to collect or link identifying information. Choose confidential if you must know who the participants are—for example, for follow-ups or multi-phase studies—but ensure their information is securely protected. Choose anonymous when no identifying details are collected at all, so responses can never be traced back to individuals. In short, confidential protects identity; anonymous removes it entirely.

HAVE ANY
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Anonymous or Confidential? That is the question!

Confidential and anonymous data both protect participant privacy, but in different ways. In a confidential study, the researcher can identify participants, either directly or through coded information, but promises to keep their identities private and secure. Data can be linked back to individuals if necessary, but only by authorized personnel. In contrast, an anonymous study collects no identifiers at all, so the researcher cannot trace responses back to any participant. While confidential data requires careful handling and may involve confidentiality agreements, anonymous data inherently prevents identification, making it impossible to link responses to individuals.

Want to see examples?

Scan this QR code to learn more about confidential and anonymous data. Use it to understand the differences and help you make the right decision for your research protocol.





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STREAMLYNE ADMINISTRATOR'S

COMMUNITY UPDATE

JANUARY 2026

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YOUR DATA IS AT RISK! HERE'S HOW TO PROTECT AND SHARE IT SAFELY

Protecting data is essential to ensure the privacy and confidentiality of research participants, preventing unauthorized access to sensitive information. It also upholds ethical standards and maintains trust, encouraging participants to provide accurate and complete information. Additionally, secure data handling ensures compliance with legal and institutional requirements, safeguarding the integrity of the research.

Here's why data protection is critical:



Maintaining Trust – Participants are more likely to provide honest and complete information when they know their data is protected. This trust is essential for the integrity of the research.

Ethical Responsibility – Researchers are ethically obliged to handle participants' information with care. The IRB ensures studies follow ethical principles like respect for persons and beneficence.



Data Integrity – Secure data handling prevents unauthorized alterations or loss, ensuring that study results are accurate and reliable.

Legal and Regulatory Compliance – Many studies are governed by laws (e.g., HIPAA in the U.S.) or institutional policies that require secure handling of identifiable data. Non-compliance can result in penalties or study suspension.



Participant Privacy and Confidentiality – Protecting data prevents unauthorized access to participants' personal, medical, or sensitive information. Breaches could harm participants or expose them to stigma, discrimination, or legal consequences.

Want to learn more about your responsibilities as researcher?

Scan this QR code to learn more about what IRB looks for in your protocol when it comes to DATA SAFETY.

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14TH EDITION
FEBRUARY 2026

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Submitting your Case Report, Case Study, or Record Review correctly to the IRB ensures patient privacy, regulatory compliance, and eligibility for publication. Even if a project seems exempt or minimal risk, official IRB determination protects both the investigator and the institution.

CASE REPORTS, CASE STUDIES, AND RECORD REVIEWS:

WHAT INVESTIGATORS NEED TO KNOW BEFORE SUBMITTING IN STREAMLYNE

Scan the QR code to learn more about:

- Differences between case reports, case studies, and record reviews
- When IRB review is required
- Required elements: study design, variables, instruments, data collection, data security
- Confidentiality & HIPAA compliance
- Waiver of consent considerations
- Common submission mistakes to avoid

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15TH EDITION
MARCH 2026

STREAMLYNE ADMINISTRATOR'S

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INTELLECTUAL PROPERTY RIGHTS

Intellectual property rights are essential for protecting and inventions of individuals and organizations. They ensure that inventors, artists, and creators receive financial benefits from their work. Intellectual property rights include patents, which protect new inventions; protect creative works like books, music, and films; safeguard brand names and logos; and trade secrets, which protect confidential business information. By safeguarding intellectual property, we encourage innovation and creativity, fostering an environment where new ideas can flourish and contribute to cultural growth.

ing intellectual property rights and prevent the unauthorized



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Ensure your research stays compliant and approval-ready by confirming that all study tools are either properly authorized with documented copyright permission or clearly identified as free for research and educational use.

COPYRIGHT AND PERMISSION REQUIREMENTS FOR RESEARCH TOOLS AND INSTRUMENTS

Any tools or instruments submitted must include proof of permission if they are copyrighted.

If the tool is not copyrighted, the researcher must clearly state that it is:

- Free to use, or
- Free for research/investigational or student purposes.

The goal is to ensure proper ethical and legal use of research instruments before approval.

Obtaining approval to use research tools or instruments is essential because it protects everyone involved in the study. For the institution and IRB, it ensures compliance with legal and ethical standards, preventing delays or rejection of the study. For the principal investigator (PI) and students, it demonstrates academic integrity, avoids potential copyright violations, and supports the credibility of the research. Failing to obtain proper approval can lead to serious consequences, including denied IRB approval, reputational damage, or legal issues.

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16TH EDITION
APRIL 2026

STREAMLYNE ADMINISTRATOR'S

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You should regularly check the status of your protocol to prevent delays. For instance, if your protocol has not progressed and you are unaware that a co-investigator still needs to provide approval, your submission may remain pending for an extended period, potentially delaying the review process.



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HOW TO VERIFY YOUR PROTOCOL STATUS

Follow this Quick Guide to see where your protocol stands:

- 1 Search for your protocol in Streamlyne
- 2 Click on the "Protocol Actions" tab in the left menu
- 3 Select "Route Log" from the available options
- 4 Scroll down to "Pending Action Requests" (click to expand if needed)

This section will show you whether:

- A member of your study team still needs to approve the protocol, or
- Your protocol is already with a Streamlyne or IRB reviewer for review

17TH EDITION
MAY 2026

STREAMLYNE ADMINISTRATOR'S

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Completing Part A accurately helps reduce delays, prevent common errors, improve compliance, and support a smoother IRB review process.



GUIDANCE FOR COMPLETING PART A OF THE STREAMLYNE QUESTIONNAIRE



Scan the QR code to see in detail how to answer all 12 questions of PART A on Streamlyne Questionnaire

PART A of the Streamlyne Questionnaire is the section where researchers explain the full research study to the IRB. It asks about the study's goals, benefits, study sites, timeline, recruitment process, participant characteristics, inclusion and exclusion criteria, research methods, risks, safety precautions, and how confidentiality and data protection will be handled. The purpose is to help the IRB determine whether the study is scientifically appropriate, ethical, and safe for participants.

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If PART A is answered incorrectly, vaguely, or incompletely, it will be returned, which can delay approval. Vague answers may lead to repeated requests for clarification, and inconsistent or incorrect information can raise compliance concerns. The study will not be approved until all sections are clear, complete, and consistent.

We invite you to go over the presentation through the QR code to learn more about how to answer each question correctly.

18TH EDITION
AUGUST 2026

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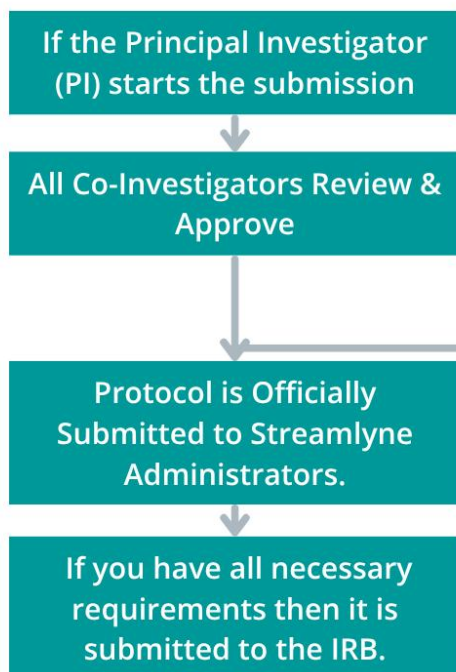
COMMUNITY UPDATE

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BEFORE YOU SUBMIT... KNOW WHO MUST APPROVE!

The submission process depends on WHO starts the protocol:



Submitting a protocol in Streamlyne involves more than clicking "Submit." Many investigators believe their protocol has been submitted to the IRB, when in fact it is still waiting for required approvals from the Principal Investigator and/or Co-Investigators

You can review your protocol status by clicking on the "Protocol Action" tab, then selecting "Route Log," and finally clicking on "Pending Action Request." This section will show you the next step in the protocol lifecycle.

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