



Morehouse School of Medicine  
INSTITUTIONAL REVIEW BOARD

USER MANUAL FOR CAYUSE eIRB SYSTEM

Version 1.0, July 2024, created by ACT

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## HOW TO USE THIS DOCUMENT

- This document is meant to serve as a step-by-step guide to the new Cayuse IRB application for Morehouse School of Medicine. This guide will detail how the response to some questions will populate different forms and additional questions.
- If you are looking for a specific form in the Cayuse application, the quickest and most efficient way to search this document is to utilize the Search and Find feature.
  - Push the **CTRL** and **F** keys at the same time on your keyboard to initiate the navigation feature. In the pop-up, type the name of the form you are looking for, and all mentions of that form will automatically populate.
- The appendices in this document will have additional guidance on commonly asked questions. If you need assistance in developing certain documents, refer to the appendices, or refer to the MSM website for templates.

**If you cannot find the answer to your questions in this document,  
please reach out to the IRB at [IRB@msm.edu](mailto:IRB@msm.edu)**

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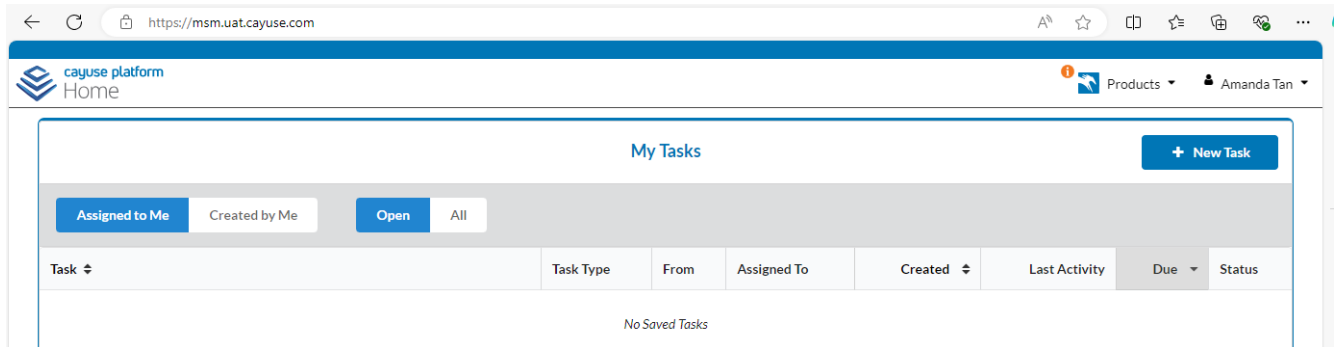
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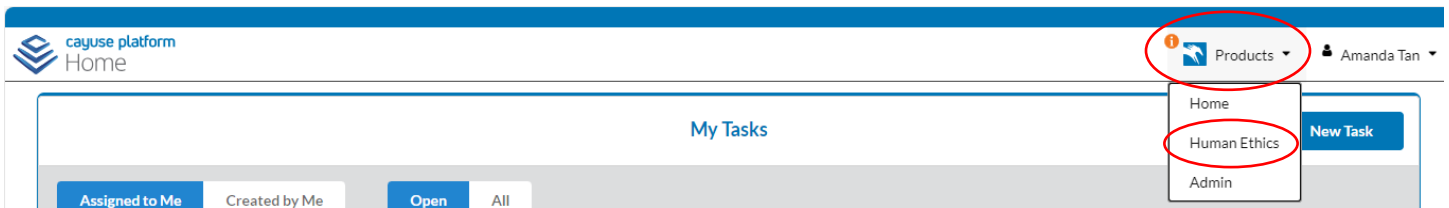
## How to create an IRB submission in Cayuse- Overview

### I. Study Initiation

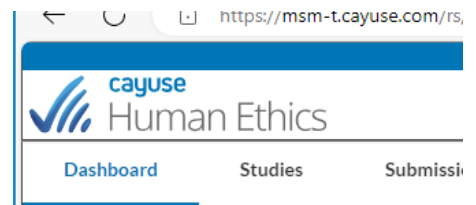
1. Upon logging in to Cayuse, you will be taken to the “Home” screen.



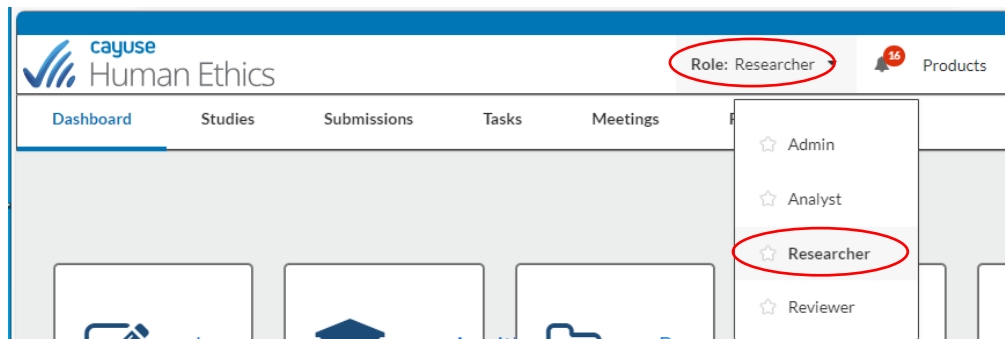
2. Under “Products” on the top right side of the screen, select “Human Ethics.” You may or may not have access to multiple Cayuse systems, so it is important to select the correct option.



3. Always note that the platform you are on will always appear in the top left corner of the page. You should notice once you click “Human Ethics,” the platform changes accordingly from “Home” to “Human Ethics.”



4. There are multiple roles you can have in the Human Ethics platform. If you are an IRB board member, you will have this role, as well as the researcher role. You always want to check that you are in the correct role before you start a new study submission. To begin a new study, or to access your current or pending studies, you need to be in the role of “Researcher.”



★ **TIP: If you select the star next to the role, it will automatically default to that role each time you enter the Cayuse system.**

5. On your **Dashboard**, you'll see a list of widgets with different key information on your IRB submissions. The five buttons across the top are options to click to see the full detailed list of all of your studies in each respective status (In-Draft, Awaiting Authorization, Pre-Review, Under Review, and Post Review). Under these options are lists of your current studies, pending tasks, the a list with all the types of submissions you have open, your approved studies, studies that are expiring within 30 days, and studies that have already expired. Certain questions can be answered in the Cayuse system by clicking the “?” button at the bottom right side of the page.

The screenshot shows the Cayuse Human Ethics dashboard. At the top, there is a navigation bar with the logo and user information: Role: Researcher, Products, and Amanda Tan. Below the navigation bar are tabs for Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, and More. A '+ New Study' button is located in the top right corner. The main content area is divided into several sections:

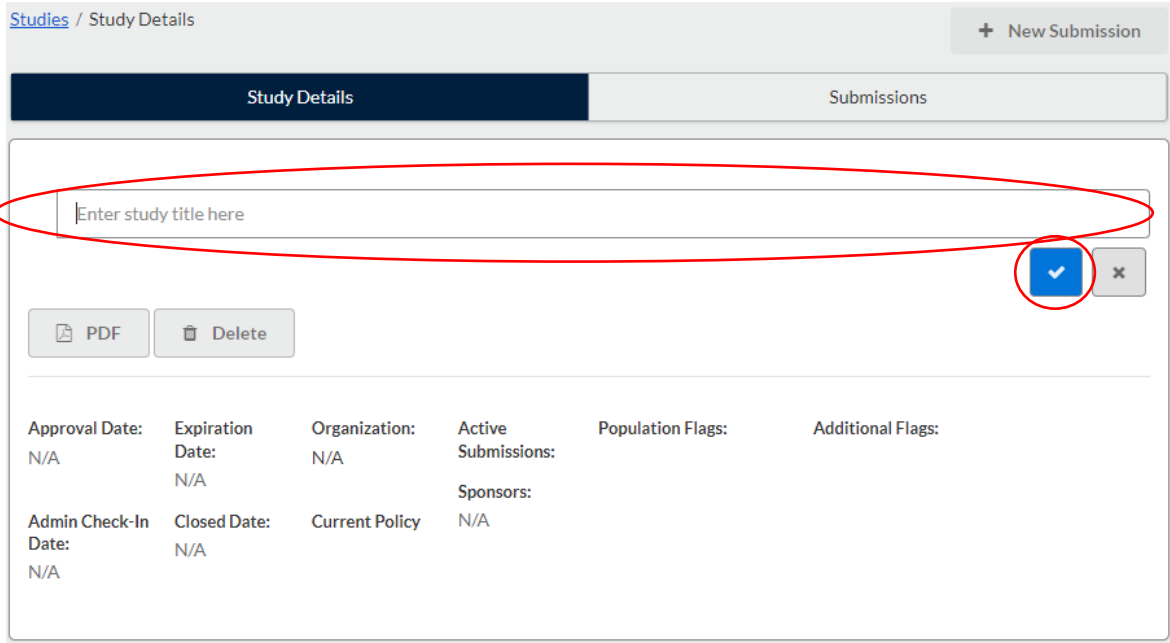
- Status Buttons:** Five buttons with icons and arrows pointing right: In-Draft, Awaiting Authorization, Pre-Review, Under Review, and Post Review.
- My Studies:** A table listing studies with columns for ID, Title, and a 'View All' button at the bottom.
- My Tasks:** A table listing tasks with columns for ID and Status (Complete Submission), with a 'View All' button at the bottom.
- Submissions by Type:** A table showing counts for various submission types: Renewal (0), Initial (7), Modification (0), Incident (0), Withdrawal (0), Closure (0), and Legacy (0).
- Approved Studies:** A table listing approved studies with columns for ID and Title.
- Studies Expiring in 30 days:** A section with a smiley face icon and the text 'No Expiring Studies'.
- Expired Studies:** A section with a smiley face icon and the text 'No Expired Studies'.

A red circle highlights a question mark icon in the bottom right corner of the dashboard.

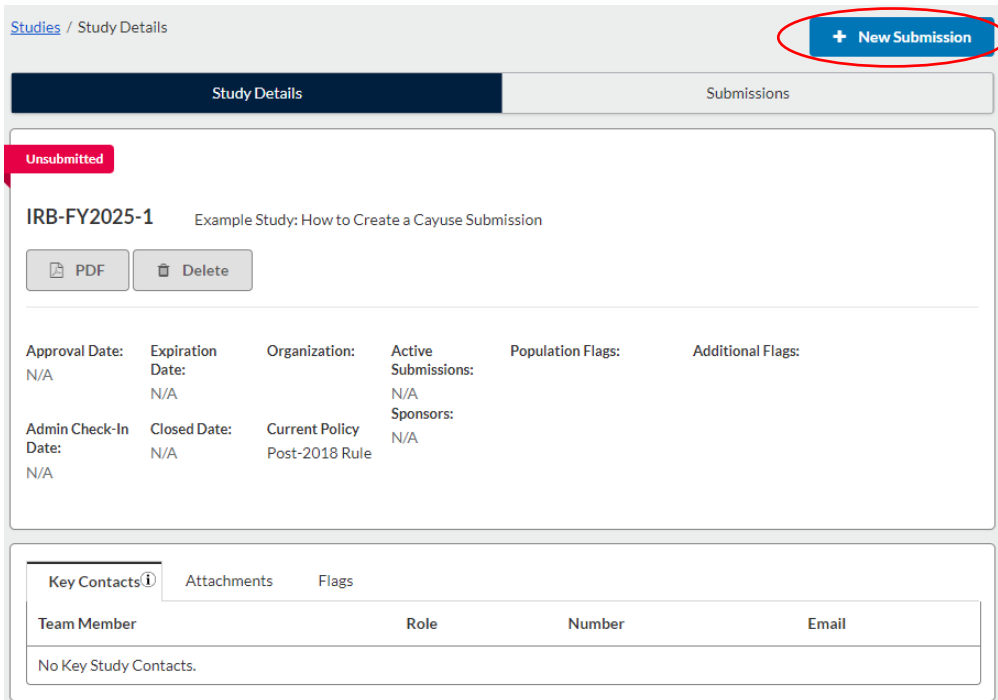
6. To begin a study, at the top right of the page click the blue “+ New Study” button.

This is a close-up screenshot of the top right corner of the Cayuse Human Ethics dashboard. It shows the navigation bar with the logo, user information (Role: Researcher, Products, Amanda Tan), and the navigation tabs (Dashboard, Studies, Submissions, Tasks, More). The '+ New Study' button is highlighted with a red circle.

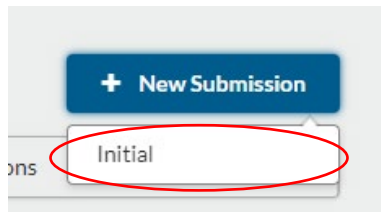
7. Enter the Title of your study and then click the blue checkmark.



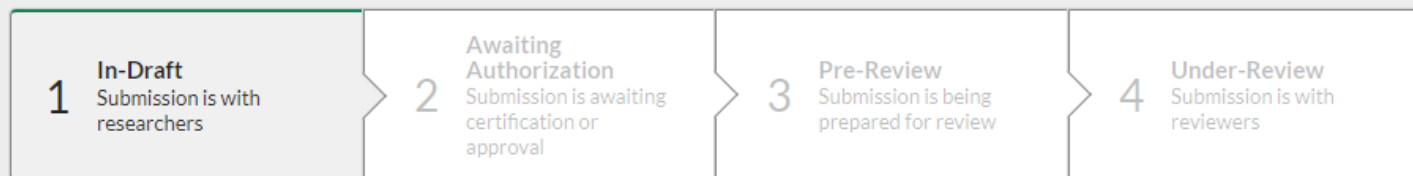
8. Once you click the checkmark, you will be able to start your submission. Click the “+ New Submission” button to begin.



9. For a new submission, the only option will be “Initial.”



10. Here you'll see what step your study is in at the top of the page. To start your submission, click “Edit.”



Unsubmitted

### Initial

IRB-FY2025-1 - Example Study: How to Create a Cayuse Submission

Edit
PDF ▾
 Delete

PI:	Current Analyst: N/A	Decision: N/A	Policy: Post-2018 Rule	Required Tasks: <a href="#">Assign PI</a>
Review Type: N/A	Review Board: N/A	Meeting Date: N/A		<a href="#">Assign PC</a> <a href="#">Complete Submission</a>

Approvals    Task History    Attachments

### Research Team

Name	Role	Result	Date
No entries.			



## II. Filling out the IRB Application

The IRB Application is a Smart Form. This means that different questions will populate depending on the answers provided. This is intended to make simpler studies, such as retrospective chart reviews and surveys, less cumbersome to complete. This also means that **it is extremely important to pay attention to what answers you select to ensure the correct questions appear.**

### 1. Getting Started

On this form, you'll find a list of all the items you will need in order to complete your Cayuse application. The necessity of some of the documents will depend on the type of study you are submitting.

#### ALL studies require the following:

- Detailed Study Information (you will enter this into the Smart Form application directly).
- Protocol (this is not the grant proposal. See *Appendix A- Grant to Protocol Guidance* for more information).
- Research Team Information



- Documentation of Scientific Review
- Participant Information (even if you are requesting any waivers for consent/HIPAA, you will be required to describe your study population).

**Some studies require:**

- Consent forms (if your study involves interactions directly with participants)
- Study Recruitment Documentation (any flyers, advertisements, letters, emails, etc. that will be sent to potential participants).
- Blood/Tissue Storage Banking Information (if you are collecting any human specimens- blood, saliva, tissue, urine, etc.)

**If your study involves the use of a drug or device:**

- Investigator Brochure
- FDA letter (approval for use)
- IND/IDE, if applicable

**If your study involves sites outside of MSM:**

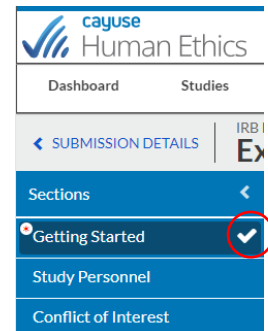
- Letter of agreement from MSM-nonaffiliated sites supporting their participation in the research
- CITI certificates (or equivalent training) from non-MSM personnel

To continue with the IRB application process, you must acknowledge that you have read the information and are ready to proceed.

\* I have read the information above and I am ready to begin my submission.

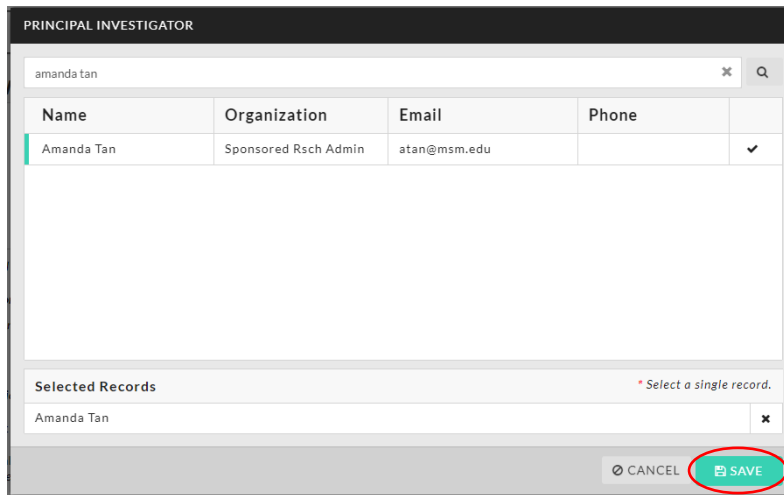
Yes

Upon checking the “Yes” button, you will receive a checkmark next to the “Getting Started” form, and two additional required forms will populate at the top left of the page. **★ Checkmarks will let you know that a form is complete.**



**2. Study Personnel**

- When you click on the “Study Personnel” form, you will be directed to enter information for the Principal Investigator. Click the “Find People” button and search. The PI will be required to provide a signature on the submission once it is ready to submit to the IRB.
  - If you cannot find the person who is the PI in the “Find People” search section, reach out to the IRB office immediately at [IRB@msm.edu](mailto:IRB@msm.edu) to add this information.
  - Click the person’s name to select them (it will show you the selected record at the bottom) and click “Save.”



- Next, select the PI's affiliation with Morehouse School of Medicine.

### a. Faculty and Staff

- You will need to assign a Primary Contact to the submission. It will default to yourself if you do not select anyone. You can only assign (1) primary contact. This person will be able to edit the study, create amendments, and will receive study communications. To change it from yourself, click the “X” button and then use the people finder to select the correct person.

\* Primary Contact  
 Any person listed as the  
 FIND PEOPLE

\* Primary Contact

Any person listed as the primary contact will have edit access to this study, can create follow-on submissions after Initial approval, and will be included in study communications.

Name	Organization	Address	Phone	Email	Trainings	
John Smith	Sponsored Rsch Admin			Josmith@msm.edu	View	X

### b. Student

- Students are required to indicate the program they are in.

\* What is the PI's affiliation with MSM?

- Faculty
- Student

Student PIs are permitted but are required to have a faculty advisor to sign off on all research-related activities.

- MD Student
- GEBS Student (PhD, MS, MSCR)
- MPH Student
- PA Student

- As well as their Faculty Advisor.

\* Faculty Advisor

If the PI is a student, provide the name of the supervising faculty member. The person listed as the Faculty Advisor will have edit access to this study, can create follow-on submissions after Initial approval, and will be included in study communications.

FIND PEOPLE

### c. External PI and Other

- An External PI should only be selected if you are in an organization that uses MSM as their IRB of record. You will likely need to submit a request to have individuals added to the system for your Primary Contact and other External Collaborators.
- Please reach out to the IRB before selecting the “Other” category to ensure this is the correct option for you.

#### d. American Cancer Society

- This option should only be selected if you are employed by and submitting a study on behalf of the American Cancer Society. If you are a MSM investigator who has a study funded by ACS, please select Faculty or Staff.
- When you select this option, the only Smart Forms that will populate are the Conflict of Interest form, the Basic Study Details form (once COI is complete), and the ACS IRB Application. Scroll down to Section 15 titled American Cancer Society (ACS) IRB Application for details on this form.

If you have External Collaborators (people who work outside of MSM), you will select “Yes” and provide the requested information on all team members. You will also be required to submit Documentation of Training for all external collaborators, as the CITI integration only covers individuals who complete the CITI training through Morehouse School of Medicine with their MSM-affiliated email address.

##### \* External Collaborators

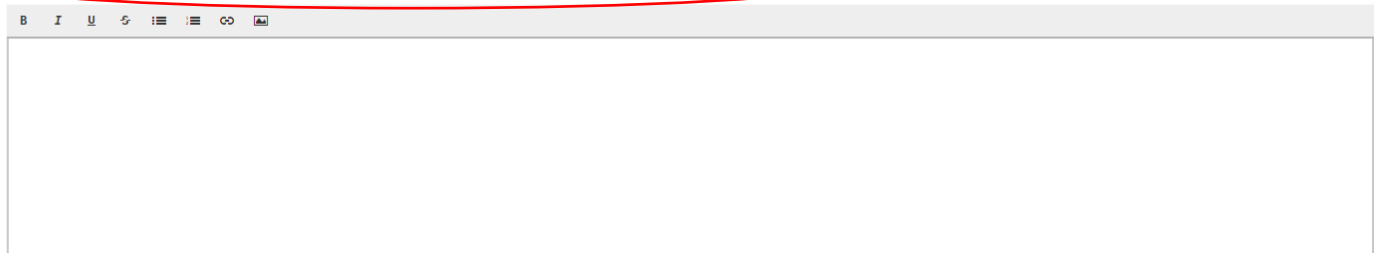
Will any External Collaborators (people who work outside of MSM) be involved in research-related activities?

- Yes  
 No

##### External Collaborator Details

###### \* Name and Affiliation of all External Collaborators

List all External Collaborators, the institution/company they are affiliated with (if any), and all activities they will be conducting during the study.



###### \* Training Documentation for External Collaborators

Upload all training documentation for External Collaborators. CITI does not automatically connect for non-MSM personnel. CITI training only automatically transfers into the Cayuse system if it is completed through MSM CITI and you use your MSM-associated email address.

ATTACH

You will also be asked if there are any employees outside of MSM that will assist in the conduct of the research (for example, if you will be using hospital phlebotomists to draw research blood samples or Grady Health System nurses to administer experimental drugs to participants). These individuals will not be required to complete CITI training to conduct these responsibilities, unless they are specifically affiliated with study (e.g., a nurse who is administering medications but is also on the study team and will be included on publications). If this question does not apply, you can indicate this by inputting “N/A” or simply leaving it blank.

### 3. Conflict of Interest

- The COI form is specific to the study you are submitting currently. Any questions that apply to you (i.e., you check “yes”) will require you to elaborate in a free-text field. Regardless of whether or not you have submitted the COI to the Office of Compliance and have a COI management plan in place, you are required to indicate any relevant COIs in this section.
- You are also required to have all members of the research team participate in some kind of education/training on COIs.
- Only the PI should attest to the last statement on the COI page.

\* All investigators and research personnel need to review the [Institutional Conflict of Interest policy](#). If not already completed, please review this document now and when it is completed, check the box below.

By checking this box, I attest that all investigators and research team members have reviewed and understand the Institutional Conflict of Interest policy.

## 4. Basic Study Details

### a. Study Basics

- **A protocol is required for all submissions.** For guidance and templates, please refer to the Resources guide provided on the MSM website.

\* Protocol Document

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- If your study involves *any* type of consent, assent, or parental consent form (verbal, written, electronic, etc.), you will need to upload it in the Consent/Assent Forms section. Multiple documents can be submitted in this section. All documents must **not** include track-change, comments, highlighting, etc. The documents submitted should only be **clean, final documents**.
  - Note that Cayuse uses a document stamping feature that will stamp the bottom right corner of the document. Please ensure the bottom right corner of your documents is clear for stamping, i.e., do not use narrow margins.

#### Consent/Assent Forms

Upload all documents used in the Consent/Assent/Parental Consent process, including the templates provided by the Reviewing IRB (if applicable) or Lead Site and any forms that will be used at MSM sites.

If consents will be in more than one language, upload the translated documents as well as the official translation certificate.

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- If your study involves the transfer of Data or Material (specimens, paper documents, electronic data, etc.) you will be required to execute a DUA or MTA.

#### Data Use Agreements/Material Transfer Agreements

If your study will involve sending or receiving data or specimens to or from another institution, organization, or company, please upload the completely executed agreement here.

If you have not yet created or received a DUA or MTA, you will need to develop one and route it through Agiloft for signature. You cannot sign the DUA or MTA yourself, it must be signed by the formal institutional signatory.

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- **A lay summary is required for all submissions.** Please review *Appendix B- Lay Summary Guidance* for assistance.

#### \* Lay Summary

A lay summary is a brief and clear overview of a research project that can be easily understood by people who are not experts in the subject.

B I U ↺ ☰ ☷ ↻ 🖼

- Your study timeline should be the expected start date and expected end date of the project. These dates do not have to be exact (unless your study has a specified funding period).
  - For chart review studies, do not use the dates you are pulling records from. The timeline should reflect when you anticipate to begin actually reviewing charts, to whenever you believe the analysis will be completed.

\* Study Timeline

If you are conducting a retrospective chart review, do not put the dates you are pulling records from.

These dates should indicate when you would like to begin the project itself, and when you anticipate when the project will be completed.

Date study is expected to begin:

Date study is expected to end:

b. Project Type

- One of the most important questions on this application will be the Project Type question. Your response to this question will populate other questions and forms that will be based on the type of project you are submitting for review. **It is very important to select the appropriate response here, so you fill out the correct forms. If you answer this question inappropriately, you may be told to go back and redo the submission.**

- If you select one of the first three options: “Research Study,” “Clinical Trial,” or “Establishment of a Biorepository or Data repository,” you will be required to submit documentation of Scientific Review. This can be as simple as a letter of support from your department’s chairperson stating they have reviewed and support the protocol, or evidence of grant reward/approval.

\* Project Type

What type of project is this submission for?

- Research Study
- Clinical Trial

A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. These interventions include drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and diagnostic strategies.

[Source: Clinical Trial Definition](#)

- Establishment of a Biorepository or Data repository

A biorepository or biobank is fundamentally a library that stores and manages biosamples, also known as biospecimens, for use in research.

A data repository acts as a centralized database where information is gathered, stored, analyzed, and archived in one organized space.

[Source: Biorepository Definition](#)

Scientific Review Documentation

List all the groups/organizations that have reviewed the application and the dates.

\* Upload documentation of scientific merit review of the proposed research. Documentation may come from external funding agencies and/or departmental or institutional research review committees. For the departmental sign-off form, please go back to the “Getting Started” tab.

\*Note: The IRB does not conduct scientific reviews. Simply submitting this application does not qualify as such.

ATTACH

- If you select “Activities Without a Plan to Conduct Research (Case Report, Quality Improvement project, Public Health project) OR Research in which this Institution is Not Engaged” or “118 Determination/Future Human Research,” then you **must select the last option in the next question about IRB Oversight Arrangements.** Please see Section 14 for more information about the NHSR Smart Form, and Section 15 for the 118 Determination Smart Form.

- Activities Without a Plan to Conduct Research (Case Report, Quality Improvement project, Public Health project) OR Research in which this Institution is Not Engaged

Select this option if either are true:

- You are not sure if your project requires IRB oversight.
- You need a formal determination from the IRB on if the project requires IRB oversight.

- 118 Determination/Future Human Research

Select this option if BOTH are true:

- This research project will involve or may involve human subjects in the future, but future protocol development must take place first.
- You need documentation of IRB review in order to release your grant funds.

- If you select “Single Patient, Treatment Use, Continued Access Drug/Device Study” or “Emergency (or Compassionate) Use of Investigational Drug or Device,” you will proceed to the IRB Oversight Arrangements question.
  - Note that MSM does not currently allow for Emergency (or Compassionate) Use of Investigational Drug or Device. If you feel your study falls in this category, please reach out to the IRB immediately.
- The “I am submitting a study for review on behalf of the American Cancer Society” option should only be selected by those who have also selected “American Cancer Society” as their PI affiliation on the *Study Personnel* Smart Form.
  - I am submitting a study for review on behalf of the American Cancer Society.

### c. IRB Oversight Arrangements

- IRB Oversight Arrangements refers to how IRB oversight is organized for this study. Will your study involve more than just Morehouse-affiliated facilities? Will it be conducted at more than one institution? Each option is broken down as follows.

#### \* IRB Oversight Arrangements

Indicate how IRB oversight is organized for this study.

*The difference between a study involving more than 1 site and a multi-site project is the protocol involvement.*

*An example of a study involving more than 1 site would be if an MSM investigator was working directly with an investigator at another institution to conduct a trial or study.*

*An example of a multi-site study would be a clinical trial where the same drug is being tested according to the same protocol at multiple sites across the country, but each site is conducting the study independently.*

- Study solely at MSM site(s)
- Study involving more than 1 site where each site will conduct their own IRB review
- Study involving more than 1 site where MSM is the Reviewing IRB (IRB of Record) for other sites
- Study involving more than 1 site where MSM is Relying on an External IRB
- Multi-site study (multiple US sites participating in a research study using the same protocol) where MSM is the Reviewing IRB (IRB of Record) for all sites
- Multi-site study (multiple US sites participating in a research study using the same protocol) where MSM is Relying on an External IRB
- Click this option if you selected either of these options for the previous question:
  - Activities Without a Plan to Conduct Research (Case Report, Quality Improvement project, Public Health project) OR Research in which this Institution is Not Engaged
  - 118 Determination/Future Human Research

- **Study solely at MSM site(s)**
  - This option is for a research study or clinical trial that is only being done on Morehouse School of Medicine campuses. The MSM IRB will have full oversight and is needed to provide full review and approval of the study. No external collaborators or partners that are involved in Human Subjects Research (informed consent, access to identifiable information, etc.)
- **Study involving more than 1 site where each site will conduct their own IRB review**
  - This would apply to studies that fall into Exempt categories. MSM (and a majority of other academic institutions) do not enter into reliance agreements for studies that qualify under Exempt research categories. For this reason, each participating site would need to submit their own separate IRB application to their respective institution.
- **Study involving more than 1 site where MSM is the Reviewing IRB (IRB of Record) for other sites**
  - This option is for studies that involve external collaborators where each site may have a different role in the study and are working together as a team. For example, the MSM investigator and an investigator at another institution are both recruiting participants via Zoom calls and have one MSM research coordinator entering the collected data into REDCap. In this option, MSM is the Reviewing

**IRB**, meaning that MSM will be responsible for oversight of the study (this is typically the case when the MSM PI is the main PI for the study).

- You will be asked to indicate whether or not you will be using SmartIRB.
- **Study involving more than 1 site where MSM is Relying on an External IRB**
  - Similar to the above option, except in this scenario, the main PI is likely at the other institution, and we are deferring to their IRB for review of this study.
    - Please note that for studies that are deferred, the local PI at MSM is still responsible for submitting all study-related documents, and all approved amended documents, adverse events, unanticipated problems, and IRB communications to the MSM IRB.
- **Multi-site study (multiple US sites participating in a research study using the same protocol) where MSM is the Reviewing IRB (IRB of Record) for all sites**
  - This would be a study where each site that is participating in this research study is acting independently of one another. They are all following the same protocol, but typically the data is being aggregated and analyzed on the backend by the sponsor. In this case, MSM is the Reviewing IRB meaning that MSM is responsible for oversight of the study (this would only apply if the main PI is at MSM).
  - You will be asked to indicate whether or not you will be using SmartIRB.
- **Multi-site study (multiple US sites participating in a research study using the same protocol) where MSM is Relying on an External IRB**
  - This is the most common option for pharmaceutical and large-scale device trials. In this scenario, multiple sites are conducting the same protocol independent of one another, and we are Relying on an external IRB to review and approve the study and all amendments.
    - Please note that for studies that are deferred, the local PI at MSM is still responsible for submitting all study-related documents, and all approved amended documents, adverse events, unanticipated problems, and IRB communications to the MSM IRB.
- **Click this option if you selected either of these options for the previous question:**
  - Activities Without a Plan to Conduct Research (Case Report, Quality Improvement project, Public - Health project) OR Research in which this Institution is Not Engaged
  - 118 Determination/Future Human Research
  - **This option must be selected only if your response to Project Type was one of the two responses listed.**

#### d. Study Sites

- List all of the local MSM-affiliated locations involved in the study. This is a multi-select question, so check all locations that apply.

• Study Site(s)

---

List all sites/locations within MSM involved with this project.

- MSM Clinical Research Center (CRC)
- National Center for Primary Care (NCPC)
- Grady Memorial Hospital
- Hurt Plaza Building
- Lee Street Clinic
- Howell Mill Clinic
- East Point Clinic
- Princeton Lakes Clinic
- Other

Please specify

- Next, if applicable, list all the sites/locations *within the United States* that will be involved in the project. If not applicable, leave this section blank or indicate N/A.

External Site(s) in the US

---

List all sites/locations outside of MSM (but in the United States) that are involved with this project.

B I U G L I O I

- If your study is going to involve International Sites, the next question should be marked “Yes.”
  - This will prompt a new Smart Form called “International Research.” See section 12 for more information about this form.

\* International Sites

Will any research activities occur at non-US sites?

- Yes  
 No

e. Emergency Preparedness Plan

A requirement by AAHRPP (the Human Research Protection Program accreditation organization), all studies must include an Emergency Preparedness Plan. You will be required to share a summary of your Emergency Preparedness Plan in your application. Please see *Appendix D* at the end of this document for further guidance and examples.

5. Study Design

*The Study Design* smart form includes questions about the overall product design and background. **Do not cut and paste from or merely suggest referring to the protocol in this section.** All descriptions should be understandable to an educated non-scientist. This section should take time and thought to complete to ensure that the IRB analyst reviewing the study will understand the overall purpose.

- Provide the study background information. Why are you doing this project? Why is it important for scientific knowledge? What do you think it will benefit/contribute to society?

\* Study Background

Provide the background and rationale of the study.

- Note what your hypothesis of the study is. What do you predict will happen?

\* Hypothesis

State the hypothesis of this research.

- Clearly indicate the goals and objectives of the study (specific aims and anticipated outcomes).

\* Goals and Objectives

Describe the goals and objectives (specific aims, anticipated outcomes) of this research.



- Next is the study design question. Provide a detailed explanation of how you will achieve the goals and objectives mentioned in the previous question (i.e., what are you proposing to do?).





\* Study Design

Describe the overall approach of the study. For example, if the study is prospective, interventional, retrospective, etc.; or, if your study includes more than one group, arm, or subject population, describe that here (e.g., a study with a prospective interventional arm and a retrospective chart review arm); etc.

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- Provide a clear summary of the role of the participants. Are they being asked to utilize a new drug? Are they being asked to complete a survey or participate in a focus group?


\* Explain clearly the role of the participants (i.e., what are they being asked to do?)

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- The final question on this form is to indicate what type of clinical trial this study is. **If your study is not a clinical trial, you must mark “Not a Clinical Trial” to complete the form.** Select all that apply.

\* Type of Clinical Trial (if applicable)

Check the type of clinical trial below. Check all that apply.

-   Not a Clinical Trial  
 Randomized  
 Non-Randomized  
 Use of Placebo  
 Blinded  
 Other

- If your study is *Randomized*, you will be asked to describe how the randomization will be completed for the study.
- If your study *Uses a Placebo*, you will be asked to provide a rationale for using a placebo.
- If your study is *Blinded*, you will be asked to indicate whether it is a single-blind or double-blind.
- If you select *Other*, you will be asked to describe what you mean by “other.”

## 6. Participants (Selection, Recruitment, Protection)

The Participants smart form will be the longest form you have to complete for your IRB application. This is because the IRB’s focus is on the protection of human subjects. Provide as much detail and information as possible in this section. The more details you provide, the less questions you will likely receive from the IRB if you communicate clearly.

### a. Waivers or Alterations to the Informed Consent Process

- Indicate whether your study will be requesting a waiver of informed consent. A full-waiver would be requested in studies such a retrospective chart reviews, or studies where the only linking identifier would be the informed consent form. A partial-waiver is typically used in studies where the team would like to pre-screen patients for eligibility by looking at their medical records, and if they seem to meet the qualifications, the participant would then be approached to provide informed consent. If you will be consenting participants prior to the start of study activities, select “no” for this question.

## Informed Consent Process

### \* Waivers or Alterations to the Informed Consent Process

Will this project in part or in full involve any waivers or alteration of the informed consent process?

- Yes, full waiver  
 Yes, partial waiver  
 No

- If you select “Yes, full waiver” or “Yes, partial waiver,” you will be asked to check all responses that apply:

#### \* Type of Waiver or Alteration to the Informed Consent Process

Check all that apply for in part or in full to this project:

- Waiver of Documentation of Consent (i.e., verbal consent only will be obtained).  
 Waiver of Consent (e.g., the entire process of obtaining consent) and/or HIPAA Waiver (e.g., you are doing a medical record chart review).  
 Use of Short Form Consent Form  
 Alteration or Waiver of some elements of Consent (e.g., you want to prescreen clinic patients for eligibility prior to their appointment so you know if you should approach them for the study).

- If you select “Yes, partial waiver” or “No” to the waiver question, you will be asked to describe the procedures for obtaining informed consent.

## b. Consent Process

If you select “Yes, partial waiver” or “No” to the waiver question, you will be asked to describe the procedures for obtaining informed consent.

- Describe all consenting procedures, the setting where the informed consent discussion will be conducted, the time between signing the consent and study procedures beginning, etc.

### Consent Process

Describe the procedures for obtaining informed consent.

- Indicate how the participant’s understanding of the consent process will be assessed.
- Identify the setting under which consent/assent will be obtained, including a) a description of the setting in which participant recruitment will be conducted, and b) the time element involved between introduction of the participant to the proposed research and actual enrollment into the proposed research.
- If vulnerable populations are included, specifically address how consent/assent will be obtained for such populations.
- If any waivers or alterations are noted above, describe them.

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## c. Participant Selection

If you respond to the question for “Type of Waiver or Alteration to the Informed Consent Process” with any of the following responses: Waiver of Documentation of Consent; Use of Short Form Consent Form; Alteration or Waiver of some elements of Consent, questions regarding participant selection will be required.

- Note how many participants will be enrolled in this study, both at this institution (all MSM facilities) and the total study enrollment (across MSM and external facilities). If MSM is the only site involved, the numbers for these questions should be the same.

### Participant Selection

#### Subject Enrollment

Enter the number of subjects that will be enrolled in this study.

##### \* Enrollment at this Institution

Please enter the number of subjects that will be enrolled at this Institution.

Note: “This institution” includes all Morehouse School of Medicine facilities/locations.

##### \* Total Study Enrollment

Please enter the total number of subjects to be enrolled at all study sites.

Note: “All study sites” includes all MSM facilities/locations AND all external sites participating in this study. If this study is solely at MSM, the number from the last question should be the same as this number.

- Indicate the ages, or age range, for participants you are including in your study.

**\* Ages**

Indicate the age range of subjects included in the study. You may indicate ranges for distinct populations (e.g., if fetuses are included, less than 1 month age, or ranges like 12-17 and 30-89).

- Indicate what language(s) the consent form and consent discussion will include. Note that if you select a language other than English, you will need to provide copies of the consent form in every language you plan to consent participants in, as well as a translation certificate.

**\* Language**





What language(s) will the informed consent form and informed consent discussion occur in?

- English
- Spanish
- Other

- List all Inclusion Criteria and Exclusion Criteria for the study.





**\* Inclusion Criteria**

List all inclusion criteria for participant eligibility.  
This includes criteria that would include a record for a chart review study.

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**\* Exclusion Criteria**

List all exclusion criteria that would disqualify a participant from being enrolled in the study.  
This includes criteria that would exclude a record from a chart review study.

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- Indicate whether your study will be excluding or including individuals based on their age, race, ethnicity, sex, etc. and justify why you will be purposefully including or excluding people.

**\* Population Relevance/Specificity**

Indicate and justify the race/ethnicity of the research subjects intended to be enrolled in this study. Justify any exclusions based on age, sex, race or ethnicity:

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- Next, you will indicate any and all vulnerable populations that you will be including in your study. Check all that apply. If no vulnerable populations will be used in the research, select the last option.

### Vulnerable Populations

Knowingly including a vulnerable population means:

1. Subjects will belong to the vulnerable population at any time during the intervention, interaction, or collection of identifiable private information for the study; AND
2. You will obtain knowledge that identifies a subject as a certain member of the vulnerable population.

While you generally aren't required to determine a subject's status as a member of a vulnerable population (unless determining status is necessary to minimize risks or ensure an appropriate informed consent process), you still need to consider the involvement of vulnerable populations even if you are not specifically targeting a vulnerable population for enrollment.

#### \* Included Vulnerable Populations

Please indicate any population(s) that will knowingly be enrolled. Check all that apply.

- Fetuses
- Pregnant Women
- Neonates (birth to less than 1 month)
- Children (including infants from birth to less than 1 month determined to be viable)
- Prisoners

*\*Note that persons on parole or probation are not considered to be "prisoners."*

- Adults lacking capacity to consent for themselves (e.g., because of serious medical conditions or mental incapacity, cognitive, emotional or intellectual impairment, including educationally disadvantaged)
- Individuals currently hospitalized or in nursing homes
- Individuals whose primary language is not English
- Students

*\*Note that residents and post-docs are not considered students.*

- MSM Employees
- Other
- No vulnerable populations will be used in this research.

- If you select any of the vulnerable populations listed above, you will be required to include information about their necessity of inclusion and describe the additional safeguards for each vulnerable population you will be including.

#### Justification of Vulnerable Populations

##### \* Necessity of Inclusion

For each vulnerable population that will knowingly be included in the study, explain why their inclusion is appropriate and does not pose unreasonable additional risks. Consider:

- If the risk to the population is minimal or greater than minimal.
- The prospect of direct benefit.
- If generalizable knowledge about the subject's disorder or condition may be gained.

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##### \* Additional Safeguards

For each vulnerable population that will knowingly be included in the study, describe any additional measures to ensure protection of the rights and welfare of these populations.

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### d. Participant Recruitment

- Describe your recruitment process, including any materials you will be using for recruitment. Be sure to include all recruitment documents in the attachments section.

#### Participant Recruitment

##### \* Recruitment Process

Describe your recruitment procedures (e.g., when, where, and how potential subjects will be identified and recruited). Also, describe any materials that will be used to recruit subjects.

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##### Recruitment Documents

Upload all recruitment materials used in the study (e.g., flyers, advertisements, telephone scripts, etc.).

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- Describe in detail how long the participants will be in the study, how long each visit will take (including an estimate for survey completion time, if applicable, and a study visit table/chart if available).

\* Participant Duration

Describe the duration of study participation, the length and number of study visits, and the timetable for study completion.

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If you have a study visit table/chart, please upload it here.

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- Indicate whether Compensation will be provided to the participants. If you plan to use a drawing method as an incentive for participation, please see *Appendix C- Drawings as Incentives for Participation* for guidance.

\* Compensation

Will subjects be given any compensation/material inducements for participation?

- Yes  
 No

- If “Yes,” you will need to describe how much, when, how, and where payments will be distributed. Include information about whether the payment accumulates over time, or if each visit will be paid separately. Will the participant need to complete the study to be paid? If there is a crossover arm, will they be paid for both study arms, or just the first?

\* Compensation

Will subjects be given any compensation/material inducements for participation?

- Yes

Describe the amount, method, and timing of any payments to subjects, including how payments will be prorated for subjects who partially complete the study.

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e. Participant Protection

- First you will address all of the potential risks associated with your project. **Do not state that there are no risks or that you do not anticipate any risks. All research studies have risks.**

Participant Protection

\* Potential Risks

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to the subjects participation in the research. Consider that the risk of breach of confidentiality is common to almost all research studies.

- Describe the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks, including extra financial costs or time burden the subject may incur from participating.
- If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.
- If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.
- If applicable, describe risks to others who are not subjects.

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- Next, list and describe the potential benefits for subjects, if any. Compensation, gifts, or items provided by the study should not be listed here.

\* Potential Benefits

Describe the potential benefits for subjects (if any). Include the probability, magnitude, and duration of the potential benefits.

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- If the study poses more than minimal risk, **or** you have included a Data & Safety Monitoring Plan **or** have a Data & Safety Monitoring Board, check “yes” to the question below. Answering yes to this question will populate a new smart form titled *Data & Safety Monitoring* (see section 13 for guidance).

**\* Data & Safety Monitoring**

Indicate if this project either:

- Poses greater than minimal risk.
- Includes a Data & Safety Monitoring Plan or Data Safety & Monitoring Board/Committee Charter.

Yes  
 No

- Indicate whether or not there will be Deception used as a method of data gathering.

**Deception**

**\* Will deception be used as a method of data gathering?**

Yes  
 No

- If “yes,” you will need to provide a justification for the use of deception, as well as debriefing script that you will read to participants once the study has concluded.

**Deception Justification**

Justify and support the use of deception in the project.

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**Debriefing Script**

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- Next, describe the steps that will be taken to protect subjects’ privacy.  
**Privacy is the ability of the participant to control the access of others to themselves.**

**\* Participant Privacy**

Describe the steps that will be taken to protect subjects’ privacy during recruitment, consent and study procedures.  
 Privacy is the ability of the participant to control the access of others to themselves.

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- Finally, describe the steps taken for maintaining the confidentiality of data.  
**Confidentiality is an agreement between the investigator and participant in how data will be managed and used.**

**\* Participant Confidentiality**

Describe methods for maintaining the confidentiality of data.  
 Confidentiality is an agreement between the investigator and participant in how data will be managed and used.

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- If your study is covered by a Certificate of Confidentiality, answer “yes” and upload a copy of the CoC. If it is not covered, check “no.”

Is this study covered by a Certificate of Confidentiality (CoC)?

Research is automatically covered by a CoC when the study is funded in whole, or in part, by NIH and involves identifiable, sensitive information. Identifiable, sensitive information is defined as information that is about an individual and that is gathered or used during the course of research a) through which an individual is identified; or b) for which there is at least a very small risk, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

The investigator can also apply for a CoC when the study is funded by agencies other than NIH.

Yes

Please upload the CoC here.

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No

## 7. Study Procedures

- The first question in the Study Procedures form will be the longest. Outlined below are all of the points to consider when describing your study procedures and methods. Again, this **should not be** a copy and paste from the protocol.

### \* Study Procedures

Describe all study procedures and methods. For example:

- All research procedures being performed and when they are performed, including timing and amount of all samples collected for research purposes.
- Which procedures will be conducted for research as opposed to standard of care procedures. In determining what procedures are research vs. standard of care, consider what procedures would happen to any individual subject who joins the study versus procedures that would occur exactly as described in the protocol even if the individual does not join the study.
- Measures taken to lessen the probability or magnitude of risks (monitoring for safety, preventing complications, etc.).
- All drugs and devices used in the research and the purpose of their use.
- Data collection tools and their use.
- What data will be collected (including what identifiers will be collected, even with consent), including long-term follow-up.
- Procedures that will be followed when subjects withdraw from the research, including withdrawal from intervention but continued data collection.
- Any anticipated circumstances under which subjects will be withdrawn from the research without their consent.

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- The Additional Procedures question is optional and should only be answered if it applies to your study.

### Additional Procedures

Provide the rationale for medication wash-out periods or the use of placebos, if applicable, and state the authority (professionally accepted, e.g., practice or other written guidelines) upon which this determination is based and describe measures that will be taken to ensure additional safety protections for participants undergoing medication wash-out periods, change of medication, or use of placebos.

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- Next, list all of the Resources your study will require to be conducted. This question is asked to assess feasibility. The IRB cannot approve a study for which resources are unavailable, as this indicates the study will not actually ever begin. For example, if you require funding for your study but do not have any funding secured, the IRB will not proceed with review until funding is available.

### Resources

\* Describe the resources required to conduct this research (personnel, specialized equipment, genetic or psychological counseling services, space, administrative assistance, consultants, etc.).

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\* Are these resources available for the research?

Yes

Not currently, but there are funds to purchase/support what is needed.

No

- The Study Products question is important because the answer to this question will determine whether or not to populate the *Study Products* smart form (See Section 8- Study Products). You must select “Yes” to this question if your study involves any type of drug, biologic, device, diagnostic, dietary supplement, food additive, cosmetic, etc.

**\* Study Products**

Will the study involve any study products that **may be** FDA-regulated? For example, drugs, biologics, devices, diagnostics, dietary supplements, or food additives.

Please note that even if you know your device may be exempt from FDA-review, it is the responsibility of the IRB to make this determination and your answer below should be “yes.”

- Yes  
 No

- The next question is about Study Instruments. If applicable, list all of the study instruments being used in the study (names of all the surveys, scripts for focus groups/interviews/phone calls, scales, questionnaires, blank evaluation forms, curriculum or training materials, etc.). Attach a copy of all instruments using the attachment button. You can upload as many documents as you need.

**Study Instruments**

List all instruments being used in this study (i.e. surveys, scripts, personality scales, questionnaires, evaluation blanks, etc.) to be used in the study.

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Attach all instruments here.

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- The next set of questions are about Data & Specimens. The first question will inquire about whether the project will involve the collection or use of data and/or specimens that are recorded in such a way that the identity of the individual who provided said data could be ascertained.

**Data & Specimens**

**\* Identifiable Data/Specimens**

Does this project involve the collection or use of materials (data or specimens) recorded in a manner that could identify the individuals who provided the materials, either directly or through identifiers linked to these individuals (coded data with access to the key)?

- Yes  
 No

- If your answer to the question above is “No,” you will check “None” for the next question, then skip to the Data Analysis question.
- If your answer to the question above is “Yes,” you will be required to provide a comprehensive explanation of Collection and Handling procedures. Be sure to address each of the questions listed in this section.

**Collection & Handling**

Describe the information to be gathered and the means for collecting and recording data/specimens. Be sure to address:

- Where and how will data or specimens be stored?
- What information will be included in that data or associated with the specimens?
- How long will the data or specimens be stored?
- Who is responsible for receipt or transmission of the data or specimens?
- How will data and specimens be transported?
- If previously collected data is to be used, describe both the previous and proposed uses of these data.

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- Next, indicate what type of specimens you will be collecting for your study. If you are not collecting specimens, select the answer “None.” If you are collecting more than one type of specimen, make sure you check the box next to all applicable answers.

**\* Biological Specimens**

Will the study involve the collection of any biospecimen? Select all that apply.

None  
 Saliva  
 Blood (by finger stick, heel stick, ear stick, or venipuncture)  
 Urine  
 Stool/fecal matter  
 Excreta and external secretions (i.e., sweat, semen)  
 Hair samples  
 Nail clippings  
 Other

Please specify:

---

- Since you indicated you will be generating data or specimens from participants, you must describe how relevant results will be shared with other providers. If it is not relevant to share research data with participants’ providers, you can simply type in this section “N/A.”

**\* Sharing Results with Other Providers**

*If a participant is under the care of other physicians/health professionals, describe how communication/coordination relevant to this research will be managed. If it is not relevant to share research data with participants’ providers, indicate N/A.*

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- If you indicated that biological specimens will be collected, indicate whether or not a CLIA certified lab will be used if results will be shared with participants or their providers. Then, indicate whether or not results will be shared with participants.

**\* CLIA Certified Laboratory Results**

*If laboratory results will be shared with subjects or their healthcare providers, confirm if the laboratory conducting the test is CLIA certified.*

Yes  
 No  
 N/A

**\* Sharing Results with Subjects**

*Will study results or individual subject results be shared with subjects or their providers (e.g., incidental findings, results of standard or research lab tests, genetic test results, etc.)?*

Yes  
 No

- The next three questions pertain to Data and Specimen Banking and storage for future research.

**Data/Specimen Banking & Future Research**

---

*Will any data and/or specimens from this project possibly be used for future research?*

Yes  
 No

- If you select “Yes” to the question above, you will be prompted to indicate whether future genetic research may be possible with the banked samples, as well as what the Data and Specimen Banking Procedures are for your study. Make sure to address each of the items listed below.

Yes

**Future Genetic Research**

Is it possible that the future research may include genetic research?

Yes  
 No

**Data & Specimen Banking Procedures**

Describe what data and/or specimens from this project will be banked for future use. Be sure to address:

- If the data/specimens will be banked in a separate, shared repository or a repository within this study.
- Where the data/specimens will be stored.
- How long they will be stored.
- How they may be accessed, and who will have access to the data/specimens.
- Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

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- Next, indicate whether the data will be submitted to a NIH data repository. If “Yes,” make sure to complete the MSM GWAS Data Submission Application and include the associated Modular Language in your consent form.

\* Will data be submitted to a NIH data repository?

Yes

Will a Genome Wide Associated Studies (GWAS) Data Submission Certificate be required?

Yes  
 No

Please complete the [MSM GWAS Data Submission Application](#) and include the associated [modular language](#) in the consent form.

No

- Finally, indicate whether data or specimens will be submitted to a MSM biorepository. If “Yes,” name the location of the biorepository.

\* Will data/biospecimens be submitted to a Morehouse School of Medicine biorepository?

Yes  
 No

Please indicate the location of the biorepository.

- If you answer “No” to the Identifiable Data/Specimens question, you will finish this form with the Data Analysis question. Provide a summary of the statistical plan you will use for the study.

\* Data Analysis

Describe the data analysis plan, including any statistical procedures and a power analysis (if applicable). Describe any procedures that will be used for quality control of collected data.

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## 8. Study Products

The *Study Products* smart form appears if you answer “yes” to the following question in the *Study Procedures* smart form. If your study does not involve a study product, return to the *Study Procedures* smart form and change the answer for this question to “no.”

\* Study Products

Will the study involve any study products that may be FDA-regulated? For example, drugs, biologics, devices, diagnostics, dietary supplements, or food additives.

Please note that even if you know your device may be exempt from FDA-review, it is the responsibility of the IRB to make this determination and your answer below should be “yes.”

Yes  
 No

- The first question in this form asks about the type of product(s) that will be used for this study. Select all that apply. Your response to this question will populate important questions specific to the product type.

\* Study Product Type

Indicate the type of product(s) that are required/specified to be used in this project.

- Drug
- Biologic
- Food
- Cosmetic
- Device
- Other

- “Biologic” encompasses vaccines, blood products, cellular and gene therapy products, tissue and tissue products, allergenics, and others. Ensure that you select all that apply.

Biologic

- Vaccine
- Blood and blood products
- Cellular and gene therapy products
- Tissue and tissue products
- Allergenics
- Other biologic product

- “Food” is broken down into multiple categories. Ensure you select all that apply.

Food

- Medical Food
- Dietary Supplement
- Food Additives
- Infant Formula
- Substance Generally Recognized As Safe (GRAS) for use in food
- Other food product

a. Drugs, Biologics, Food, Cosmetics

- If you check Drug, Biologic, Food and/or Cosmetic to the above question, the following questions will appear. **Make sure to include responses for all products related to your submission.**
  - If you have more than one study product, the questions will only appear once so ensure that each product is appropriately addressed for each of the following questions.

Drugs, Biologics, Foods, and Cosmetics

\* Drug/Biologic/Food/Cosmetic Description

Describe the Drugs/Biologics/Foods/Cosmetic products required/specified to be used in this project. Include:

- Name of product
- Purpose of its use
- For each product, if it is (1) Intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; AND/OR (2) Intended to affect the structure or any function of the body of man or other animals.

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\* Drugs/Biologics/Foods/Cosmetic FDA Approval Status

Describe the FDA approval status of all Drugs/Biologics/Foods/Cosmetic products required/specified to be used in this project. For example:

- FDA Approved
- Investigational Drug requiring an IND (provide IND number and who holds IND)
- Investigational Drug that IND Exempt (be sure to explain which exemption under 21 CFR 312 it meets and how)
- Doesn't meet criteria for regulation under 21 CFR 312 (e.g., all GRAS ingredients; not used in diagnosis, cure, mitigation, treatment or prevention of disease; etc.)

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- If your product will be billed to the subject or the subject's insurance provider, you will be required to attach the FDA letter that approves charging for this product.

\* Insurance Billing

Will the drug or biologic be billed to the subject or their insurance carrier?

Yes

FDA Insurance Letter

Attach the FDA letter which approves charging for this product.

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No

- o You will be required to include all FDA approval documentation for the product, as well as the Investigators Brochure, Package Insert, etc. This attachment section allows for the upload of as many documents as needed.

\* Drug/Biologic/Food/Cosmetic Documentation

Provide documentation for all study drugs/biologics/food/cosmetic, in particular:

- Risk documentation (e.g., Investigator Brochure (IB), package insert, etc.)
- FDA Approval documentation (IND documentation, IND exemption determinations, etc.)
- Formulation/Ingredient information (for foods, supplements, etc.)

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b. Devices

- You should select and complete the Device section even if you believe your device falls into the Nonsignificant Risk Device category. It is up to the IRB to make the formal determination of NSR. Ensure that you select all categories that apply.

Device

- Surgical implant or prosthetic
- Dental device
- Electronic wearable device
- Electronic product that emits radiation (e.g., x-ray equipment, ultrasonic therapy equipment, mercury vapor lamps, sunlamps, etc.)
- Mobile Medical Application
- Software or Algorithm (e.g. involving Artificial Intelligence, Machine Learning, etc.)
- Other device

- You will then need to respond to the following questions:

Devices

\* Device Description

Describe the Devices required/specified to be used in this project. Include:

- Name of device
- Purpose of its use
- For each device, if it is (1) Intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; AND/OR (2) Intended to affect the structure or any function of the body of man or other animals; BUT does not achieve its primary intended purposes through chemical action within or on the body of man or other animals, NOR is dependent upon being metabolized for the achievement of its primary intended purposes.

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\* Device FDA Approval Status

Describe the FDA approval status of all Devices required/specified to be used in this project. For example:

- FDA Approved
- Investigational Device requiring an IDE (provide IDE number and who holds IDE)
- Investigational Device that IDE Exempt (be sure to explain which exemption under 21 CFR 812 it meets and how)
- Doesn't meet criteria for regulation under 21 CFR 812 (e.g., study does not evaluate the device being used for safety or effectiveness; not used in diagnosis, cure, mitigation, treatment or prevention of disease; etc.)

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- If you believe your device is a Non-Significant Risk Device, you will answer the following question “yes” and will provide the justification. If your device has an IDE, this question should be answered “no.”

**\* Non-Significant Risk (NSR) Device**

Are you requesting a Non-Significant Risk determination for any Devices in this study?

This is applicable to Investigational Devices that are subject to regulation under 21 CFR 812, but do not have an IDE or are otherwise IDE Exempt. If the FDA has not already determined the device is Significant Risk, the IRB can evaluate risk to determine if a device is Non-Significant Risk (and so does not require an IDE).

Yes

**NSR Justification**

Provide the risk assessment and justification for any devices for which you are requesting an NSR determination. Ensure any supporting risk documentation is uploaded in the Device Documentation area below.

No

- You will attach all device documentation (IDE letter, instructions, user manuals, risk documentation, etc.) in the following attachment link. This attachment section allows for the upload of as many documents as needed.

**\* Device Documentation**

Provide documentation for all study devices, in particular:

- Risk documentation
- Description/Instructions (e.g., Instructions for Use (IFU), Instruction Manuals, etc.)
- FDA Approval documentation (IDE documentation, IDE exemption determinations, etc.)

ATTACH

**c. Other Products**

- If you select “Other,” you will be asked to describe, and the IRB will reach out to indicate to you which option from the list you should select so you can complete the appropriate questions. You may also reach out directly to the IRB at [IRB@msm.edu](mailto:IRB@msm.edu) to inquire.

**\* Study Product Type**

Indicate the type of product(s) that are required/specified to be used in this project.

- Drug
- Biologic
- Food
- Cosmetic
- Device
- Other

Please describe.

The IRB will likely request more information and/or indicate which of the previous options you should select.

**9. MSM Reviewing IRB**

In addition to all of the study-specific forms, you will be required to complete the MSM Reviewing IRB smart form if your multisite study is utilizing MSM as the IRB of record for all sites.

- The first question asks whether the MSM PI is the lead investigator of the entire multi-site study.
  - If the answer is “no,” you will be required to indicate why MSM is being listed as the IRB of record. In most cases, MSM IRB should not be the IRB of record if the lead PI is not affiliated with MSM. Reach out to [IRB@msm.edu](mailto:IRB@msm.edu) if you need to select no to this question for further discussion.

**\* Is the MSM PI the lead investigator of the entire multi-site study?**

- Yes
- No

- If you select “yes,” you will be prompted to answer three questions about the management of the multi-site study.






\* Is the MSM PI the lead investigator of the entire multi-site study?

Yes






*Explain how information about unanticipated problems involving risks to participants or others will be managed in this multi-site study.*

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*Explain how information about interim results will be managed in this multi-site study.*

B I U     

*Explain how information about protocol modifications will be managed in this multi-site study.*

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- This form is complete once all three questions are answered.

## 10. MSM Relying IRB

- When MSM is **relying on** another IRB to conduct the review, you will select one of the **Relying** options in the IRB Oversight Arrangements question in the Basic Study Details form.
- Once you select this, you will be asked whether or not the study will be utilizing the SMART IRB platform for the reliance agreement.
  - The SMART IRB platform is only for reliance agreements. You do not submit and receive approval for the study on SMART IRB. SMART IRB is not required for reliance agreements, and is typically only used when studies involve multiple (3 or more) sites.

My study will be utilizing the SmartIRB system for reliance agreements.

[SMART IRB | National IRB Reliance Initiative](#)

Smart IRB is a platform developed for the sole purpose of streamlining the single IRB review process.

If you are not sure what the Smart IRB system is, your answer to this question is likely "no."

- Yes  
 No

- You will be required to provide all information for the Reviewing IRB.

• Relying on an External IRB

• Name of Reviewing IRB

Identify the IRB of Record for this study.

• Reviewing IRB Point of Contact (POC)

List the name, email, and phone number of the POC.

• Name of Lead Site

Identify the lead site for this study.

• Lead Site PI Name

Name the PI at the Lead Site.

- You will then upload all study documents that were approved by the reviewing IRB, such as surveys, questionnaires, interview scripts, advertisements, instructional pamphlets, etc. **Make sure to edit consent forms and advertisements appropriately to reflect MSM-content. Also note that MSM requires all consent forms to be at an 8.9 reading level or lower, regardless of what the reviewing IRB approves.**
- You must also upload the Reviewing IRB approval letter indicating what documents were reviewed/approved, and that MSM is approved as a site.

Study Documents

Upload study documents provided by the Reviewing IRB or Lead Site, such as recruitment templates, study surveys, questionnaires, interview scripts, advertisements, instructional pamphlets, etc.



• Reviewing IRB Approvals

Upload approval letters from the Reviewing IRB, such as the overall study approval and the approval adding this site to the study.



- If not utilizing SMART IRB, you will need to upload the executed reliance agreement as well. Please note that all reliance agreements must be routed in Agiloft for signature by Dr. Rick Kittles. You cannot sign your own reliance agreements.

Reliance Agreements

Upload all applicable reliance agreements for any External Collaborators or US External Sites (Individual Investigator Agreements (IIA), IRB Authorization Agreements (IAA), MOUs, etc.).

All Reliance Agreements must be routed in Agiloft for signature by Dr. Rick Kittles.



- Finally, if applicable, you will enter the names of other participating sites relying on the reviewing IRB.

Other participating sites relying on the same IRB

If known, list all of the other sites involved in this research study that will also be relying on the IRB of record.

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- The application will then be marked as complete.
  - See *Section III. Submitting Your Study* for further details on submitting the application.

Please note that the MSM IRB does not enter reliance agreements for studies that fall solely under the exempt categories. If you believe your collaborative study is approvable only via exempt categories, please contact us at [IRB@msm.edu](mailto:IRB@msm.edu) for further guidance.

## 11. HIPAA and Consent Waiver Application

### HIPAA and Consent Waiver Application

The HIPAA Privacy Standard at 45 CFR 164.512(i) requires that certain criteria be met in order to grant a waiver of individual authorization for research uses of Protected Health Information (PHI, i.e., individually identifiable health information held by a health care provider or health plan covered by HIPAA,). In addition to these criteria, the federal Common Rule (45 CFR 46 section 116(d)) stipulates that “whenever appropriate, the subjects will be provided with additional pertinent information after participation.”

- The HIPAA Privacy Rule applies to projects where PHI is being obtained, used, or released/disclosed by a Covered Entity for the purposes of Research.
- Even if your project is Not Human Subject Research or this institution is Not Engaged in Research, you may still have requirements under HIPAA if PHI is being obtained, used, or released/disclosed by a Covered Entity.
- Protected Health Information (PHI) = health information + one or more of the 18 identifiers.

One of the important things to note with HIPAA and consent waivers is that even if you are not *recording* PHI or PII in your research records, you still need a waiver to *access* PHI/PII. For example, if you are requesting to collect data from patients’ medical records, even if you only extract non-identifiers from the system, it is reasonable to assume you will inevitably view PHI (such as name, DOB, MRN, etc.) while extracting this data, and therefore you would need to request a waiver and list the identifying information you will access and what you will extract.

- First, you will specify whether you are requesting a full or partial HIPAA/consent waiver. A full waiver would be for studies that will not utilize a consent form at all (for example, a retrospective chart review study, or a study that is administering an anonymous survey where the only identifying link to identity would be the consent form). Partial waivers are typically requested when the study team needs to pre-screen potential participants for eligibility, and if they meet pre-screening requirements, the participant can be approached for consent to the study. For example, if a study is administering a drug to participants that have hypertension and have failed 3 or more other medications to manage/control their high blood pressure, a partial waiver could be requested to review potential participants’ medical records to compile a list of potentially eligible people based on this inclusion criteria, and then the team would know who to approach in the clinic for study enrollment.

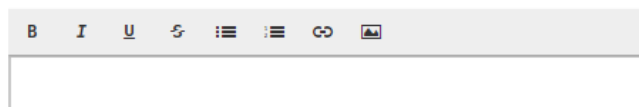
\* This request is for:

- TOTAL WAIVER OF CONSENT AND/OR HIPAA AUTHORIZATION
- PARTIAL WAIVER OF CONSENT AND/OR HIPAA AUTHORIZATION

*When a partial waiver is requested, you may request that certain required elements of the HIPAA authorization be altered or that the HIPAA authorization be waived for a portion of the study. [For instance, you may request a waiver for subject identification or recruitment purposes but not for enrollment purposes. For example, you may request a waiver of the HIPAA authorization requirement so that a treating physician may obtain verbal permission from the patient/parent so that the physician can notify the study coordinator of the patient’s/parent’s interest in the study. Once the study coordinator has discussed the study with the interested patient and parent, they will consent the participant and parent and obtain a full authorization.]*

- Next, describe what you are requesting the waiver for (HIPAA or consent, pre-screening, retrospective chart review, surveys, interviews, focus groups, etc.)

\* Please specify what you are requesting the waiver (total or partial) for:



- Then, **select all** identifying information that you will access AND/OR record for the project.



\* HIPAA Identifiers Collected

Indicate all identifiers that will be accessed/recorded for this project.

- Patient/Participant Names
- All elements of Dates (except year) that are directly related to an individual (i.e., birth date, appointment dates, etc.)
- Age information for those over 89
- Geographic subdivisions smaller than a State (with exceptions for initial 3 digits of zip code)
- Telephone Numbers
- Fax Numbers
- Email Addresses
- Social Security Numbers
- Medical Record Numbers
- Account Numbers
- Health Plan Beneficiary Numbers
- Certificate/License Numbers
- Device Identifiers and Serial Numbers
- Vehicle Identifiers and Serial Numbers (including license plate 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 identifying images
- Results of a Genetic Test
- Any other unique identifying number, characteristic, or code
- None of the above

- The following question is an acknowledgment that the 3 items mentioned are in place. If your study documents (such as the protocol) do not mention how the following three items will be addressed, your HIPAA waiver will be rejected.

\* Does the use or disclosure of PHI involve no more than a minimal risk to the privacy of the individual based on at least the presence of the following:

There is...

1. An adequate plan to protect the identifiers from improper use and disclosure.
2. An adequate plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research unless there is a health or research justification for retaining the identifiers or as otherwise required by law.
3. Adequate written assurances that the protected health information will not be reused or disclosed to another person or entity, except as required by law, for authorized oversight of the research study, or other research for which the use or disclosure of PHI would be permitted.

- Yes
- No

- Once you have created the plans based on the 3 points mentioned in the previous question, you will describe those 3 plans in the next set of questions.

\* Describe the plan to protect the identifiers (names, addresses, telephone numbers, social security numbers, medical record numbers, photos, and other identifying information etc.) from improper use and disclosure.

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\* Describe the plan to destroy the identifiers at the earliest opportunity or provide justification for retaining the identifiers.

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- You will then indicate whether a waiver will adversely affect the privacy rights of the individuals whose data is being collected. If the waiver *will adversely affect* the privacy rights of individuals, it is unlikely a waiver will be granted.

\* Will a waiver adversely affect the privacy rights of the individual?

- Yes
- No

- Justification will be required for why the research cannot be practicably done without the waiver (you cannot simply reiterate that it is impractical, you must describe *why* it is impractical to do the research without the waiver. For example, a reason may be that there are a large number of records queried for a retrospective chart review, and it would not be appropriate to attempt to contact those patients to tell them about the study retrospectively, particularly for a study where results will not change care the individuals have already received).
- If the research can be done without the waiver, then a waiver will not be granted.

\* Could the research be practicably done without the waiver?

- Yes  
 No

*Justify why the research cannot practicably be done without the waiver:*

- Similar to the previous question, you must explain whether the research could or could not practicably be done without access to, use or disclosure of the PHI identified.

\* Could the research practicably be done without access to, use, or disclosure of the PHI identified below?

- Yes

*If the research can be practicably done without access to, use, or disclosure of PHI, indicate what PHI you want to use, how it will be beneficial for the research, and why you are requesting this waiver for PHI access:*

- Next, you will be asked whether the privacy risks are reasonable in relation to the benefit for the individual's whose records you are accessing. If yes, you will be asked to provide the risk/benefit analysis relating to the waiver request. If no, your waiver will be rejected (risks cannot outweigh potential benefits).

\* Are the privacy risks to individuals whose PHI will be used or disclosed reasonable in relation to the anticipated benefit, if any, to the individuals?

- Yes  
 No

- Yes

*Describe the risk/benefit analysis relating to the waiver request:*

- The next question asks for you to list ALL persons that will have access to, use of, or disclosure of PHI/PII. If there is a code being used that could link identifiers back to participants, all individuals who have access to the code will need to be listed as well.

\* List ALL persons that will have access, use, or disclosure of PHI:

FIND PEOPLE

*If you cannot find a person, or if the individual is external to MSM, list them and their role on the study below:*

- If you will be sharing PHI amongst sites outside of Morehouse School of Medicine, you will need to list those sites, what will be shared, and note under what authorization the PHI is being released under.

\* Sharing of PHI

Will this project involve this institution receiving PHI from and/or sharing PHI with any outside entities?

Yes

How and What PHI is Shared

Describe how PHI will be shared and with which entities. Be sure to address the following:

- What PHI will be shared.
- Who is receiving the data (e.g., Name of entity and if it is a Covered Entity).
- Under what authorization PHI is release (e.g., Limited Data Set under a Data Use Agreement, subject authorization, under a waiver of authorization, etc.).

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- Finally, the PI will need to attest to the Investigators Agreement for the HIPAA/Consent waiver to be completed. Note that in the system, technically the Primary Contact is able to complete this information. Do not name a primary contact that you would not feel comfortable allowing them to sign this document on your behalf. As the PI, you are ultimately responsible for adhering to this agreement. For student PIs, the Faculty Advisor must provide sign-off for the agreement.

\* INVESTIGATORS AGREEMENT:

As Principal Investigator of this study, I assure the Office for Human Subjects Protection that the following statements are true:

The information that is provided in this form is true and accurate. I will seek and obtain prior written approval from the IRB for any substantive modifications to the proposal, including but not limited to, changes in procedures and co-investigators. I will report in writing any significant new findings that develop during the course of this study that may affect the risks and benefits to the individuals whose PHI are being obtained.

I will not begin my research, including subject identification or recruitment, until I have received written notification of IRB approval. I will comply with all IRB requests to report on the status of the study.

I will not reuse or disclose any PHI to any other person or entity, except as required by law, for the authorized oversight of research or for other permitted research.

I will conduct the research in compliance with all applicable federal and state laws and regulations and Morehouse School of Medicine policies governing human subject research.

I will not utilize the PHI of any patient who has opted out of use of their information for research.

By typing your name below, you are agreeing to the terms above.

Note: Only the PI can sign this agreement. Applications with signatures from other study personnel will be denied. If you are a student PI, your faculty advisor must be the person to sign this agreement.

\* Today's Date

MM-DD-YYYY

## 12. International Research

The International Research smart form appears when the International Sites question in the *Basic Study Details* smart form is answered “yes.”

\* International Sites

Will any research activities occur at non-US sites?

Yes  
 No

### a. Justification

- Be prepared with this form to answer multiple questions about the handling of international research, including justification for why it is necessary to conduct the research in an international setting.

\* Justification of International Setting

Explain the scientific and ethical justification for conducting research in an international setting.

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





b. Location(s) and Personnel

- Next, you will need to list all of the cities and countries where the research activities will take place.

**\* International Locations**

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List all cities and countries where research will be conducted.

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




- More specifically, in the next question you will provide the actual sites, their roles, and name the PIs and study personnel along with their roles at each site.

**\* International Collaborators**

---

List and describe all collaborating international sites, agencies, or institutions involved in research. Be sure to address the following:

- Name of site
- Role of site (e.g., performance site, data coordinating center, etc.)
- Names and qualifications of individuals at the site participating in research
- Role/activities of any individuals at the site related to the research

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





- Next, you will identify the institution(s) and/or government(s) that will have access to any data/specimens, along with the level of identifying information they will be receiving or generating.

c. Data and Specimens

**\* Data/Specimen Access**

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- Identify the institution(s)/government(s) who will have access to the data/specimens
- Specify the level of data/specimens which they will access to (e.g., anonymous, coded, individually identifiable, etc.).

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d. Local Context Information

- The next 4 questions all relate to the local context at each international site. Be sure to address these questions for each international site involved.

**Local Context Information**







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For each site, as applicable, address the questions below.

*\*Note: When conducting research in other countries, you are required to follow the country's laws, policies, regulations as they may not follow US laws, policies, etc.*







**\* International Oversight Requirements**

Identify all required local permissions required to conduct research (e.g., institutional permissions, local government requirements/procedures, etc.). Explain if you will obtain approval from a local IRB or ethics committee, evaluation by a consultant, or input from another individual or entity with knowledge of the study site.

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**\* Applicability of Research to Location**

Describe how the research may address an important scientific question regarding the host community/country. If applicable, describe how the proposal is responsive to local health needs of the host community/country. Describe both the standard of care in the USA and the available standard of care/alternatives in the host community/country.

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**\* Community Consultation**

Outline the PI's knowledge of the local community.

- Include discussion of planned or completed community consultation activities regarding the consent process, consent documentation, study instruments.
- Identify the participants in the planned or completed community consultation.
- Describe the methods, discussions, and meetings.

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**Additional Local Context**

Describe any other relevant aspects of the local context where the research will take place. Include information about local customs, laws, standard of care, privacy concerns, logistics, etc.

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**e. Participant Protections**

For the next 4 questions, it is important to provide as much detail as possible on the literacy/consenting processes, the status of women and children in each respective country, and clarification on research vs treatment *in that country*.

For each question, review the italicized font for a list of all the information you will need to provide.

**Participant Protections**

For each site, as applicable, address the questions below.

**\* Literacy and Study Documents**

- Describe the literacy level of the population.
- Discuss how subjects' comprehension of the consent process will be maximized.
- Explain how the cultural appropriateness of the consent process and consent document (if applicable), study instruments, etc. has been determined.
- Describe your plan to ensure that consent form and other documents as applicable will be translated into the appropriate language(s) after the English versions are approved by the IRB.

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**\* Status of Women**

Discuss the status of women in the local community/country.

If the status of women in the international location(s) is different than in the United States, address the following issues:

- How will you ensure women's voluntary participation in the research?
- If women's consent will be supplemented by a male (spouse, brother, father, etc.), explain why it is impossible to conduct the research without obtaining supplemental male permission for female subjects.
- Explain why failure to conduct the research could deny its potential benefits to women in the host country.
- Outline the measures to be incorporated in the research protocol to respect women's autonomy to consent.
- Provide written assurance that no competent adult woman be enrolled in research solely upon the permission of another person.

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**\* Status of Children**

Discuss the status of children in the local community/country. If the status or definition of children in the international location(s) is different than in the United States, explain how.

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#### Clarification of Research vs. Treatment

Research may provide subjects with beneficial care. In some developing countries, the type and level of clinical care provided to subjects may not be available to those subjects outside of the research context. It is a misconception to believe that the purpose of clinical trials is to administer treatment rather than to conduct research. With that in mind, address the following:

- Explain how the investigator will minimize the likelihood subjects will believe mistakenly that the purpose of the research is solely to provide treatment rather than to contribute to scientific knowledge.
- Clarify whether there has been an effort to secure continued access for all subjects to needed experimental interventions that have been proven effective at the conclusion of the project.
- Explain how the investigator will secure continued access (for subjects) to needed experimental interventions that have been proven effective at the conclusion of the project. Alternately, explain why the investigator has not secured continued access (for subjects) to needed experimental interventions that have been proven effective at the conclusion of the project.
- Explain whether, if proven effective, the procedures will be available to some or all of the host country population. Also explain either (1) why the research procedures (if effective) will NOT be made available to the host country's population, OR, (2) how the research procedures (if effective) will be made available to the host country's population. Please include a description of any pre-negotiations among sponsors, host country officials, and other appropriate parties aimed at making interventions available after the research.



#### f. Export Controls

- If your study will involve any of the following exports list in the question below, you will be required to describe what those are. You will also be required to contact John Mulcahy at [jmulcahy@msm.edu](mailto:jmulcahy@msm.edu) to do an analysis to determine if an export or deemed export license is required for your study.

##### \* Export Controls

Will you be shipping, transferring, or transmitting certain controlled data, devices, technology/electronics (hardware/software), biological/chemical agents or toxins, etc. to the international country you will be doing research in?

- Yes  
 No

#### g. Attachments

Finally, there are two attachment points for the International Research form. The first is a spot for letters of support and/or documentation of approval for international research, and the second is an optional section to upload any other documents relevant to the international research portion of the study.

##### \* Letters of Support and/or Documentation of Approval for International Research

Upload Letters of Support from all international institutions that will be participating in the research, or documentation that the international sites have agreed to allow this research to be conducted at their site.

ATTACH

##### Additional Documentation

Upload any additional documentation related to International Research, as applicable.

ATTACH

### 13. Data & Safety Monitoring

As mentioned in *Section 6 Participants, subpart e. Participant Protection*, this smart form appears when you respond “yes” to the Data & Safety Monitoring question.

#### a. Monitor(s) and Responsibilities

- The first question will be where you indicate if a DSMP document has been issued by the lead site or sponsor. If “yes,” click attach and include the document.

\* Has a DSMP document or Charter been issued by the Lead Site or Sponsor?

For example, industry sponsored clinical trials often issue documentation on data and safety monitoring plans.

Yes

**DSMP Documentation**

Please upload any officially issued DSMP or DSMB/C Charter documentation.

ATTACH

For any subsequent text field questions about DSMP related information, you can answer them directly or state what pages/sections to reference in the uploaded documents.

No

- Next, indicate by checking all that apply, who will be responsible for monitoring the study data for safety.

\* Study Monitor

Indicate the entity that will monitor the study data for safety. Check all that apply:

- Investigator
- Monitor independent of the study team (e.g., sponsor's medical monitor)
- Data Safety Monitoring Board or Committee (DSMB/C)

- Provide the requested information for all of the monitors or DSMB members.

\* Monitor or DSMB/C Information

Provide the following information for the monitor(s) or DSMB/C members:

- Name
- Credentials
- Role in Study Monitoring
- Expertise
- Title/Organization

If this information is not known, please provide a description of the expertise of the anticipated monitor(s) or board/committee members.

B I U

- Next, you will describe how the objectivity of the monitoring entity and the monitoring process will be ensured.

\* Objectivity of Monitoring Entity

Explain how the objectivity of the monitoring entity and the monitoring process will be ensured.

(E.g., if the monitor is the investigator, the investigator should verify absence of conflict of interest, or when the monitor is from the sponsor, he/she is neither directly nor indirectly involved in the conduct or analyses.)

B I U

- Then, identify the roles in gathering and monitoring data. You will need to identify who has what responsibility. Review the list in the question below:

\* Roles & Responsibilities Gathering and Monitoring Data

Describe the roles in gathering and monitoring data for the investigators/research team, research coordinators, sponsor, monitoring entity, statistical consultant, etc. Be sure to address who has the following responsibilities:

- Recording data
- Verifying data accuracy, including the method and frequency (e.g., double data entry, outside audit, visual verification)
- Verifying procedures are conducted per the approved protocol
- Conducting periodic assessments
- Evaluating events/incidents to determine if any represent unanticipated problems involving risks to subjects or others and the appropriate action as a result of those events

B I U

## b. Monitoring Process

- The monitoring process will begin with a question asking for description of what data will be monitored and reported, how reports will be submitted, frequency of reports, and timeframes for reporting certain events to monitoring entities and the IRB.

## Monitoring Process

### \* Monitored Information and Reporting

Describe the following:






- The data and/or events that will be monitored, assessed, and reported to/by the monitoring entity.
- The mechanism(s) through which reports will be submitted to the monitoring entity.
- The frequency of any reports that will be submitted to the monitoring entity.
- The timeframe for reporting certain events, including unanticipated problems involving risks to subjects or others, to the monitoring entity and the IRB.

B I U      

- Next, you will be asked to answer five questions about the frequency, procedures, actions, communications, and confidentiality of the reported study data. Elaboration for each question is under each section of bolded text.

### \* Frequency of Monitoring and Reporting

Indicate the frequency with which the monitoring entity will review and assess the data and/or events.

B I U      



### \* Evaluation Methods

Describe the procedures and methods the monitoring entity will use to evaluate the data and/or events, such as statistical analysis. For studies monitored by a DSMB/C, also describe the meeting structure, format, and quorum requirements.

B I U      

### \* Criteria and Response to Findings

Describe the criteria and plan for taking action in response to monitoring entity findings (e.g., reporting, stopping rules, protocol changes, or modifying subsequent monitoring activities).

B I U      

### \* Communicating Findings

Describe both the frequency and method in which monitoring entity findings and recommendations will be communicated to the investigator, sponsor, and other entities (e.g., FDA, other sites, etc.).

B I U      

### \* Confidentiality of Data

Describe how the confidentiality of the data provided to the monitoring entity will be maintained.

B I U      

## 14. NHR or Not Engaged in Research

This form starts by reviewing the definitions of “Research” and “Human Subjects.”



## a. Definition of "Research"

Does the project meet definition of "Research"?

As defined by 45 CFR 46, research is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

\* Is the activity a systematic investigation?

For example, a project that is a careful examination or inquiry, which has a system, method, or plan, with the intention of ascertaining facts. Consider that randomizing individuals/groups/organizations or designating them to receive different interventions for comparison tends to indicate systematic investigation.

- Yes  
 No

\* Is the project intended to develop or contribute to generalizable knowledge?

- Consider if the knowledge gained in this project could be generalizable, or universally applied/accepted, to other contexts or situations.
- Case studies of more than a couple patients/subjects are generally considered research.

- Yes  
 No

\* Based on the 2 answers above, does this project meet the definition of "Research"?

- Yes (both answers above were Yes)  
 No (at least one answer above was No)

- If one or both of the answers to the above questions are "no," then you will be asked to provide an explanation of why the response does not meet the criteria for systematic investigation or contributing to generalizable knowledge. If one or both of the responses are "no," then you will select "no" for the third question and the form will end.

\* Based on the 2 answers above, does this project meet the definition of "Research"?

- Yes (both answers above were Yes)  
 No (at least one answer above was No)

Thank you for this information. The IRB will review your responses above and will let you know if our determination on the status of whether this is HSR or NHR.

If the project is determined by the IRB to be HSR, you will be required to go back and complete the standard initial application.

- If both responses to the research questions are "yes," then you should respond "yes" to the question *Based on the 2 answers above, does this project meet the definition of "Research"?*

## b. Definition of "Human Subjects"

- You will then be prompted to answer questions about whether the research meets the definition of involving "human subjects."

Does the project meet the definition of "Human Subject" research?

As defined by 45 CFR 46, a human subject is "a living individual, about whom an investigator (whether professional or student) conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

\* Will the investigator conducting the research obtain data about living individuals through intervention OR interaction?

- Intervention: Physical procedures or manipulations of those individuals or their environment.
- Interaction: Communication or interpersonal contact with the individuals.

- Yes  
 No

\* Will the investigator conducting the research gather data that is individually identifiable private information?

- Identifiable: The identifies of the subjects are readily ascertainable to the investigator, either directly or indirectly through a coding system.
- Private: For example, information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record).

If the project only involves data and/or specimens that were pre-existing, or collected for some purpose other than this project, consider the original source of the data/specimens, how they are provided to investigators, if the data/specimens are identifiable in any way to investigators, etc.

- Yes  
 No

Based on the answers to the previous 2 answers above, does this project meet the definition of "Human Subject" Research?

- Yes (at least one answer above was Yes)  
 No (both answers above were No)

- If you select "no" to either of the first two questions, you will be prompted to explain why.

- If the answer is “yes” to at least one of the 2 questions regarding human subjects, then the answer to the third question *Based on the answers to the previous 2 answers above, does this project meet the definition of “Human Subject” Research?* should be “yes.”
  - In this case, the project would be considered human subjects research and you will be required to return to the Project Type question to change your response and complete a full IRB application.

Based on the answers to the previous 2 answers above, does this project meet the definition of “Human Subject” Research?

- Yes (at least one answer above was Yes)
 

This project is considered Human Subject Research and will require regular IRB review. Please return to the Project Type question in the Study Details section and select a more applicable project type (e.g., research study, clinical trial, etc.), unless you think this institution is NOT Engaged in Research. In that case proceed to the next question below.
- No (both answers above were No)

### c. Definition of “Engaged in Research”

- If the answers to both questions are “no,” you will need to answer the question about whether or not the institution meets the definition of being “Engaged in Research.”

Does the project meet the definition of this institution being “Engaged in Research”?

Per OHRP Guidance [Engagement of Institutions in Human Subjects Research \(2008\)](#), an institution is considered engaged in research if employees, students, or other agents of that institution do any of the following: (1) Intervene or interact with human subjects for the purposes of a research project, or (2) obtain individually identifiable private information about human subjects for a research project, or (3) obtain the informed consent of individuals for participation in a research project.

Will any employees, students, or other agents of this institution do ANY of the following as part of this research project:

- Intervene or interact with human subjects for the research project.
- Obtain individually identifiable private information about human subjects for the research project.
- Obtain the informed consent of individuals for participation in the research project.

- Yes
- No

- If the answer to this question is “yes,” then you will be required to return to the Project Type question to change your response and complete a full IRB application.
- If the answer to this question is “no,” then you will be prompted to explain why, and you will be able to submit your form for determination by the IRB.

Thank you for this information. The IRB will review your responses above and will let you know if our determination on the status of whether this is HSR or NHR.

If the project is determined by the IRB to be HSR, you will be required to go back and complete the standard initial application.

- Note that if the IRB determines that the project *is* HSR, then a full IRB application will be required.
- See *Section III. Submitting Your Study* for further details on submitting the application.

## 15. 118 Determination/Future Human Subjects Research

### Definition:

§46.118 Applications and proposals lacking definite plans for involvement of human subjects. Certain types of applications for grants, cooperative agreements, or contracts are submitted to Federal departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution’s responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects’ involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. Except for research waived under §46.101(i) or exempted under §46.104, no human subjects may be involved in any project supported by these

awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the Federal department or agency component supporting the research.

- The first question in this section is whether or not there is a definite plan for involvement of human subjects. If the answer to this question is “yes,” you will be required to return to the *Basic Study Details* form to select a more appropriate response to the “Project Type” question.

\* Human Subject Plans

---

Does your research project currently contain a definite plan for involvement of human subjects?

Yes  
 No

- If the answer to the first question is “no,” then you will be required to answer 3 questions about project description, protocol development, and the timeline to human subject participation.

Project Description

---

Provide a non-technical description of the research project as is currently known, such as the Purpose, Study Population information Procedures, etc.

B I U

Protocol Development

---

Describe what must be done before human subjects would be involved in the research project (e.g., development of measures, recruitment materials, assays, etc.).

B I U

Timeline to Human Subject Participation

---

Explain the estimated timeline for the involvement of human subjects.

B I U

- Finally, there will be a space to upload all relevant documents to support the NHSR determination (i.e., the grant application, a brief protocol, etc.)

118 Determination Supporting Documentation

---

Please upload any documents related to this 118 determination, such as the grant application, a brief protocol document, etc.

ATTACH

- Once you have answered the 3 questions and uploaded all applicable documents, you will be able to route the submission for certification. Please see “Section III. Submitting Your Study” for more details.

## 16. American Cancer Society (ACS) IRB Application

NOTE: This application is only intended for use by the American Cancer Society. If you are not affiliated with ACS and this form has appeared, please return to the Study Personnel section and select a different affiliation.

- This application is also only for Exempt study types. If you are submitting a study that will not qualify for an Exempt status, or Quality Improvement, you will be required to complete the entire standard IRB application for studies that would be reviewed via Expedited or Full-Board procedure.
- The ACS application starts with listing all Study Personnel. ACS is responsible for tracking and maintaining CITI training for their research personnel, so CITI certificates are not required to be uploaded for MSM IRB

review, however, when new personnel are added to a study, it required that the IRB be notified of the person's name and role on the study.

- To ensure the proper smart forms populate, you must select “American Cancer Society” as the PI’s affiliation with MSM in the *Study Personnel* form.

## Study Personnel

### \* Principal Investigator

The person listed as the PI will be required to certify submissions before they are sent to the IRB for review. They will also have edit access to this study, can create follow-on submissions after Initial approval, and will be included in study communications.

#### \* Principal Investigator Name

Note: If you cannot find a person in the people finder, please contact the IRB Office immediately.

Name	Organization	Address	Phone	Email	Trainings	
Amanda Tan	Sponsored Rsch Admin			atan@msm.edu	<a href="#">View</a>	✘

#### \* What is the PI's affiliation with MSM?

- Faculty
- Student
- Staff
- External PI

Select this option if you are an organization that uses MSM as the IRB of record.

- American Cancer Society
- Other

- In the *Basic Study Details* form, you must select the last option for the Project Type question.

### \* Project Type

What type of project is this submission for?

- Research Study
- Clinical Trial

A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. These interventions include drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and diagnostic strategies.

[Source: Clinical Trial Definition](#)

- Establishment of a Biorepository or Data repository

A biorepository or biobank is fundamentally a library that stores and manages biosamples, also known as biospecimens, for use in research. A data repository acts as a centralized database where information is gathered, stored, analyzed, and archived in one organized space.

[Source: Biorepository Definition](#)

- Activities Without a Plan to Conduct Research (Case Report, Quality Improvement project, Public Health project) OR Research in which this Institution is Not Engaged

Select this option if **either** are true:

- You are not sure if your project requires IRB oversight.
- You need a formal determination from the IRB on if the project requires IRB oversight.

- 118 Determination/Future Human Research

Select this option if **BOTH** are true:

- This research project will involve or may involve human subjects in the future, but future protocol development must take place first.
- You need documentation of IRB review in order to release your grant funds.

- Single Patient, Treatment Use, Continued Access Drug/Device Study
- Emergency (or Compassionate) Use of Investigational Drug or Device

- I am submitting a study for review on behalf of the American Cancer Society.

- You should then note that the following smart forms are the only ones that should populate:

Sections	<
Getting Started	✓
Study Personnel	✓
Conflict of Interest	✓
Basic Study Details	✓
ACS IRB Application	

## ACS IRB Application






This application is only intended for use by the American Cancer Society. If you are not affiliated with ACS, please return to the Study Personnel section and select a different affiliation.

- You will be asked to list all study personnel for your project.

**\* Study Personnel**

---

List all study personnel that will be involved in this study. Includes names, titles, credentials, and contact information.

B I U     

- Next, you will identify which exempt research category the study falls under (if more than one, check all that apply). If you believe your project is not research, select the last option “Project does not meet any of the above eight categories.”

**\* Exempt Research Categories**

---

Select all categories that describe the proposed research activity:

The exemptions outlined below do not apply to ANY research involving prisoners, fetuses, pregnant people, human in vitro fertilization or FDA regulated products. Research involving children may be exempt with specific restrictions.

- You will then need to answer seven yes/no questions.

**\* Will the project involve testing an experimental drug, device (including medical software or assays) or biologic?**

- Yes  
 No

**\* Has the project received funding (e.g., federal, industry) to be conducted as a human subjects research study?**

- Yes  
 No

**\* Is this a systematic investigation designed with the intent to contribute to generalizable knowledge (e.g., testing a hypothesis; randomization of subjects; comparison of case vs. control; observational research; comparative effectiveness research; or comparable criteria in alternative research paradigms)?**

- Yes  
 No

**\* Will the results of the project be published, presented, or disseminated outside the institution conducting it?**

- Yes  
 No

\* Will this project occur regardless of whether individuals conducting it may benefit professionally from it?

- Yes
- No

\* Is the project intended to improve or evaluate the practice or process within a particular institution or a specific program?

- Yes
- No

\* Will you be obtaining information about a living individual through direct intervention or interaction with that individual? This would include any contact with people using questionnaires/surveys, interviews, focus groups, observations, treatment interventions, etc.

Please note: Merely obtaining information from an individual does not mean you should answer "yes," unless the information is also about them.

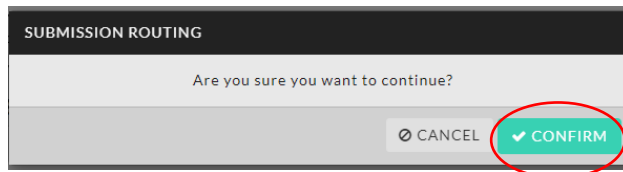
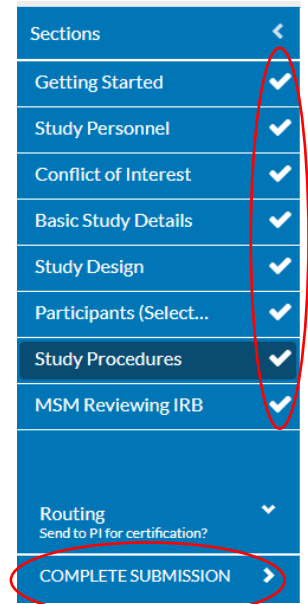
- Yes
- No

- Once all questions have been addressed, you will be able to submit your study. Go to section *III. Submitting Your Study* for further guidance.

### III. Submitting Your Study

Before you can submit your study, you must confirm that all of your smart forms are complete. As described in *Section II: Filling out the IRB Application*, you will have different forms depending on your responses to questions. If a form is completed, it will display a checkmark next to it. If the checkmark does not appear, you will need to go back and review the form to determine what was missed. All questions that populate a text box for further details after checking "yes" or "no" are required.

Once all of the checkmarks are fulfilled, you will see the option for **Routing**. In Cayuse, the PI must certify the submission before it will be sent to the IRB for pre-review. Upon clicking the COMPLETE SUBMISSION > button, it will ask you to confirm that you want to submit for routing. Click the green CONFIRM button. This will send the submission to the PI for certification.



In the Submission Details section, you will then be able to see that the submission is now in Step 2 Awaiting Authorization.

Role: Analyst | Products | Amanda Tan

Dashboard | Studies | Submissions | Tasks | Meetings | More

Studies / Study Details / Submission Details

**1 In-Draft**  
Submission is with researchers

**2 Awaiting Authorization**  
Submission is awaiting certification or approval

**3 Pre-Review**  
Submission is being prepared for review

**4 Under-Review**  
Submission is with reviewers

**Awaiting Certification**

**Initial**  
IRB-FY2025-2 - Example Study Protocol

View PDF Delete

Routing: Return Certify

PI:	Current Analyst:	Decision:	Policy:	Required Tasks:
Amanda Tan	N/A	N/A	Post-2018 Rule	N/A
Review Type:	Review Board:	Meeting Date:		
N/A	N/A	N/A		

To see what the submission includes, click the “View” button circled in the above picture on the left. If issues are noted, you will need to click “Return” to push the submission back into a *In-Draft* mode to make edits.

If everything looks ready to submit to the IRB, click Certify to send it into *Pre-Review* for the IRB team to begin their assessment.

#### IV. IRB Reviewing Process

Once your study has been submitted to the IRB for Pre-Review, an IRB analyst will review your application within 5 business days. They can make comments and provide feedback/ask questions in the IRB application itself, directly to your original responses. You will also be able to respond to the comments as well in the application.

##### Basic Information

Please upload your Protocol Documents

Protocol Template can be found here

● Collapse Comments

Amanda Tan Today at 2:57 PM Visibility: Unrestricted

Please address the following: example of a comment

Edit Reply

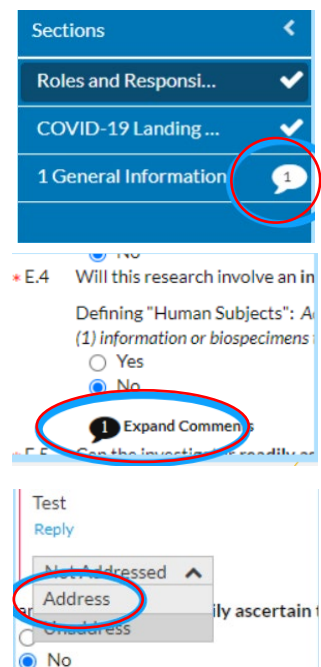
**Feedback Requested**

B I U ↻ ☰ ☷ 🔗 🖼

SAVE COMMENT

## Resolving Comments

- Comments from a reviewer or analyst will appear as a bubble beside the smart form section that the comments are located in.
- To locate the comment(s), type “CTRL” and “F” at the same time, then search for the word “Expand”. Click on the “expand comment” button to view the comment. Note that there may be more than one comment in a section.
- To address/respond to the comment, reply to the comment then **fix the issue in the actual submission.**
- Once you have replied to the comment and fixed the issue, click the “Not Addressed” button in the drop down and change it to “Addressed.”



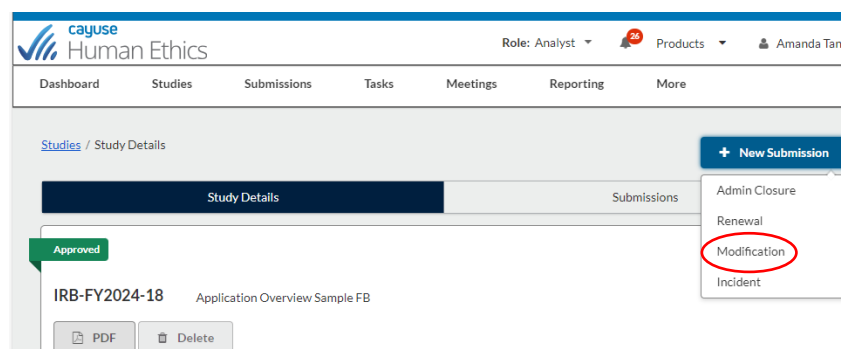
If the IRB analyst determines that there needs to be items addressed in your initial submission prior to submitting it to the full-board or a reviewer for approval, they will send it back to the study team and the submission will go back to the “In-Draft” step for modifications. Once modifications have been made and comments have been addressed, follow the steps “Submitting Your Study” once more to route and certify the submission, then the IRB analyst can review again.

## V. Amendments

Unlike the previous eIRB system, Cayuse has a feature that compares all changes between documents. This means that all documents that are submitted in the Cayuse system need to be clean, final documents. This means free of comments and free of track-changes. If you submit draft or marked documents, your submission will be returned to you without being reviewed.

An important note is that when you make a change to your application, you must consider every category that the change affects. Consider changes to risks/benefits, resources needed, personnel changes, study procedures, etc.

- Once your study has been approved, you will need to submit a “Modification” application for any changes to the submission post-approval.



- You will be asked to confirm that you want to make changes to your application.



IRB NUMBER: IRB-FY2024-18

## Application Overview Sample FB - Modification

← SUBMISSION DETAILS

- Sections <
- Modification Information
- Getting Started ✓
- Project Personnel ✓
- Conflict of Interest ✓
- Basic Information ✓
- Study Design ✓
- Study Selection ✓
- Study Procedures ✓
- Participant Protect... ✓
- Attachments ✓

### Modification Information

**IMPORTANT REMINDER**

The only way to make changes to the study protocol is to make them in a modification submission.

- If you are looking to renew study approval, a Renewal submission is needed.
- If you are looking to report an event or incident with the study, an Incident submission may be needed.
- If the study is complete, a Closure submission may be needed.

\* Are you making changes to the project?

Yes  
 No

Please make your changes in the sections to the left.

Remember to consider all applicable categories when updating your submission. Do not just upload amended protocol or consent documents without reviewing the questions in the submission (i.e., update "resources" if the amendment changes the necessary resources to conduct the study. Make sure all personnel training is completed and uploaded. Change the risks/benefits section if applicable, etc.)

- The entire application pulls up for every amendment/modification submission. Make sure you change everything that applies to the modification prior to routing for review. This is different from the previous eIRB system, so it is extremely important to review your submission carefully!
- **You do not need to note what has changed.** On the IRB reviewer side, the system tells us what has been deleted and added in each individual box, as well as what attachments have changed, so you just have to make your edits, and the IRB will be able to see it.
- Similar to the initial application, you will route the completed submission to the PI for certification, and then it can be submitted to the IRB for review.

## VI. Continuing Reviews

Similar to Amendments, you will select the **+ New Submission** button under the study you are requesting Continuing Review for. Then, click **Renewal**.

The screenshot shows the Cayuse Human Ethics system interface. At the top, the user is logged in as 'Amanda Tan' with the role of 'Analyst'. The navigation menu includes Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, and More. The main content area shows 'Study Details' for 'IRB-FY2024-18 Application Overview Sample FB', which is marked as 'Approved'. A '+ New Submission' button is visible, and a dropdown menu is open, showing options: Admin Closure, Renewal (circled in red), Modification, and Incident. There are also PDF and Delete buttons at the bottom of the study details card.

- You will be asked if you are requesting more time for your project. If the answer is “no,” click on the submission details button at the top of the page, then click on the grey button with the trash can to delete the submission. If your project is expiring and you do not need to continue it, create a Closure submission instead.

## Check-in & Continuing Review

### \* Request for More Time

---

Are you requesting more time for the project?

- Yes  
 No

- Once you click “yes,” you will need to select the IRB Oversight Arrangements (should be the same as the initial submission).
- If your study is relying on an external IRB to be the IRB of record, you will be prompted to Attach the renewal/continuing review approval letter:

### \* Reviewing IRB Approvals

---

Please upload the Reviewing IRBs renewal/continuing review approval letter.

ATTACH

- Regardless of whether MSM is the reviewing IRB or if we are relying on an external IRB, you will be required to submit a brief report on the current status of your project.

### \* Study & Subject Status

---

Check all that apply.

- Study has not started or is on hold  
 Study enrollment is open; NO enrollment to date  
 Study enrollment is open and ongoing  
 Study enrollment is closed  
 Treatment and/or active follow-up continues  
 Long-term follow-up only (no intervention/interaction)  
 Remaining activities limited to data analysis

- Next, you will be required to enter numbers for Enrollment in your study. These numbers **must be exact**. Do not enter estimates.

**Enrollment**

For intervention/interaction studies or aims, Enrollment includes subjects who gave consent to participate, either in writing, orally, or by voluntary completion of a survey or participation in a focus group.

For data or specimen studies or aims, Enrollment includes subjects whose identifiable records/specimens have been reviewed.

\* Total subjects enrolled to date at all sites

\* Total subjects enrolled to date at this institution

\* Total subjects enrolled at this institution since the last Renewal (or since Initial approval if this is the first Renewal)

\* Total number of withdrawals at this institution since start of the study

*NOTE: Includes subjects who consented but were determined ineligible, left voluntarily, or were withdrawn by study investigators.*

\* Have there been any withdrawals at this institution during the this approval period?

*NOTE: Includes subjects who consented but were determined ineligible, left voluntarily, or were withdrawn by study investigators.*

- Yes
- No

• Indicate whether there have been any subject complaints during this approval period:

**\* Complaints**

Have there been any subject complaints during this approval period?

Please address for this institution only, UNLESS we are the Reviewing IRB for other sites. In that case, consideration should include all sites (be sure to reference the site name).

- Yes
- No

• Study amendments and modifications for studies where MSM is the relying IRB must be submitted to the MSM IRB within 10 business days of approval from the external IRB. Remember that even minor changes to study documents must be submitted to the IRB prior to implementation.

**\* Modifications**

Have there been any changes to the study during this approval period that you have NOT already submitted as a Modification?

Please address for this institution only, UNLESS we are the Reviewing IRB for other sites. In that case, consideration should include all sites.

- Yes
- No

• Indicate whether there have been any reportable events during this approval period, even if you submitted an Incident report already. If you have not submitted an Incident report for the mentioned events, you must do this immediately.

**Reportable Events**

This includes adverse events or protocol deviations that were required to promptly be submitted as an Incident per IRB Policy.

\* Have any Reportable Events occurred during this approval period?

Please address for this institution only, UNLESS we are the Reviewing IRB for other sites. In that case, consideration should include all sites (be sure to reference the site name).

- Yes
- No

- Unreportable events are protocol deviations or adverse events that are not required to be promptly submitted as an Incident. The PI should be tracking these events to be submitted during every continuing review period. If you have unreportable events, you will be asked to describe them in this section, as well as upload applicable documents such as event trackers.

**Unreportable Events**

---

*This includes adverse events or protocol deviations that weren't required to promptly be submitted as an Incident per IRB Policy.*

\* Have any Unreportable Events occurred during this approval period?

- Yes  
 No

- If your study has any new relevant information, you will indicate and describe that in this section.

**\* New Information**

---

*Is there any New Information to report for this study?*

*Please address for this institution only, UNLESS we are the Reviewing IRB for other sites. In that case, entries should include all sites (be sure to reference the site name).*

*For example:*

- Change in funding*
- Publications or scientific findings relevant to the risks and benefits to subjects*
- Independent Monitor/DSMB/DSMC findings*
- Interim analysis*

- Yes  
 No

- If your study expired and you are submitting this renewal post-expiration date, you will be required to indicate that here.

\* Is this Renewal being submitted AFTER the Study Expiration Date has already passed?

---

*This is applicable ONLY to studies that have a Study Expiration Date (e.g., full board studies and some expedited studies), NOT studies that have an Admin Check-in Date.*

- Yes  
 No

- If you indicated “yes” to the question above, you will be asked some additional questions. Note that if you continue study activities post-expiration, you must indicate in publications that these activities were not IRB approved.

\* Are you requesting that study activities continue while the study is expired?

*It may be important for subject safety to continue with any study procedures or treatment during the expiration period.*

Note: *These activities cannot be represented as having "IRB Approval".*

- Yes

\* Requested Activities

*Please describe the proposed activities and safety rationale for each.*

B I U ↺ ☰ ☰ ↻

- Next, you will be asked to describe why you allowed the study to expire, and the corrective action plan you will be implementing to ensure this does not happen in the future.

\* Reason for Expiration

Please explain why the study was allowed to expire (e.g., delay of renewal submission, outstanding information request, delayed documentation from IRB of Record, etc.), AND your plan to prevent this study from expiring in the future.

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- Finally, there is a section for any Additional Information or Documentation you wish to include in your renewal/continuing review.

Additional Information

Additional Information or Comments

If applicable, you can provide additional information that you think to be beneficial to review of this Renewal (e.g., summary of project progress, concerns or comments about risks to subjects, etc.).

B I U ↺ ☰ ☰ ☰ 🖼️

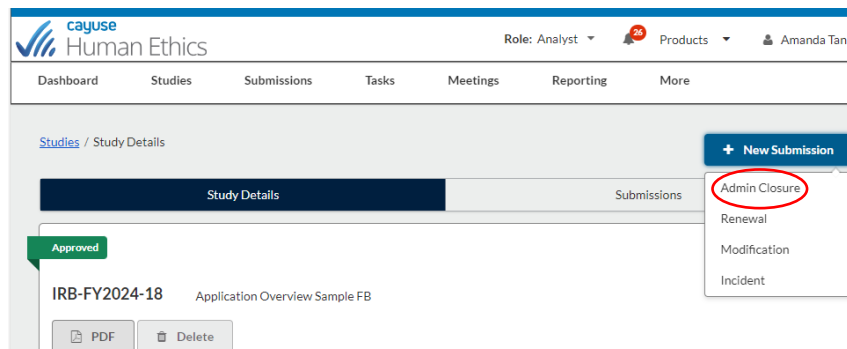
Additional Documentation

If you have any additional documentation to provide for this Renewal, upload it here.

ATTACH

## VII. Study Closure

To close your study, you will create a new submission, and select the Closure option.



- To begin, you will confirm that you wish to close the study. You will then indicate the reason for study closure. If you select “Project never started,” “Study terminated by sponsor,” or “Other,” you will be prompted to provide additional information.

\* Closing Study

Do you wish to close this study?

Yes

\* Reason for Study Closure:

- Completed per Protocol
- Project never started
- Study terminated by sponsor
- Other

Explain for what reason the study is being closed.

No

- You will then indicate the IRB Oversight Arrangements once more, and if using an External IRB (i.e., MSM is relying), you will be asked to upload the IRB closure letter from the external IRB.

**\* IRB Oversight Arrangements**

Indicate how IRB oversight is organized for this study. This should match what is in the latest approved version of this study (latest approved Modification or Initial approval).

- Study solely at MSM site(s)
- Study involving more than 1 site where each site will conduct their own IRB review
- Study involving more than 1 site where this site is the Reviewing IRB (IRB of Record) for other sites
- Study involving more than 1 site where this site is Relying on an External IRB
- Multi-site study (multiple US sites participating in a research study using the same protocol) where this site is the Reviewing IRB (IRB of Record) for all sites
- Multi-site study (multiple US sites participating in a research study using the same protocol) where this site is Relying on an External IRB

**Reviewing IRB Closure Letter**

Please upload documentation from the Reviewing IRB approving the closure of the study or this site.

ATTACH

- Next, you will indicate what the study and participant status is. If your study is still enrolling or if treatment is still ongoing, your study closure request will be rejected. If your study is still using identifiable data, your study closure request will be rejected.
  - Studies where all data is deidentified can be closed and analysis can continue without IRB oversight.

**\* Study & Participant Status**

Check all that apply.

- Study has not started or is on hold
- Study enrollment is open; NO enrollment to date
- Study enrollment is open and ongoing
- Study enrollment is closed
- Treatment and/or active follow-up continues
- Long-term follow-up only (no intervention/interaction)
- Remaining activities limited to data analysis
  - \* Indicate what kind of data is in use:**
    - Identifiable data is still in use (including coded data for which a link to the identifiable information is retained)
    - ONLY Coded data where BOTH are true:
      - ALL links to identifiable information have been destroyed
      - There is NO ability to link the data in use back to identifiable information
    - De-identified data ONLY

- Enrollment questions are self-explanatory and must be completed accordingly.


## Enrollment

For intervention/interaction studies or aims, Enrollment includes participants who gave consent to participate, either in writing, orally, or by voluntary completion of a survey or participation in a focus group.

For data or specimen studies or aims, Enrollment includes participants whose identifiable records/specimens have been reviewed.


\* **Date First Participant Enrolled**

For chart reviews or biospecimen analysis studies, indicate the date of the first day that data/specimen was pulled.

MM-DD-YYYY 

\* **Date Last Participant Completed Study**

For chart reviews or biospecimen analysis studies, indicate the date of the last day of analysis.

MM-DD-YYYY 

\* **Total of participants that were enrolled to date at all sites**

For chart reviews and biospecimen analysis, indicate the total number of records reviewed or the total number of participants whose specimens were included in the analysis.

\* **Total of participants that were enrolled to date at this institution**

For chart reviews and biospecimen analysis, indicate the total number of records reviewed or the total number of participants whose specimens were included in the analysis.

\* **Total of participants that were enrolled at this institution since the last Renewal (or since Initial approval if no Renewals)**

For chart reviews and biospecimen analysis, indicate the total number of records reviewed or the total number of participants whose specimens were included in the analysis.

\* **Total of participants that have completed the study to date at this institution**

For chart reviews and biospecimen analysis, indicate the total number of records reviewed or the total number of participants whose specimens were included in the analysis.

\* **Total of participants that have completed the study to date at all sites**

For chart reviews and biospecimen analysis, indicate the total number of records reviewed or the total number of participants whose specimens were included in the analysis.

\* **Total of screen failures to date at this site.**

A screen failure is a prospective participant who did not meet enrollment criteria and therefore was not actually consented/enrolled in the study. For chart reviews and biospecimen analysis, indicate how many total records/specimen were reviewed and purposefully excluded due to not meeting the proper study criteria.

\* **Total number of withdrawals at this institution since start of the study**

**NOTE:** Includes participants who consented but were determined ineligible, left voluntarily, or were withdrawn by study investigators.

\* **Have there been any withdrawals at this institution during the this approval period?**

**NOTE:** Includes participants who consented but were determined ineligible, left voluntarily, or were withdrawn by study investigators.

- Yes  
 No

- Indicate whether there have been any subject complaints during this approval period:

\* **Complaints**

---

Have there been any participant complaints during this approval period?

Please address for this institution only, UNLESS we are the Reviewing IRB for other sites. In that case, consideration should include all sites (be sure to reference the site name).

- Yes  
 No

- Study amendments and modifications for studies where MSM is the relying IRB must be submitted to the MSM IRB within 10 business days of approval from the external IRB. Remember that even minor changes to study documents must be submitted to the IRB prior to implementation.

\* **Modifications**

---

Have there been any changes to the study during this approval period that you have NOT already submitted as a Modification?

Please address for this institution only, UNLESS we are the Reviewing IRB for other sites. In that case, consideration should include all sites.

- Yes  
 No

- Indicate whether there have been any reportable events during this approval period, even if you submitted an Incident report already. If you have not submitted an Incident report for the mentioned events, you must do this immediately.

**Reportable Events**

---

This includes adverse events or protocol deviations that were required to promptly be submitted as an Incident per IRB Policy.

\* **Have any Reportable Events** occurred during this approval period?

Please address for this institution only, UNLESS we are the Reviewing IRB for other sites. In that case, consideration should include all sites (be sure to reference the site name).

- Yes  
 No

- Unreportable events are protocol deviations or adverse events that are not required to be promptly submitted as an Incident. The PI should be tracking these events to be submitted during every continuing review period. If you have unreportable events, you will be asked to describe them in this section, as well as upload applicable documents such as event trackers.

**Unreportable Events**

---

This includes adverse events or protocol deviations that weren't required to promptly be submitted as an Incident per IRB Policy.

\* **Have any Unreportable Events** occurred during this approval period?

- Yes  
 No

- If your study has any new relevant information, you will indicate and describe that in this section.

\* **New Information**

---

Is there any New Information to report for this study?

Please address for this institution only, UNLESS we are the Reviewing IRB for other sites. In that case, entries should include all sites (be sure to reference the site name).

For example:

- Change in funding
- Publications or scientific findings relevant to the risks and benefits to participants
- Independent Monitor/DSMB/DSMC findings
- Interim analysis

- Yes  
 No

- If your study expired and you are submitting this closure post-expiration date, you will be required to indicate that here.



\* Is this Closure being submitted AFTER the Study Expiration Date has already passed?

This is applicable ONLY to studies that have a Study Expiration Date (e.g., full board studies and some expedited studies), NOT studies that have an Admin Check-in Date.

- Yes
- No

- If you indicated “yes” to the question above, you will be asked why you allowed the study to expire.

Yes

\* Reason for Expiration

Please explain why the study was allowed to expire (e.g., delay of renewal submission, outstanding information request, delayed documentation from IRB of Record, etc.).

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- If your study has been externally audited, please upload all audit reports.

\* Has this protocol been externally audited since it was last reviewed by the IRB?

- No
- Yes

Check all that apply below and upload a copy of the corresponding report.

FDA  
FDA 483 or FDA Audit Report

ATTACH

Sponsor  
Sponsor Report

ATTACH

Other  
Other Audit Report

ATTACH

- If you have a Final Progress Report, you will upload it in the next question.

**Final Progress Report**

Please upload the final progress report, if applicable.

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- Finally, there is a section for any Additional Information or Documentation you wish to include in your closure report.

#### Additional Information

##### Additional Information or Comments

If applicable, you can provide additional information that you think to be beneficial to review of this Closure.

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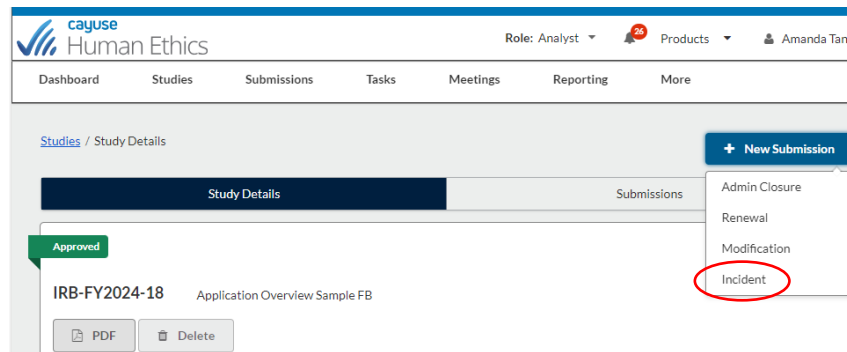
##### Additional Documentation

If you have any additional documentation to provide for this Closure, upload it here.

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## VIII. Incident Reporting

To create an Incident report, you will click the **+New Submission** button, and then click **Incident**.



- You will first be asked to indicate what type of incident you are reporting. Check all that apply.

• Incident Type

An incident/event (or series of related events) may fit into more than one category, so check all that apply. Distinct or events unrelated to another should generally have separate Incident submissions.

- New or Increased Risk
  - For example:
    - Unanticipated Problems
    - Adverse events
    - Serious adverse events (SAE)
  - Certain information may indicate new risks or that subjects may be at higher risk than previously recognized:
    - Investigator's Brochure (IB) updates identifying new or increased risks
    - New FDA Black Box Warning
    - DSMB/C report identifying new risks
    - Publications identifying new risks
    - Unauthorized disclosures of subject information
    - Unanticipated Adverse Device Effect
- Protocol Deviation and/or Noncompliance
  - This is deviation/noncompliance in relation to federal regulations governing human subject research, with the protocol, or requirements/determinations by the IRB. For example:
    - Events that harmed a subject.
    - Events that increased risk of harm.
    - Serious Noncompliance: where events may adversely affect subjects rights or welfare.
    - Continuing Noncompliance: where a pattern of noncompliance is likely to continue without intervention, or failure to work with the IRB to resolve noncompliance
    - Deviations from the research plan made to avoid apparent and immediate hazard to a subject (ex: procedure/lab required by protocol not done or outside of the required window).
- Written Reports
  - Any of the following when conducted by a federal agency, funding agency, the IRB, monitor, state agency, or other oversight agency:
    - Audits
    - Inspections
    - Inquiries
- Suspension or early Termination of the Study
  - This unplanned suspension or termination could be required by the sponsor, investigator, or institution.
- Other
  - For example:
    - Unexpected incarceration of a subject when the study is not approved to include prisoners
    - Data/security breach
    - Significant or unresolved subject complaint
    - Lapse in Study Approval
    - Loss of adequate resources
- None of the above

- For any incident type you select, you will need to indicate IRB Oversight Arrangements. If your study is using an external IRB (MSM relying), you will be prompted to Attach the external IRB determination.

• IRB Oversight Arrangements

Indicate how IRB oversight is organized for this study. This should match what is in the latest approved version of this study (latest approved Modification or Initial approval).

- Study involving more than 1 site where each site will conduct their own IRB review
- Study involving more than 1 site where this site is the Reviewing IRB (IRB of Record) for other sites
- Study involving more than 1 site where this site is Relying on an External IRB
- Multi-site study (multiple US sites participating in a research study using the same protocol) where this site is the Reviewing IRB (IRB of Record) for all sites
- Multi-site study (multiple US sites participating in a research study using the same protocol) where this site is Relying on an External IRB

Reviewing IRB Determination & Documentation

Please upload documentation from the Reviewing IRB regarding their determination for this Incident and any supplemental documentation.




ATTACH

- For any incident type you select, you will then need to describe the event. Make sure to describe all events if you have more than one incident.

## Event Information

### \* Event Description

Please provide a detailed description of the event, incident, experience, or outcome. If applicable, provide the subject number/identifier of affected participants.

B I U   

### \* Location(s) of Event

State the location(s) the event(s) occurred, as applicable.

### \* Date(s) of Occurrence

Indicate when the event occurred. This may be a single date, a range of dates (start and end say for onset of adverse event), a series of dates for a recurring issue, etc.

### \* Date of Discovery

Indicate the date the study team discovered the event(s).

MM-DD-YYYY 

## a. New or Increased Risk

- If you have a *New or Increased Risk*, you will need to describe the Expectedness and Relatedness of the risk, as well as the Risk of Harm.

### New or Increased Risk Information

#### Expectedness

##### \* Expectedness Assessment

Considering the research procedures described in the protocol and consent form AND the characteristics of the subject population being studied, is the event Unexpected in terms of ANY of the following:

- Nature of the event
- Severity of the event (more serious than expected)
- Frequency of the event (more frequent than expected)

- Yes  
 No

##### \* Expectedness Rationale

Explain your rationale for your assessment of expectedness.

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#### Relatedness

##### \* Relatedness Assessment

Is the event EITHER related or possibly related to participation in this research (e.g., whether the incident, experience, or outcome may have been caused by the research procedures)?

- Yes  
 No

##### \* Relatedness Rationale

Explain your rationale for your assessment of relatedness.

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#### Risk of Harm

##### \* Risk of Harm Assessment

Does this event suggest that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized?

NOTE: If the event is Serious, this answer should be Yes.

- Yes  
 No

##### \* Risk of Harm Rationale

Explain your rationale for your assessment of Risk of Harm.

B I U   

- If the above three questions were all answered with “yes,” then this is a Reportable event.

\* Is this a **Reportable** Event?

- Yes - (Expectedness, Relatedness, and Risk of Harm were ALL Yes)  
Indicating Yes to Expectedness, Relatedness, and Risk of Harm means this event is Reportable and subject to prompt reporting requirements.
- No - (At least one was answered No for Expectedness, Relatedness, and/or Risk of Harm)

b. Protocol Deviation/Noncompliance

- If you have a *Protocol Deviation and/or Noncompliance* incident, you will be asked about the Risk of Harm to the subject.

Protocol Deviation and/or Noncompliance

Risk or Harm to Subject

\* Risk or Harm to Subject Assessment

Did the deviation or noncompliance harm the subject(s) OR increase risk to the subject(s)?

- Yes
- No

\* Risk or Harm to Subject Rationale

Explain your rationale for your assessment of risk/harm.

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- If you indicate that, “no,” the deviation did not harm the subject or increase risk to the subject, you will be asked if the change was to eliminate an apparent and immediate hazard to a subject.

Eliminating Hazard to Subject

\* Eliminating Hazard to Subject Assessment

Was this a change in the research plan to eliminate apparent and immediate hazard to a subject?

- Yes
- No

\* Eliminating Hazard to Subject Rationale

Explain your rationale for your assessment of eliminating hazard to subject.

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- If the answer to the question above is “no,” then you will be asked additional questions about the role of the researcher in the protocol deviation/noncompliance.

Role of Researcher

\* Role of Researcher Assessment

Did the deviation or noncompliance occur due to the action or inaction (regardless of intent) of the researchers?

“Researchers” includes:

- When this institution is the IRB of Record for this site or others, anyone Engaged in Research under the IRB oversight of this institution.
- When this institution is relying on a Reviewing IRB, anyone Engaged in Research affiliated with this institution.

- Yes
- No

\* Role of Researcher Rationale

Explain your rationale for your assessment of the role of the researcher(s) in this event.

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- Next, if the deviation/noncompliance was a result of a researcher’s action, you will be asked about whether the deviation affected the rights of the subject.

### Rights of Subject

#### \* Rights of Subject Assessment

Did the deviation or noncompliance adversely affect the rights of the subject(s)?

Yes

No

#### \* Rights of Subject Rationale

Explain your rationale for your assessment of the affect on the rights of the subject(s).

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- If the deviation/noncompliance did not affect the rights of the subject, you will be asked if the deviation was due to a failure to complete corrective actions previously required by the IRB.

### Failed Corrective Action

#### \* Failed Corrective Action Assessment

Was there a failure to complete corrective actions previously required by the IRB?

Yes

No

#### \* Failed Corrective Action Rationale

Explain your rationale for your assessment of if previously existing corrective actions failed.

B I U

- If the deviation/noncompliance was not due to a failure to complete corrective actions previously required by the IRB, you will be asked if this is a recurring incident of deviation/noncompliance.

### Recurrence of Deviation/Noncompliance

#### \* Recurrence of Deviation/Noncompliance Assessment

Were there multiple similar instances of the deviation or noncompliance?

Yes

No

#### \* Recurrence of Deviation/Noncompliance Rationale

Explain your rationale for your assessment of recurrence of this deviation/noncompliance.

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- Finally, if the answer above is “yes,” then you will be asked if this event is likely to continue without a corrective action plan.

### Recurrence Intervention

#### \* Recurrence Intervention Assessment

Is this a pattern that is likely to continue without intervention (e.g., corrective action)?

Yes

No

#### \* Recurrence Intervention Rationale

Explain your rationale for your assessment of if intervention is needed to prevent recurrence of this deviation/noncompliance.

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## c. Written Reports

- No specific additional questions are required for written report incidents. Complete all general required questions for submission.

## d. Suspension or early Termination of the Study

- No specific additional questions are required for suspension or early termination incidents. Complete all general required questions for submission.

## e. Other

- No specific additional questions are required for Other incidents. Complete all general required questions for submission.

## f. Corrective and Preventative Actions

- For all incident report types, you will be asked if the event is being reported in a prompt manner per IRB policy. If the answer is “no,” you will need to explain why it was not reported promptly. Please note that prompt reporting is a requirement and there are consequences to late reporting.

### \* Prompt Reporting of Reportable Information

Is this event being promptly reported per IRB Policy?

- Yes  
 No

- For all incident report types, you will be required to submit corrective and preventative action plans, as described below. For corrective actions, be sure to immediately submit a Modification application to change the protocol to reflect these actions.

#### Corrective Actions

Describe any changes to the protocol or other corrective actions that have been taken or are proposed in response to the event.

NOTE: Changes to the protocol MUST ultimately be submitted via a Modification.

B I U S [bulleted list] [numbered list] [undo]

#### Preventative Actions

Explain what measures have been taken to prevent recurrence of the event.

B I U S [bulleted list] [numbered list] [undo]

- Finally, there is a spot for Additional Information, if applicable. You may upload Additional Documentation that you wish to include here as well.

#### Additional Information

##### Additional Information or Comments

If applicable, you can provide additional information that you think to be beneficial to review of this Incident.

B I U S [bulleted list] [numbered list] [undo]

##### Additional Documentation

If you have any additional documentation to provide for this Incident, upload it here (e.g., revised risk documentation, records on affected subject, Corrective Action Plan, etc.).

ATTACH

## IX. Withdrawals

If you wish to withdraw your initial submission, you will need to submit a Withdrawal Request. Start the Withdrawal application, indicate that “yes” you wish to withdraw the submission, and provide a justification. Then, submit the application for IRB review.

## Withdrawal Request

\* Do you want to withdraw your Initial submission?

This will withdraw not only your Initial submission, but also archive this Study. You will **NOT** be able to reopen this study or Initial submission after this, and would have to start over and create a New Study (if needed).

- Yes  
 No

Justification

Please provide the reason(s) for withdrawal.

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## X. Legacy Submissions- TBD

## APPENDIX

### Appendix A- Grant to Protocol Guidance

#### Differences in the Goals of a Grant vs. a Protocol

#### Grant vs. Protocol Goals

- Grant/Proposal:
  - Written to convince reviewers
    - That your project is worthy
    - That you can complete the project
- Protocol
  - Written to explain who, what, where, when, why of your project
  - Must be clear and understandable
  - Detailed - without boxing you in when research meets real world



A **grant or proposal** is written to convince reviewers that your proposed project is scientifically sound and you have the expertise and resources to conduct the study.

A **protocol** is written to explain the who, what, where, when, why of your project. A protocol must be clear, understandable, and detailed, without being so specific that you have protocol deviations when the conduct of the study meets the real world.

#### Grants and Protocols

- A grant can include multiple protocols
- A protocol can be funded by multiple grants, foundations and/or pharma contracts



There isn't always a one-to-one relationship between the grant and the # of protocols.

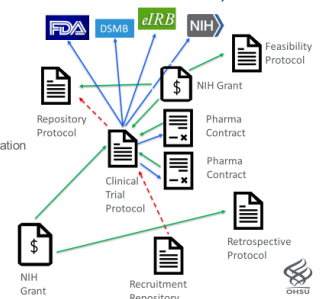
Some grants describe multiple project phases/protocols that will be implemented over time. Some protocols are revised over and over again as new funding is obtained, new sub analysis is planned, or new ideas occur to the PI.

Matching multiple grant/ protocol goals can get complicated if you don't have a strategy for regulatory compliance. Protocols that try to include too many objectives and study populations may no longer be understandable.

There can be frustrating consequences if you don't have a plan for compliance with different funding requirements or future use of the study data.

#### If you want to Combine Grants/Protocols, You Need a Strategy

- Think carefully about:
  - Does it scientifically/operationally make sense
  - How/when you will **share/destroy** information
  - Regulatory/reporting** obligations
  - Funding/contractual** obligation
  - See study guide for more info





## Determine whether to revise an existing protocol or write a new protocol

There will be times when you receive a new grant after you already have an IRB approved protocol. If the research is similar, you need to decide whether to revise the existing IRB approved protocol to add the new grant aims/activities or write a new protocol to submit to the IRB. If the changes make the protocol confusing to the IRB, study team and/or study participants, it is best to write a new protocol. The following are some things to consider when making this decision.

### New Protocol or Revise Existing Protocol



- Consider writing a new protocol when:
  - New patient population
  - Unrelated aims
  - Risk of the new study is greater than the existing protocol
    - e.g. don't add an investigational drug to an observational study
  - Different study design
  - Different regulatory requirements
  - Different contractual requirements
- Consider revising an existing protocol when:
  - Aims of the study and design are the same/similar
  - Population, risks, design are the same
  - Minimal changes are needed
    - Extending the study duration
    - Increasing the number of participants
    - Add a new sub-analysis

Sometimes investigators already have an IRB approved protocol when they receive a new grant. There can be a temptation to revise an existing protocol instead of submitting a new protocol to decrease the study start-up time but this isn't always the best plan. For example, if you have a minimal risk study that has expedited/exempt IRB review, it wouldn't make sense to add study aims and procedures that were greater than minimal risk because the study would then require full board review.

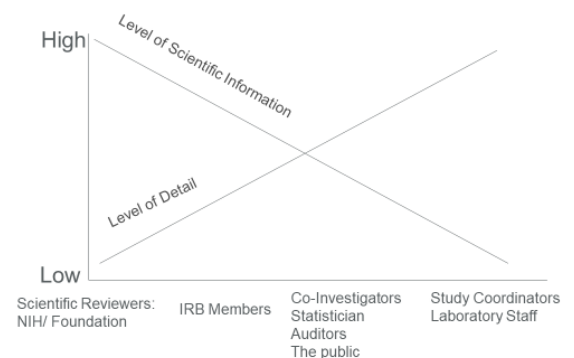
If you have multiple studies that you want to combine in one protocol, you should verify that requirements for data sharing/retention and contractual obligations/limitations align. For example, if a funder requires that they review/approve all protocol modifications before they are implemented, you might not want to add a new aim that includes Intellectual Property (IP) or other information you don't want to or cannot share.

Studies may have multiple documents that describe your research including: the grant, your protocol, operational manuals, instruction sheets, and other helpful documents you may draft to make your study run smoothly. These documents will have different information for different audiences, but they must be consistent with one another.

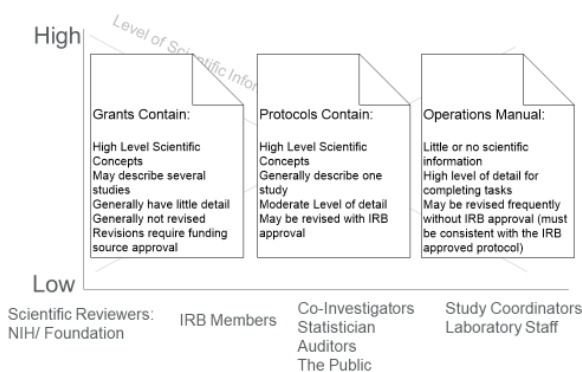
Some documents have a high level of scientific information but a low level of detail on day-to-day study conduct and vice versa.

Not all reviewers/users of the study documents require the same level of information to perform their review/ study activities.

### Study Documents



### Study Documents



The **grant**

includes a high level of scientific information but not much information on the day-to-day study operations.

The **protocol** contains both scientific information and detailed information about the inclusion/exclusion criteria, statistical plan, and what will occur at each study visit.

**Operations manuals** include very detailed information on tasks that need to be completed in a specific way to support the overall protocol. Operations Manuals may be called by other names (MOP- Manual of Procedures, MOO – Manual of Operations, work instructions, etc.) Studies may have several manuals or a large

“handbook” style document. Examples include pharmacy manuals, lab processing/sample storage manuals, shipping instructions, etc. For example, lab staff will need to know how to process, label and store samples in great detail so you can rely on the data generated from the samples but won’t need to know the study inclusion exclusion criteria.

This training focuses primarily on taking the high level of information in the grant and developing the detailed study protocol.

Reviewer	Reason for Review
IRB	Subject protection, compliance with state/federal laws, institutional policies
FDA federal oversight (if applicable)	Protect public health
Study Coordinator/staff (e.g. statistician, nurses, lab, pharmacy, etc.)	Feasibility, operational implementation
Institutional Offices (CRBO, Radiation Safety, Knight CRRC, OCTRI, etc.)	Institutional Offices (CRBO, Radiation Safety, Knight CRRC, OCTRI, etc.) for compliance with state/federal law and institutional policies
The Public	Must upload protocols in clinicaltrials.gov for applicable clinical trials

Remember your audience(s) when you write your protocol. Not all reviewers will be experts in your area of research, have your level of scientific training or the clinical context. Plan to include crucial context and highlight details that are important for reviewers to understand how the study will be operationalized.

### Conducting the Protocol for Compliance


- Once the study has IRB approval the study team is expected to adhere to the protocol without deviations (unless necessary for the safety of the subject)
- Make sure study staff read and understand the protocol
  - Have study staff acknowledge their roles in the study
  - Make sure study staff know how to identify and report deviations
  - Delegate study tasks to qualified individuals (e.g. physical exams delegated to MD, FNP, PA)
  - Supervise the conduct of delegated activities

A well-designed protocol that has been analyzed for feasibility and operational implementation shouldn’t require a lot of study modifications.

Too many modifications to inclusion/exclusion criteria or study procedures may leave you with different study populations for analysis.

You can’t avoid all modifications, so when you do modify your protocol, maintain consistency within and between the protocol, consent, and procedure manuals to avoid protocol deviations.

### Protocol Modifications

- Submit a revised protocol to the IRB to address new information or address implementation/recruitment problems
- Strive to minimize modifications so that data remains “poolable”
  - Don’t want to compare apples and oranges 
- Maintain consistency within and between the protocol, consent, and procedure manuals

Adapted from the OCTRI Research Forum: February 2024  
Mary Samuels, MD & Bridget Adams, MSHS, CCRA

### Appendix B- Lay Summary Guidance

## Lay Summary Guidance

### Lay Summary FAQs:

### *What is a lay summary?*

A lay summary for a protocol is a basic description of the research being proposed that a non-academic should be able to comprehend. Communication of the research to a broader audience is crucial to scholarly work.

### *What is the difference between a lay summary and an abstract?*

Lay summaries are non-technical explanations of the research being proposed for non-academics and/or experts in other fields, whereas abstracts are meant to summarize the project for scholars and experts in the particular field of study that the research is being conducted.

### *Why do I need to create a lay summary?*

A lay summary is required by the IRB because IRB reviewers, analysts, and members are likely not experts in the area of research being proposed. It provides an opportunity for the reviewers to understand the overall premise of the project and allows them to provide more applicable responses instead of focusing on trying to evaluate what the project is proposing. The lay summary can also be helpful in other study-related documents, such as the consent form.

### *How do I know what my lay summary's readability level is?*

In Microsoft Word:

- Click 'Home' → Click 'Editor' towards the right side of the top toolbar → Scroll down to Insights and click 'Document stats' → click "ok" in the pop-up and your readability scores and grade level will pop up in a new alert window.

## **How to Write a Lay Summary:**

### *Format:*

1. The lay summary should be no more than 200 words (about one to two paragraphs).
2. Use plain language and avoid any technical terms. If you must utilize specialized terms, be sure to define the terms in plain language.
3. Use succinct, short sentences. Pretend you are trying to explain this protocol to your family member who works in retail/fashion/hospitality. Have a non-academic read your lay summary—if they have questions, it may help prompt needed revisions.
4. Use positive, not negative, sentences: "participants will have repeat appointments once per week" instead of "the usual practice is not to schedule repeat appointments more frequently than once per week."
5. The summary should provide answers to the simple questions: "who, what, where, when, why, how?" (ex: who is this research benefiting/affecting, what is the purpose, where is it taking place, when is the research being conducted, and how will it be conducted?)

### *Outline:*

1. Start by clearly stating the purpose of your project/proposal.
  - a. What question(s) are you trying to answer and why is it relevant and important?
2. Provide a sentence or two of background information.
  - a. What prompted you to propose the project?
3. Describe the possible impact of the research being proposed (and any *major* risks).
  - a. How might the findings contribute to the field or benefit society?
4. Outline the main procedures being proposed for the research.

- a. For example, “A group of 10 participants will watch a 30-minute video about financial independence post-graduation from a 4-year bachelor’s degree program. Immediately afterwards, they will take part in a 45-minute focus group about their personal knowledge of how to be financially independent.”

### **Breakdown Example:**

#### *Non-Lay Summary*

This project comprises a focused effort to understand the evolution of prostate cancer. It will provide a detailed understanding of the molecular heterogeneity of the disease, link that heterogeneity to clinical outcome, and develop improved clinical tools for patients and clinicians. By making all data and tools available, it will create key resources for community use. ICGC controlled-tier data will be used to probe the relationship of inherited genes to prostate cancer evolution and clinical behavior.

Word count: 76 words

Readability: Grade Level 15, College graduate and above

#### *Revised Lay Summary*

Prostate cancer begins when cells in the prostate gland start to grow out of control. This is caused by changes in the DNA of normal cells. DNA is the chemical in our cells that makes up our genes. Genes control how our cells work. We know that cancer can be caused by DNA mutations or changes. This can then lead to uncontrolled cell growth.

DNA changes can be inherited from a parent or acquired during a person’s lifetime. We want to learn about when and how this happens in different people. By studying gene changes, we can help scientists to better understand how prostate cancer develops. This could help to design treatments that target those changes.

An organization called the International Cancer Genome Consortium (ICGC) has gathered data or information about the nature of various cancers. We want to study this data using powerful computers to learn about the growth and spread of prostate cancer. We want to see how certain genes are linked to prostate cancer and how our bodies react when gene changes occur.

We think that prostate cancer tumors are made up of many different types of cells. We want to know how these cells are linked to cancer treatments and outcomes. If we can see how these cell types respond to different treatments, we can find better ways to detect and treat prostate cancer. We can then add our new data to the ICGC database for use by patients and doctors in our communities.

Word count: 250 words

Readability: Grade 8

### **Additional Examples of Lay Summaries:**

#### *Biomedical Study Examples*

##### Example 1:

Sometimes people injure their knees by something poking into the joint. When the doctors suspect this has happened, they perform a test to see if there is a tear in the knee joint. During this test, a sterile dye solution is injected into the joint, away from the injury. If the knee leaks the dye solution out, the patient will be taken to the operating room to wash the knee out in an attempt to prevent infection. If the dye does not leak out, it is assumed that there are no tears in the joint and the doctor simply observes the patient. In this study there are two groups of

patients, those who have had their knees washed out and those who didn't. Both groups are asked to come back to the clinic six weeks following their injury to see how they are doing. If patients return for their 6 week follow-up visit, they will be offered \$20 which will be mailed to them.

#### Example 2:

Babies born preterm often undergo several painful procedures after birth. Exposure of these infants to repeated pain and stress may lead to poor outcomes. Sedatives provide pain and stress relief to these babies. Sedation is an important part of care for babies in the intensive care unit. Sedatives that are currently used have some side effects that are not good. It is important to find drugs which are effective and have less or no side effects. In this new study, the safety and effectiveness of a new drug will be studied. The study population will be babies who meet the study conditions and who are in need of sedation in the intensive care unit. The drug will be given through a vein for 6-24 hours. During treatment, blood will be drawn for analysis. Patients will be followed up to 7 days after stopping the study drug.

#### Example 3:

Suicide is one of the most common causes of death in the United States. Older adults are at higher risk of suicide than all other age groups. Most people who die by suicide are depressed. However, most people who are depressed do not kill themselves. It is urgent that we learn more about what might make a depressed older person die by suicide. Studies have shown that genetics may be important. However, almost nothing else is known about the role of genetics in suicide. For example, we do not know if genetics are more important for men or women, or for young or old. This lack of information is a problem; we can only prevent suicide if we understand the risk factors.

The current project will study suicide in Swedish twins. Twins born between 1886 and 1958 will be included. Information will come from several sources. These sources include questionnaires and hospital records. The researchers will also know which twins have died and how they died. The researchers will use statistical models to answer the research questions.

#### Example 4:

This education program will be evaluated to determine its effectiveness in helping pregnant women who are smoking during pregnancy stop smoking. The program is based on a 5-step program with education and referral to resources to help women stop smoking in pregnancy. The program will be delivered by midwives who care for the women during pregnancy and provide education about healthy behaviors.

### *Social and Behavioral Study Examples*

#### Example 5:

Games, models and simulations have been suggested as a good alternative to more traditional classroom strategies. However, current research has shown that bringing video games, or game-type video simulations into the classroom can have unintended outcomes. Further, not all games are equal. For example, game play is different for an arcade type game such as Donkey Kong than for strategy-based games such as the World of WarCraft. Additionally, even within specific game-type genres the play can vary such as between third person versus first person game play.

We are studying the effect that specific types of game-play have on learning outcomes. We will be using a teacher-made game "Mortimer: Adventures of an Eco-detective". We will use it with about 22 students in an eighth-grade

middle school classroom. The game teaches middle school students how to take field readings such as the temperature from a local stream. The use of the game matches the lessons for the first eight weeks of the fall semester. Version one of the game uses a "first-person" approach to game play that the students will use for about 4 weeks. A second version of the game uses a third person or birds-eye view of game play. Before introducing the game to the class, the students will take a short test that will create a baseline of their knowledge. At the end of week four and week eight, the students will take a test of their knowledge.

Example 6:

We are interested in how mood affects the way people read other's facial expressions and the way they interact with others. We want to study a sample of 80 young adults. We will ask them to come to our lab at MSM to complete the study. In the study, we will ask the participants to recall an emotional, personally-meaningful event. Then, they will complete an emotion recognition task, in which they will identify some facial expression of emotions and rate the intensity of those emotions. Finally, they will be observed while they interact with an unfamiliar person. Our main question is to see whether or not one's mood would affect the way they see other's emotional expression and the way they behave.

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Updated 042224 ACT

Appendix C- Drawings as Incentive for Participation

## Drawings as Incentives for Research Participation

A drawing style format may only be used as a research recruitment incentive if all **potential** participants can elect to participate in the drawing **without being required** to participate in the research to be eligible to win.

To use a drawing as an incentive in the state of Georgia –

- The recruitment section of the protocol must include a description of how individuals, including those who do not consent to participate in the research, will be notified of the drawing and provided with access to participate. Everyone who elects to participate in the drawing must have an equal chance of winning all prizes, regardless of participation or lack thereof.
- The informed consent must include statements that participation is not required to enter the drawing, that participants will remain eligible to win even if they withdraw from the study before completion, and state how non-participants can enter into the drawing.
- The drawing must be conducted in a way that does not compromise any participant anonymity or confidentiality that is promised within the approved protocol.
- The research may not include activities that are more than minimal risk and may not include participants who are under the age of 18.

MSM IRB will not approve an incentive strategy that meets the definition of a lottery or raffle under Georgia law.

*Under Georgia Code [16-12-22.1 \(b\)\(3\)](#) – a lottery or “raffle” means any scheme or procedure whereby one or more prizes are distributed by chance among persons who have paid or promised consideration for a chance to win such a prize. For research – that consideration would be the participants time and knowledge.*

[Adapted from Georgia Southern University IRB](#)

**Updated 071924 ACT**

[Appendix D- Emergency Preparedness Plan Guidance](#)

## **Emergency Preparedness Plan for Research Studies: Investigator Guidance**

The study team should develop a plan for an emergency or disaster that impacts the research. There are broad categories of emergencies, and different factors need to be considered for each type of emergency. Examples of emergency situations include extreme weather events, natural disasters, man-made disasters, infectious disease outbreaks, cyber threats, and chemical, biological, radiological and nuclear threats. There are some circumstances that may be out of the investigator’s control, such as access to facilities. There are also circumstances where the research will not be able to continue. The circumstances in which the study cannot be continued should be indicted in the plan. See the HRPP Emergency Preparedness plan for more information.

- When conducting your research study during an emergency, IRB approval is still required in advance of any change.
- Where reasonable, the study should maintain a contact list of research participant phone numbers and email addresses. When necessary, participants can be contacted in the event of an emergency. This list should be stored safely and securely to maintain confidentiality.
- The investigator is encouraged to develop a protocol in advance of an emergency that can be implemented quickly.

**Please provide a brief overview of an emergency preparedness plan for your research study. The plan should include each site that is utilized for the research. The following example can be modified to accommodate the research protocol.**

Example: The safety of participants and research personnel is the priority in any emergency situation. The determinations made by the Public Safety Office (MSM and/or research site location) will be followed for secure and safe access to facilities to conduct the research. Use of MSM Internet services and network for conducting the research is dependent on availability and guidance from the MSM IT department. Data integrity has been considered and the study routinely backs up data through use of multiple systems. The storage and handling of medical devices and drugs will be in compliance with FDA protocols. The research team will be trained about these emergency procedures, and they will be notified when the procedures are implemented. An emergency contact list for the study personnel, IRB office and research participants, has been prepared.

**Updated 8/5/22 BJK**