VCU Research and Innovation

HRP-811 | 02/01/2024

FORM: Basic Site Information

Use for new participating site proposals.[1] Participating site investigator must receive a copy of or link to HRP-103p – Investigator Manual pSite with this FORM.

BASIC INFORMATION

Basic Study Information	Study Details
Study IRB Number (if known):	Click or tap here to enter text.
Study Title:	Click or tap here to enter text.
Short Title:	Click or tap here to enter text.
Site Investigator:	Click or tap here to enter text.
Site Primary Contact:	Click or tap here to enter text.

FUNDING SOURCES

Include funding sources only if different than funding for the main study.

Name of Funding Source	Funding Source ID	Grant Office ID
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

FINANCIAL INTEREST DECLARATION

According to your institution's Conflict of Interest Policy, do any personnel (or an immediate family member of personnel) involved in the design, conduct, or reporting of the research have a financial interest Related to the Research?

☐ Yes ☐ No

If yes, provide the institution's evaluation of the financial interest below.

Name	Role	Involved in consent?	Evaluation (You may attach a separate page describing the outcome of the evaluation.)
Click or tap here to enter text.	Click or tap here to enter text.	☐ Yes ☐ No	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	☐ Yes ☐ No	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	☐ Yes ☐ No	Click or tap here to enter text.

[1] This document satisfies AAHRPP elements I-9

PROTOCOL INFORMATION

Provide the following documents when they exist or are applicable:

- Point-by-point response *(For a response to modifications to secure approval, deferral, or disapproval)*
- Evaluation of any Related Financial Interest
- Written materials to be provided to or meant to be seen or heard by subjects
    - Evaluation instruments and surveys that contain site specific language
    - Advertisements *(printed, audio, and video)*
    - Recruitment materials and scripts
    - Consent documents
    - If consent will not be documented in writing, a script of information to be provided orally to subjects
    - Foreign language versions of the above
- Site Supplement to the main protocol (when site activities differ from or are not described in the main protocol)

LOCAL CONTEXT

Will the process for identifying and recruiting subjects differ from that described in the multi-site protocol?	☐ Yes (Explain): Click or tap here to enter text. ☐ No ☐ NA
Will any other study activities at this site differ from those described in the multi-site protocol?	☐ Yes (Explain): Click or tap here to enter text. ☐ No
Do local requirements or state law stipulate requirements for enrolling vulnerable populations in this study differ from those described in the multi-site protocol or other study documents?	☐ Yes (Explain): Click or tap here to enter text. ☐ No ☐ NA
Do local requirements or state law stipulate requirements for how data will be accessed and/or stored at this site differ from those described in the multi-site protocol?	☐ Yes (Explain): Click or tap here to enter text. ☐ No ☐ NA
Are there any additional factors particular to this site (e.g., community attitudes, ethnic diversity, language) that may affect how this study is implemented at this site?	☐ Yes (Explain): Click or tap here to enter text. ☐ No

	☐ NA
Are there any ancillary committee reviews (i.e., biosafety, radiation safety) at this site that should be taken into consideration by the Reviewing IRB?	☐ Yes (Explain): Click or tap here to enter text. ☐ No
Will drug and/or device storage by managed centrally by a pharmacy at this site?	☐ Yes (Explain): Click or tap here to enter text. ☐ No ☐ NA
Are there any standard of care differences at this site from the multi-site protocol?	☐ Yes (Explain): Click or tap here to enter text. ☐ No ☐ NA
Will the consent process at this site be different from the multi-site protocol?	☐ Yes (Explain): Click or tap here to enter text. ☐ No ☐ NA

SITE INVESTIGATOR ACKNOWLEDGEMENT

I will conduct this protocol in accordance with requirements in the HRP-103p - INVESTIGATOR MANUAL pSite.

SITE INVESTIGATOR SIGNATURE

Date of Signature: Click or tap here to enter text.

X _____

VCU Research and Innovation

HRP-812 | 03/01/2024

FORM: Site Continuing Review

Use for both continuing review and as a final report to close a protocol.[1] If modifications are being requested, submit a separate request for a modification.

BASIC INFORMATION

Basic Study Information	Study Details
IRB Number (if known):	Click or tap here to enter text.
Study Title:	Click or tap here to enter text.
Short Title:	Click or tap here to enter text.
Site Investigator:	Click or tap here to enter text.
Site Primary Contact:	Click or tap here to enter text.

SITE ENROLLMENT STATUS

Enrollment Status	Site Enrollment Details
Number of subjects enrolled at this site in total:	Click or tap here to enter text.
Number of subjects enrolled at this site since last approval:	Click or tap here to enter text.

CURRENT SITE STATUS[2]

Check all that are <u>true</u> or not applicable.

☐ NO subjects have experienced unexpected harm.

☐ Anticipated Adverse Events have NOT taken place with greater frequency or severity than expected.

☐ NO subjects have withdrawn from the protocol.

☐ There have been NO unanticipated problems involving risks to subjects or others.

☐ There have been NO complaints about the protocol.

[1] This document satisfies AAHRPP elements I.6.B, I-9, II.2.E-II.2.E.2, II.2.F-II.2.F.3, II.3.A, II.3.C-II.3.C.1, III.1.B

[2] This refers to the status of the protocol under the supervision of the investigator, not the status of the protocol at all centers.

☐ There have been NO publications in the literature relevant to risks or potential benefits.

☐ There have been NO interim findings.

☐ There have been NO multi-center trial reports.

☐ There have been NO data safety monitoring reports.

☐ There have been NO modifications to the protocol that have not been submitted to and approved by the IRB.

☐ There have been NO regulatory actions that could affect safety and risk assessments.

☐ There has been NO other relevant information regarding this protocol, such as information about risks.

☐ In the opinion of the principal investigator, the risks or potential benefits are unchanged.

☐ All problems that require prompt reporting to the IRB have been submitted.

SITE INFORMATION

Provide one copy of the following documents:

- Point-by-point response. *(For a response to modifications to secure approval, deferral, or disapproval)*
- Evaluation of any Related Financial Interest.
- Explanation of any items above which you did not check as being true.
- Brief summary of the progress of the protocol.
- Clean copies of all consent documents. *(Not required if protocol is permanently closed to enrollment)*

INVESTIGATOR ACKNOWLEDGEMENT

I will conduct this protocol in accordance with requirements this IRB's requirements and any relevant local requirements.

INVESTIGATOR SIGNATURE

Date of Signature: Click or tap here to enter text.

X _____

VCU Research and Innovation

HRP-813 | 03/01/2024

FORM: Site Modification

Use to request a modification to previously approved site activities[1]

BASIC INFORMATION

Basic Study Information	Study Details
IRB Number:	Click or tap here to enter text.
Study Title:	Click or tap here to enter text.
Short Title:	Click or tap here to enter text.
Site Investigator:	Click or tap here to enter text.
Site Primary Contact:	Click or tap here to enter text.

SITE ENROLLMENT STATUS

Check all that are true:

☐ No subjects have been enrolled to date.

☐ Subjects are currently enrolled.

☐ The study is permanently closed to enrollment at my site.

☐ All subjects enrolled at my site have completed all study related interventions and interactions, including interventions and interactions related to collection of long-term follow-up data.

☐ No additional identifiable private information about the subjects is being obtained by me.

NOTIFICATION OF SUBJECTS

☐ Current subjects will be notified of these changes.

☐ Former subjects will be notified of these changes.

If either is checked, ensure that the submitted documents describe how current or former subjects will be notified): Click or tap here to enter text.

SITE INFORMATION

Provide the following documents when they exist or are applicable and have been modified:

- Point-by-point response *(For a response to modifications to secure approval, deferral, or disapproval)*
- Evaluation of any Related Financial Interest.

[1] This document satisfies AAHRPP element I9

- Written materials to be provided to or meant to be seen or heard by subjects at your site
  - Evaluation instruments and surveys
  - Advertisements *(printed, audio, and video)*
  - Recruitment materials and scripts
  - Consent documents *(The IRB does not require an informed consent document for HUD use.)*
  - If consent will not be documented in writing, a script of information to be provided orally to subjects
  - Foreign language versions of the above
- Site supplement to the main protocol

INVESTIGATOR ACKNOWLEDGEMENT

I will conduct this protocol in accordance with requirements in HRP-103 - INVESTIGATOR MANUAL.

INVESTIGATOR SIGNATURE

Date of Signature: Click or tap here to enter text.

X _____

VCU Research and Innovation

HRP-814 | 02/01/2024

FORM: Site Reportable New Information

Use to report information items listed at the end of this form[1]

BASIC INFORMATION

Basic Study Information	Study Details
Study IRB Number (if known):	Click or tap here to enter text.
Study Title:	Click or tap here to enter text.
Short Title:	Click or tap here to enter text.
Site Investigator:	Click or tap here to enter text.
Person completing form:	Click or tap here to enter text.

DESCRIPTION OF PROBLEM:

Reportable New Information Description Questions	Reportable New Information Details
Briefly describe the new information: (Attach supporting documents to this form)	Click or tap here to enter text.
Date you became aware of this information:	Click or tap here to enter text.
Number of business days between the date of the event and the date you became aware of this information:	Click or tap here to enter text.
Identify which specific category from page 3 of this form that this new information falls under (i.e., 1, 6):	Click or tap here to enter text.

IN THE OPINION OF THE SITE INVESTIGATOR

Reportable New Information Questions for Site Investigator	Site Investigator Responses
Does this information indicate a new or increased risk or safety issue?	☐ Yes ☐ No

[1] This document satisfies AHRPP elements I-9

Does the protocol need revision? (If "Yes", describe above and submit a modification)	☐ Yes ☐ No
Does the consent document need revisions? (If "Yes", describe above and submit a modification)	☐ Yes ☐ No

SITE INVESTIGATOR ACKNOWLEDGEMENT

I have personally reviewed this information and agree with the above assessment
(Reports completed by research staff must be signed by the investigator).

SITE INVESTIGATOR SIGNATURE

Date of Signature: Click or tap here to enter text.

X _____

SIRB USE ONLY

This information involves: (Check all that apply)

☐ Unanticipated problem involving risks to subjects or others

☐ Suspension or termination of IRB approval

☐ Serious non-compliance

☐ Continuing non-compliance

☐ Non-compliance that is neither serious nor continuing

☐ Allegation of non-compliance with no basis in fact

☐ None of the above

(Must be completed by IRB Chair or a Designated Reviewer within 5 business days of receipt of report)
For unanticipated problems involving risks to subjects or others, indicate whether any actions are warranted to eliminate any apparent immediate hazards to subjects.

SIRB SIGNATURE

Date of Signature: Click or tap here to enter text.

X _____

REPORTABLE NEW INFORMATION CATEGORIES

Report the information items that fall into one or more of the following categories to the IRB within 5 business days using this form.

Information that does not fall under any of the categories does not require reporting to the IRB.

1. Information that indicates a new or increased risk, or a new safety issue. For example:
   a. New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
   b. An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk
   c. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol
   d. Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm
   e. Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm
   f. Any changes significantly affecting the conduct of the research
2. Harm experienced by a subject or other individual, which in the opinion of the investigator are **unexpected** and **probably related** to the research procedures.
   a. A harm is "**unexpected**" when its specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.
   b. A harm is "**probably related**" to the research procedures if in the opinion of the investigator, the research procedures more likely than not caused the harm.
3. Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.
4. Audit, inspection, or inquiry by a federal agency and any resulting reports (e.g., FDA Form 483.)
5. Written reports of study monitors.
6. Failure to follow the protocol due to the action or inaction of the investigator or research staff.
7. Breach of confidentiality.
8. Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
9. Incarceration of a subject in a study not approved by the IRB to involve prisoners.
10. Complaint of a subject that cannot be resolved by the research team.
11. Premature suspension or termination of the protocol by the sponsor, investigator, or institution.

VCU Research and Innovation

HRP-815 | 02/01/2024

FORM: Institutional Profile

The purpose of this form is to record information about the Authorization Agreement established with another institution/organization. If there is more than one Authorization Agreement with another institution/organization, indicate so in the fields below, and describe nuances for those agreement in the spaces provided. [1]

INSTITUTIONAL INFORMATION

Institution: Click or tap here to enter text.

Institutional Official (IO): Click or tap here to enter text.

Point of Contact for questions about an Authorization Agreement or reporting of Non-Compliance or Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO): Click or tap here to enter text.

FWA Number: Click or tap here to enter text.

FWA Expiration Date: Click or tap here to enter text.

FWA Information (attach any relevant documentation, if applicable): Click or tap here to enter text.

IRB Registration information (attach any relevant documentation, if applicable): Click or tap here to enter text.

IORG Number: Click or tap here to enter text.

Does the institution apply its FWA to ALL research, regardless of funding?

☐ Yes

☐ No

☐ NA (no FWA)

Are there institutional components for this FWA?

☐ Yes – list all component sites: Click or tap here to enter text.

☐ No

Is this a participating institution with SMART IRB?

☐ Yes

☐ No

This Institutional Profile is currently active.

[1] This document satisfies AAHRPP elements I-9, II.5.B

☐ Yes

☐ No

QUALITY CONTROL
Describe the IRB quality control mechanisms in place to ensure the integrity of the IRB-review process at this site.

Quality control mechanism:

☐ AAHRPP Accredited

☐ OHRP IRB Self-Assessment

☐ Established QA/QI Program

☐ Other: (specify) Click or tap here to enter text.

Status: Click or tap here to enter text.
Date of most recent review: Click or tap here to enter text.

AGREEMENTS[2] AND COMMUNICATION

☐ **Is this a master reliance agreement (e.g., NCI CIRB, commercial IRB, reciprocal institution agreement)?**

☐ Yes

Is the reviewing IRB also serving as the Privacy Board?

☐ Yes

☐ No

☐ No

☐ **Authorization Agreement** 1 (Attach agreement separately)

Effective Date: Click or tap here to enter text.
Expiration Date: Click or tap here to enter text.
Notes: Click or tap here to enter text.

☐ **Authorization Agreement 2** (Attach agreement separately)

Effective Date: Click or tap here to enter text.
Expiration Date: Click or tap here to enter text.
Notes: Click or tap here to enter text.

STUDY SPECIFIC RELIANCE PLANS[3] and COMMUNICATION PLANS

[2] SMART IRB Agreement need not be uploaded. Use Study Specific Reliance Plan section to upload study specific Letters of Acknowledgement.

[3] Study Specific Reliance Plans may include the SMART IRB Letter of Acknowledgement, SMART IRB IAA Implementation Checklist, or IREx SSRP.

Communication Plan: (If not described in the Authorization Agreement, attach HRP-830 Communication and Responsibilities separately.)

Click or tap here to enter text.

Study Specific Reliance Plan: (Attach Study Specific Reliance Plan separately.)

Consent Form Instructions: Provide site-specific information that must be included in consent forms used at this site.

Click or tap here to enter text.

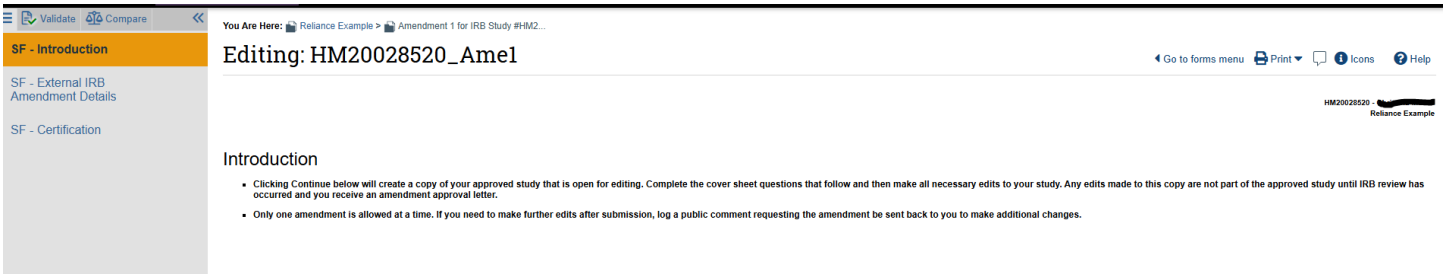
VCU Research and Innovation

HRP-816 | 11/21/2024

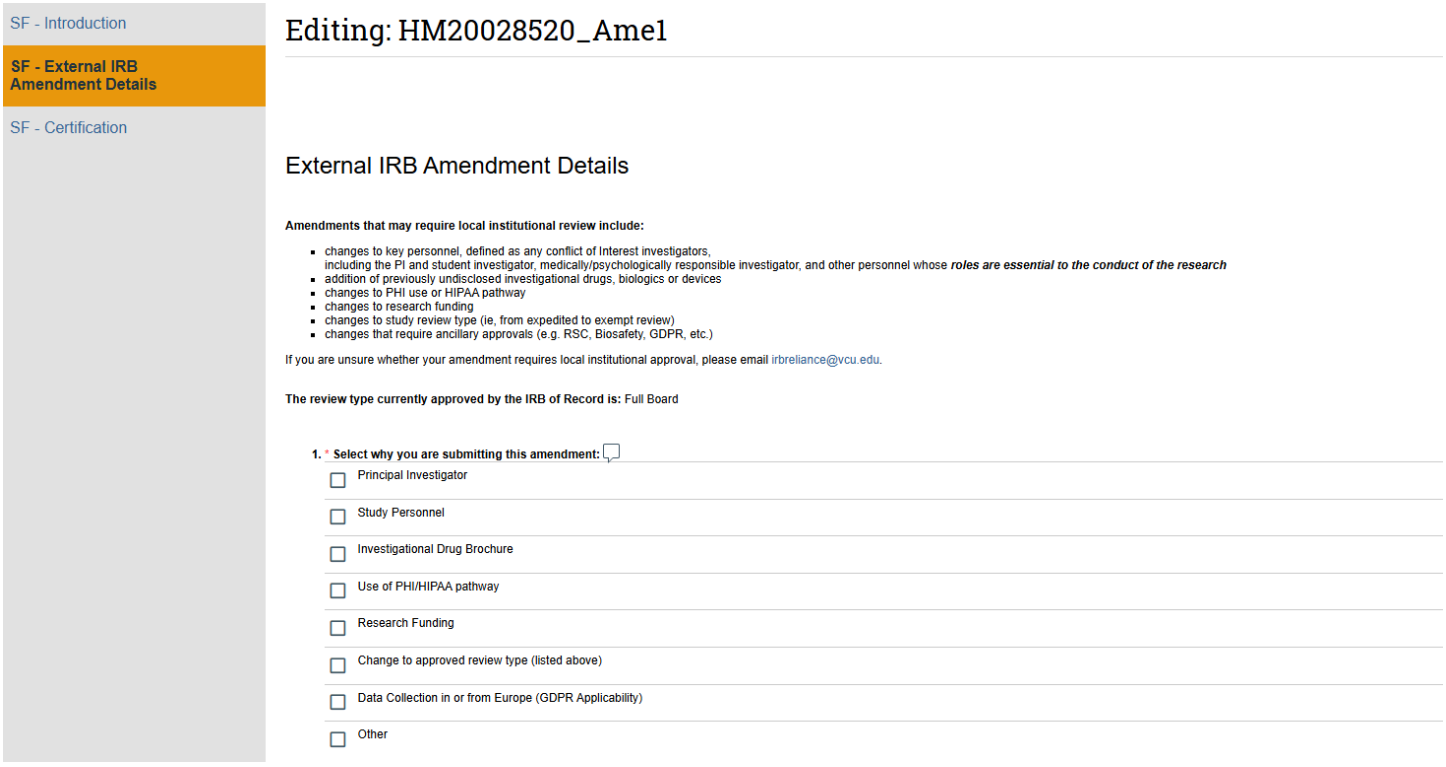
FORM: External IRB Study Update

RAMS amendment smartform is used to notify local IRB of study changes approved by the external IRB of record.[1]

BASIC INFORMATION



STUDY UPDATE INFORMATION



[1] This document satisfies AAHRPP element I-9

Amendment Details

1. * Select why you are creating this amendment (select all that apply):

Reason
PI / Sponsor Initiated

2. * Select all applicable changes being requested.

Study Personnel

3. If Other above, explain.

4. * Explain why these changes are being requested.

5. * Provide information about the study's current status and an assessment of the impact this amendment will have on current participants. In your response, ALL studies should include answers to ALL the following questions:

   1. What is the current enrollment status of the study (e.g. enrollment open, paused since [date], closed since [date])?

   2. How many subjects have been enrolled to date and how many are currently actively participating or undergoing study procedures?

   3. Since your last IRB submission, have there been any Unanticipated Problems involving risk to participants or other at a site (VCU or non-VCU) under the VCU IRB's oversight that have not already been reported to the IRB?

   4. What is the investigator's evaluation about whether, given the nature of the changes being made in this amendment, any or all subjects may need to be provided with new/updated information about the study or re-consented? If you feel that subjects should be provided additional information/notified or re-consented, please describe your proposed plan for accomplishing this.

SITE INVESTIGATOR ACKNOWLEDGEMENT

SF - Introduction

SF - External IRB Amendment Details

SF - Certification

Editing: HM20028520_Ame1

Certification

After you have finished describing the changes here, the appropriate changes should be made to the Study SmartForms.

1. If you are ready to start making edits to your Study and want to go directly to the Modified Study Smart Forms, check the box below. Otherwise click finish and you will go to the Amendment Workspace:

☐