

How to Request Not Human Subjects Research Determination

New RAMS-IRB Function!

Background

- The Common Rule requires IRB review of activities that are research involving human subjects.
- The Common Rule defines both terms, “research” and “human subject.”
- An activity only needs IRB review if it meets both regulatory definitions.

Research

45 CFR 46.102(l)

(l) Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

For purposes of this part, the following activities are deemed not to be research:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Bolded text is the definition from the pre-2018 Common Rule, underlined text was added in the 2018 Common Rule.

Human Subject

45 CFR 46.102(e)

(e)(1) **Human subject means a living individual about whom an investigator (whether professional or student) conducting research:**

- (i) **Obtains information or biospecimens through intervention or interaction with the individual, and, uses, studies, or analyzes the information or biospecimens; or**
- (ii) **Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.**

(2) **Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.**

(3) **Interaction includes communication or interpersonal contact between investigator and subject.**

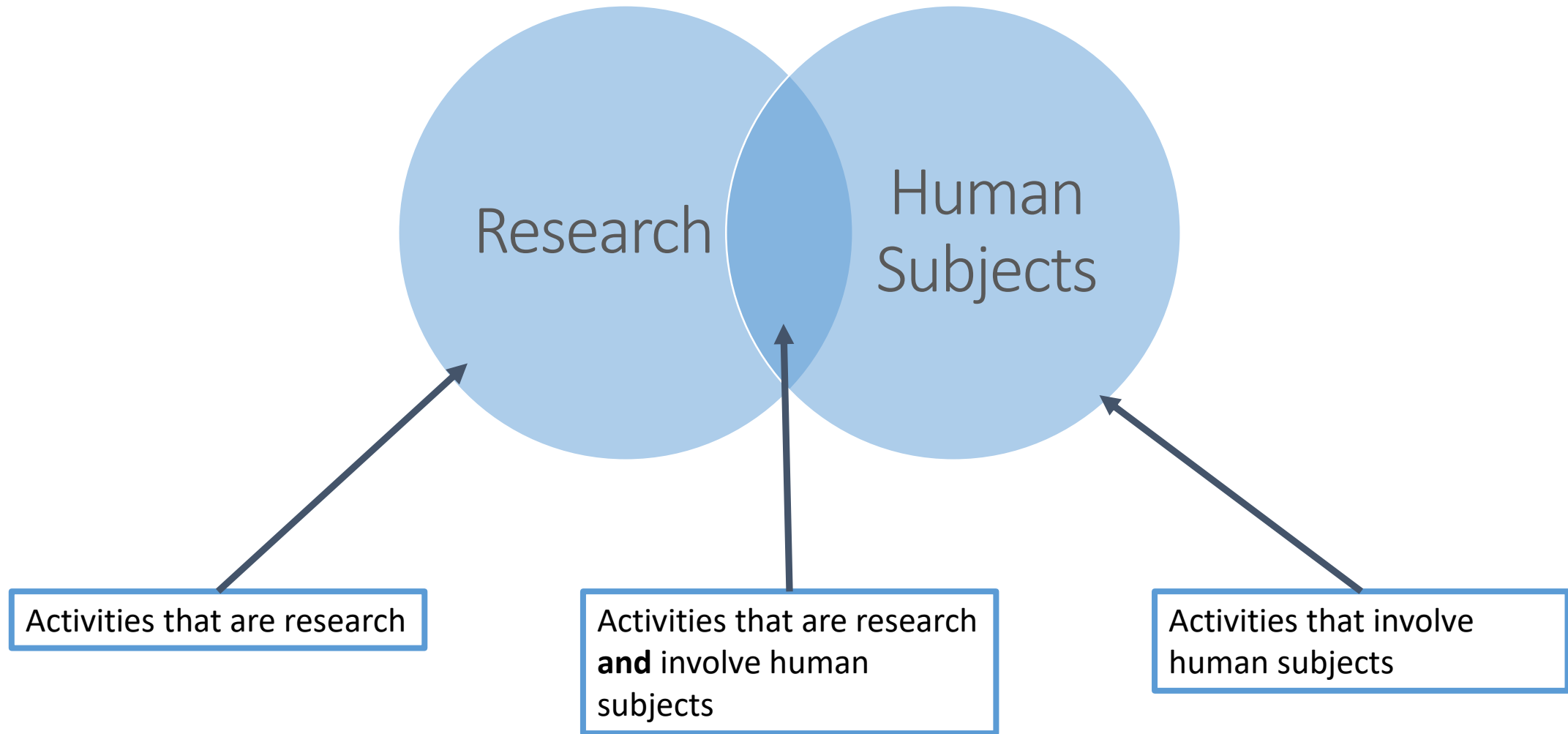
(4) **Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).**

(5) **Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.**

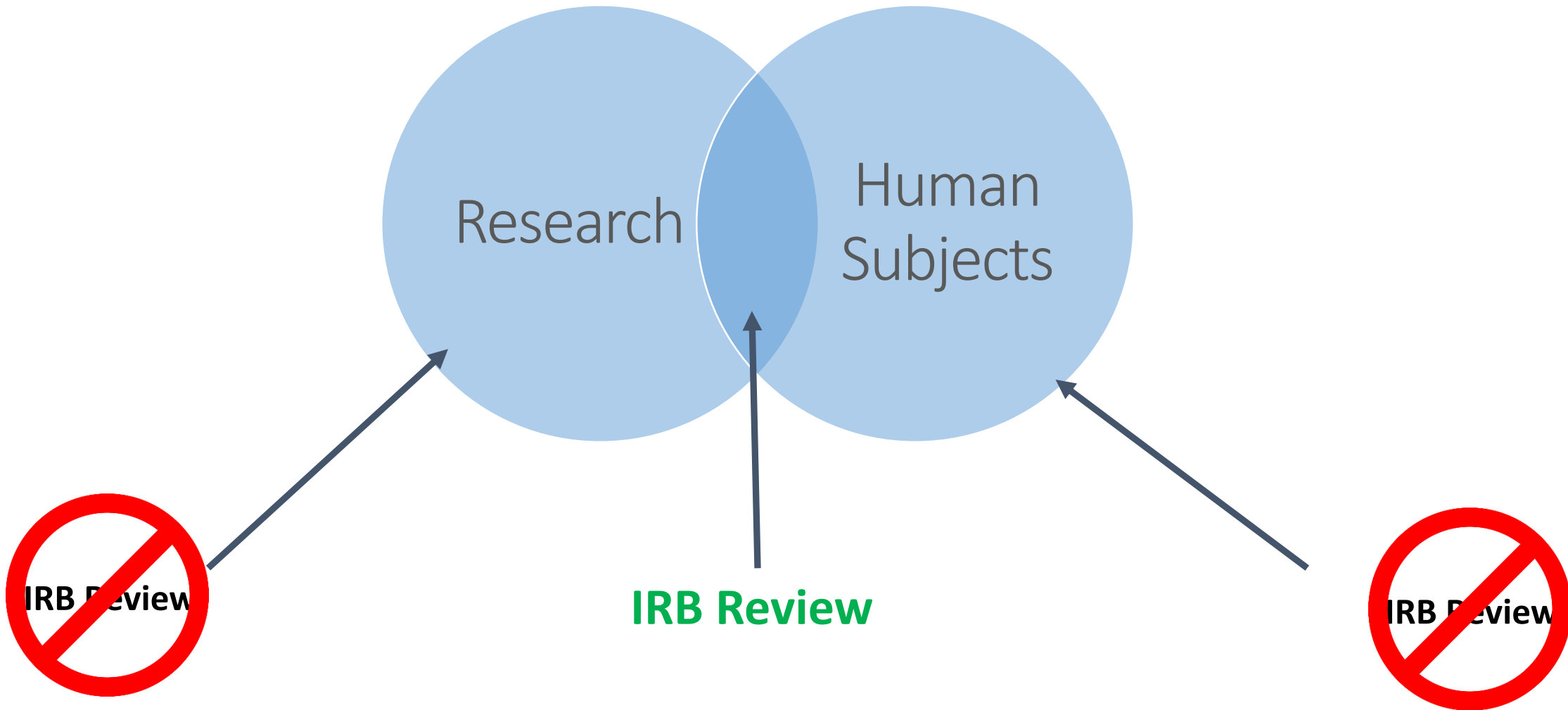
(6) **An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.**

Bolded text is the definition from the pre-2018 Common Rule, underlined text was added in the 2018 Common Rule.

According to the Federal definitions



According to the Federal definitions

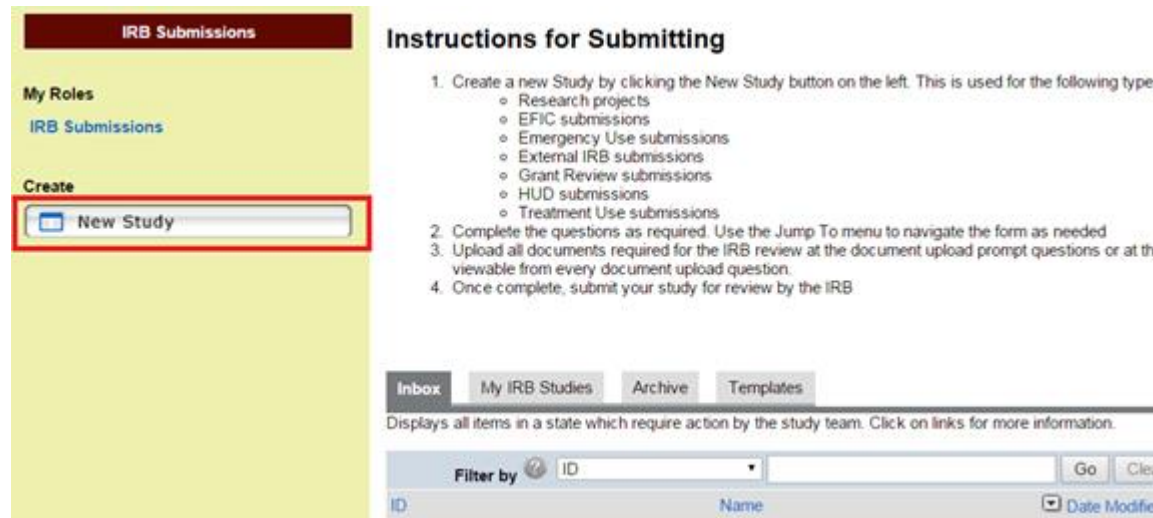


Why ask the IRB to make NHRSR determinations?

- Researchers can make this determination themselves using tools on the [VCU ORSP website](#), or the [DHHS OHRP website](#), so why ask the IRB?
- Sometimes when VCU faculty submit a NHRSR activity for publication, the publisher will request documentation from the IRB that the activity had appropriate IRB review.
 - We know that NHRSR activities don't require IRB review, but publishers want to be assured that there was an appropriate determination – preferably by someone other than the researcher.
- The IRB can't issue a retroactive determination; therefore it's best to ask the IRB before you begin your activity.

Requesting NHSR Determination

1. Sign in to RAMS IRB (irb.research.vcu.edu)
2. Create a “New Study.”



3. Fill out questions 1-6 of the “Study Identification” section.
 - Question 7 – select the last option “Request for Not Human Subject Research Determination” (see screen capture on next slide)

Study Identification

1. * Select the Principal Investigator: ?

John Horigan

2. * Study Title: ?

3. * Is this a student or trainee project in which activities will be carried out by that individual under your supervision (for example, dissertation or degree-required projects): ?

- Yes
- No

[Clear](#)

4. * Please select the primary department or center that this study is being conducted under:

Education

5. If this is associated with other VCU IRB protocols or a resubmission of a withdrawn/closed protocol, select the VCU IRB numbers assigned to those studies:

ID	Title	PI
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There are no items to display

6. Select all individuals who are permitted to edit the IRB protocol and should be copied on communications (study staff will be entered later). These individuals will be referred to as protocol editors: ?

Last Name	First Name	E-Mail	Phone	Mobile
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There are no items to display

7. * Select one of the following that applies to the project (selection will branch to new pages):

Note: VCU IRB offers guidance for many types of studies, including secondary data analysis studies, internet research, registries, EFIC, HUD, and Emergency Use protocols. See https://research.vcu.edu/human_research/guidance.htm

- Research Project or Clinical Investigation
- Exception from Informed Consent (EFIC) for Planned Emergency Research
- Humanitarian Use of Device for Treatment or Diagnosis
- Humanitarian Use of Device for Clinical Investigation
- Emergency Use of Investigational Drug, Biologic or Device
- Treatment Use (Expanded Access to Investigational Product for Treatment Use)
- Center or Institute Administrative Grant Review
- Request for Not Human Subject Research Determination (i.e. whether VCU IRB review is required for a project)

[Clear](#)

Requesting NHSR Determination

4. Click “Continue”
5. Respond to all 6 questions on the next page.
 - Description of the project/activity
 - Explain the intent of the project and how results will be used
 - Address whether the project meets the regulatory definition of research
 - Address whether the project meets the regulatory definition of human subject
 - Provide details on funding source and engagement of VCU, and
 - Lastly, indicate if the project will submit data to the NIH genomic data repository (this requires IRB certification)

These two questions help the IRB get at the same issue – just asking it two different ways

Non-Human Subject Research Justification

For additional definitions and explanations of what activities are considered research involving human subjects that require IRB review, refer to IRB Policy WPP II-2 (https://research.vcu.edu/human_research/irb_wpp/II-2.htm)

1. * Provide a full description of the project:

2. * Explain the intent of this project and how the project's results will be used:

3. * Explain how you think this project meets or does not meet the following regulatory definition of research:

Research: a systematic investigation designed to develop or contribute to generalizable knowledge.

4. * Explain how you think this project meets or does not meet the following regulatory definition of involving human subjects:

Human subject: a living individual about whom an investigator conducting research:

i. Obtains information or biospecimens through an intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens

OR

ii. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

5. * Select all that apply:

- The research is sponsored by VCU
- The research is conducted, in whole or in part, by members of the university faculty, staff or students acting in their university capacity regardless of the location of the research
- The university receives a direct federal award to conduct human subjects research, even when all activities involving human subjects are carried out by a subcontractor or collaborator
- None of the above

6. * Will this project submit data to an NIH genomic data repository that requires Institutional Certification?

- Yes No [Clear](#)

Requesting NHSR Determination

6. Click “Continue”
7. Upload any supporting documents
 - The **system requires an upload** for you to move forward;
 - Consider uploading a copy of any plans you’ve written out for the activity that would help the IRB understand what you plan to do.
 - If you have nothing to upload, include a copy of current CV for PI (see screen capture on next slide)

Documents

1. * Upload any documents that the VCU IRB will need to conduct a review of this submission:

A list of potential documents is given in the help text.

NOTE: The delete function should only be used if an incorrect document is uploaded or added to the system AND that document has not been reviewed and approved by the IRB. Do NOT delete documents that the IRB previously reviewed and approved.

Once you have uploaded a document to RAMS-IRB, any changes to that document (i.e. different versions of the same document) should be added to the IRB submission by using the Update button. To provide updated documents, follow these steps:

- Click the Update button located to the left of the document to be updated.
- In the Add Document window, click the Choose File or Browse button, select the file you are adding, and click on the Open button.
- Click OK to close the Add Document window, and the system will upload the revised document. RAMS-IRB will automatically provide a version number for the document.

To access previous versions of a document in RAMS-IRB you must use the History link associated with the document.

- Click the View or Update button located to the left of the document you wish to access.
- In the Add/View Document window, click the "History" hyperlink located to the right of the file name.
- A separate window will open that shows all versions of the document that have been added to RAMS-IRB. Click on any file name to download and view the document.



	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
<input type="button" value="Add"/>							
<input type="button" value="Update"/>	XXXXXXX	18-006.1 Submitting to An External IRB DRAFT 9-5-18_SW_JH.docx	0.01	2/6/2019 4:09 PM	John Horigan	Research Protocol	<input type="button" value="Delete"/>

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: - Documents ▾

Continue >>

Requesting NHSR Determination

8. Click “Continue”
9. Click “Finish”
10. Click “Submit Study”

Documents Complete

Protocol Progress:

- INITIAL SETUP
- BACKGROUND, RATIONALE & GOALS
- RESEARCH PLAN
- CONSENT PLAN
- RISKS, PRIVACY & CONFIDENTIALITY
- POPULATIONS WITH SPECIAL CONSIDERATIONS
- INSTITUTIONAL REQUIREMENTS
- DOCUMENTS

End of Application

Click Continue below to exit and submit this project

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Save | Exit | Hide/Show Errors | Print... | Jump To: - Document Complete ▾

Finish

Current State

In Development

My Study Forms

- Edit Study
- Printer Version
- View Differences

My Activities

- Submit Study**
- Withdraw
- Copy Study
- Edit Email List
- Log Public Comment

Study: Test Study for Guide (HM20005364)

Principal Investigator: Meghan Wright

Editors:

IRB of Record: VCU IRB

Reviewer(s):

← Your IRB Study has NOT been submitted. to the left of this workspace to st

NOTE: Access to the Submit button is limited to

History | Comments | Documents | Reviewer Notes | Change Log | IRB Inf

Activity	Author
Created Study	Wright, Meg

Next Steps

- Once submitted, the information will be forwarded to an IRB Analyst in ORSP to review.
 - If the analyst agrees the activity is NHR, they will issue an official letter from the IRB confirming that determination.
 - If the analyst requires additional information to assess, they will reach out to the PI
 - public comment in RAMS-IRB,
 - by phone, or
 - by returning the submission to you with reviewer notes.
 - If the analyst disagrees, the submission will be returned to the PI for revision so that the IRB may proceed with review under exempt, expedited, or convened IRB review procedures.
- The IRB is aiming to review the NHR submission and communicate initial questions back to the PI within 1-2 weeks.

∞ The end ∞