



VCU

VIRGINIA COMMONWEALTH UNIVERSITY

IRB Member Handbook

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VCU IRB Member Information

Welcome to the VCU IRB!

As a member, you have the responsibility and opportunity to enforce ethical research and minimize harm to human subjects involved in research.

Membership Responsibilities

- Conduct ethical and regulatory reviews of research applications
- Regular members:
 - Attend panel meetings regularly (at least 9 out of 12)
 - Participate in appropriate discussions and voting during IRB meetings
 - Serve as primary or secondary reviewer when requested and prepare written comments
 - Timely response to researcher or IRB staff questions/comments
 - Conduct a review of all meeting materials and be prepared to participate in discussion
 - Provide prior notice when unavailable to attend a panel meeting or conduct expedited reviews
- Alternate members:
 - Attend convened meetings in place of regular member when called upon
 - Attend 2 convened meetings annually
- Provide prior notice of intention to resign from the IRB
- Maintain own research in good ethical standing

*See “Meeting Procedures” page for specific reviewer responsibilities

VCU IRB Contacts

Other ORSP Contacts	Email	Phone
Michelle Stickler Executive Director	mcstickler@vcu.edu	828-0131
Christine Davison Associate Director	cmdaviso@vcu.edu	827-6090
Susan Kimbrough Assistant Director	sdkimbrough@vcu.edu	827-1533
Elicia Preslan IRB Operations QA/QI Improvement Manager	preslaned@vcu.edu	827-0899
Meghan Wright IRB Educator	wrightmk2@vcu.edu	828-4996



VCU

VIRGINIA COMMONWEALTH UNIVERSITY

Reviewing a Submission

Review Process

Initial Review – Expedited

- 1) Assigned study will appear in the reviewer's RAMS-IRB Inbox
- 2) Review the study in detail using the Reviewer's Checklist (included)
- 3) Use the RAMS-IRB Reviewer Guide to navigate the smart form & log reviewer comments for clarifications or to request edits
 - 1) Communicate and follow up with PI and/or IRB staff
- 4) Finalize review
- 5) IRB Staff will send a letter to the PI

Initial Review – Full Board

- 1) Assigned study will appear in the reviewer's RAMS-IRB Inbox - *Both reviewers are responsible for reviewing and understanding the **entire** study.*
 - 1) Primary Reviewer: Assigned based on scientific expertise
 - 2) Secondary Reviewer: Focus on Human subject protection aspect & Consent Form
- 2) Review the study in detail using the Reviewer's Guidance
- 3) Use the RAMS-IRB Reviewer Guide to navigate the smart form & log reviewer comments for clarifications or to request edits
 - 1) Communicate and follow up with PI and/or IRB staff
- 4) Prepare your notes, summary, concerns for the meeting.
- 5) IRB Staff will then finalize the review and send the letter to the PI

Continuing Review

- 1) Assigned study will appear in the reviewer's RAMS-IRB Inbox
- 2) Review the continuing review in detail using the Reviewer's Checklist (included)
 - 1) Make sure the information in the smart form is still approvable and correct
- 3) Use the RAMS-IRB Reviewer Guide to navigate the smart form & log reviewer comments for clarifications or to request edits
 - 1) Communicate and follow up with PI and/or IRB staff
- 4) *Full Board:* IRB Staff will then finalize the review and send the letter to the PI
- 5) *Expedited:* Reviewer will finalize the review and then IRB staff will send a letter to the PI

Amendment

- 1) Assigned study will appear in the reviewer's RAMS-IRB Inbox
- 2) Review the amendment in detail using the Reviewer's Checklist (included)
 - 1) Make sure to review the study as a whole and make sure the amendment is approvable within the context of the study
- 3) Use the RAMS-IRB Reviewer Guide to navigate the smart form & log reviewer comments for clarifications or to request edits
 - 1) Communicate and follow up with PI and/or IRB staff
- 4) *Full Board:* IRB Staff will then finalize the review and send the letter to the PI
- 5) *Expedited:* Reviewer will finalize the review and then IRB staff will send a letter to the PI

Reviewing a Submission

Initial Submission – Full Board Primary & Secondary Reviewer, or Expedited Reviewer

1. Read the consent document, but do not take notes or make revisions
 1. This should give you a good basic introduction to the protocol
2. Read the protocol summary
3. Read the full protocol and supporting material carefully, take notes as needed.
4. Re-read the consent document & make suggested changes or corrections.
5. Re-read other submitted documents & make suggested changes or corrections.

Use the template on the next page to guide your review.

*Note: Both primary and secondary reviewers are responsible for reviewing the **entire** submission, including all documents.*

Continuing Review

1. Determine if the study is currently enrolling, treating, or following patients
2. Determine that the number of subjects enrolled does not exceed the initially approved number, if they have accrued any subjects since the last continuing review, or if any subjects have withdrawn.
3. Review any requested protocol revisions or revisions approved by the RIB since the last review
4. Determine if the study is progressing as planned.
5. Determine if unexpected events have occurred that may indicate a need for a change in the protocol or consent document.
6. Determine if the information has become available since starting the study that indicates a need for modifications.
7. Determine if the subjects have registered any complaints about this study
8. Determine whether the consent document that is currently in use contains all previously approved revisions.
9. Review a current report from the data monitoring mechanism to determine that the study events are being evaluated relative to the appropriate stopping or modification rules.
10. Are there any new findings that may affect the subjects' willingness to participate.

Amendment

1. Identify the general category of information being revised
 1. Administrative details, inclusion/exclusion criteria, testing frequency/ methods, treatment parameters, stopping or modifying rules, consent document, recruitment procedures
2. Determine if the revision increases risk for currently enrolled subjects
3. Determine if the revision increases risk for future subjects.
4. Determine if the consent document should be revised or if the proposed revision to the consent document is adequate
5. Determine if subjects should be re-consented
6. If the proposed revision increases risk, then determine if the protocol still meets the criteria used to evaluate new studies.

Guiding Your Review

Study Name:

Risk Level:

Meet Criteria for Approval: YES NO

Introduction, Background, Aims

- A. Are the aims specified clearly and is there appropriate justification for this protocol?
- B. Are there adequate preliminary data to justify the research?
- C. Are the training and qualifications of the PI and research staff outlined and adequate?

Scientific Design

- A. Is the scientific design adequate to answer the question?
- B. Are the objectives likely to be achievable within a given period of time?
- C. Is the scientific design (randomization, placebo controls, phase I,II,III) described and justified?

Inclusion/Exclusion Criteria

- A. Are the inclusion and exclusion criteria clearly specified and appropriate?
- B. If pregnant women, children, prisoners, or other vulnerable populations are included or excluded, is this justified? Are additional safeguards (subparts B,C,D) met?
- C. Is the choice of subjects appropriate for the question being asked?
- D. Is the subject selection equitable?

Recruitment of Subjects

- A. Are the methods for recruiting potential subjects well defined?
- B. Are the location and timing of the recruitment process acceptable?
- C. Is the individual performing the recruitment appropriate for the process?
- D. Are all the recruitment materials submitted and appropriate?
- E. Are there acceptable methods for screening subjects before recruitment?

Research Procedures

- A. Are the rationale and details of the procedures accurately described and acceptable?
- B. Is there a clear differentiation between research procedures and standard care?
- C. Are the individuals performing the procedures qualified and educated?
- D. Is the location of where the procedure will be performed acceptable?
- E. Are there adequate plans to inform subjects about specific research results if necessary?

Guiding Your Review

Drugs, Biologics, Devices

- A. Is the status of the drug described and appropriate (investigational, new use of an FDA-approved drug)?
- B. Are the drug dosage and route of administration appropriate?
- C. Are the drug or device safety and efficacy data sufficient to warrant the proposed phase of testing?
- D. Is the significant risk or non significant risk status of the device described and appropriate?

Data Analysis and Statistical Analysis

- A. Is the rationale for the proposed number of subjects reasonable?
- B. Are the plans for data and analysis defined and justified, including stopping rules and end points?
- C. Are there adequate provisions for monitoring data (ex DSMB)?

Potential Risks, Discomforts and Benefits for Subject

- A. Are risks to subjects minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk?
- A. If there is no direct benefit to participants, are the benefits to future subjects of knowledge to be gained mentioned?
- B. Is the amount or type of compensation reasonable?
- C. Are there adequate provisions to avoid out of pocket expenses by the research subject, or is there justification to allow subjects to pay?
- D. If children or adolescents are involved, who received the compensation – is it appropriate?

Privacy & Confidentiality

- A. Are there adequate provisions to protect the privacy and ensure the confidentiality of the research subjects?
- B. Are there adequate plans to store and code the data?
- C. Is the use of identifier or links to identifiers necessary, and how is this information protected?

Guiding Your Review

Informed Consent/Assent

- A. Are all the elements of informed consent contained in the consent document?
- B. Is the consent document in lay language, and will it be presented so the potential subject is free from undue influence?
- C. Is the process of obtaining consent adequately described? Will subjects have sufficient time to ask questions and make a decision?
- D. Are opportunities for ongoing consent identified?
- E. Is assent or parental permission required?
- F. Is waiver or modification of consent possible?
- G. Are appropriate signature lines included? (PI, LAR, multiple parents, etc.)

Other

- A. Are adequate references provided?
- B. When should the next review occur?
- C. Have all Conflicts of Interest (COI) been identified and addressed?
- D. If Non-VCU sites are involved, is VCU oversight needed (direct federal award to VCU)?
- E. Are surveys, questionnaires appropriate?
- F. For studies involving PHI, have all appropriate HIPAA Pathways for access/use been identified?
- G. If the research involves a data registry or specimen bank, have the additional requirements been met?
- H. If applicable, have additional regulatory requirements been met for DoD, DoJ, DoEd, FDA?
- I. For sponsor studies, is the sponsor identified?
- J. Are all other required documents uploaded? (Ex. CV)
- K. Is the submission correctly categorized as Exempt, Expedited, or Full Board?
 - A. Are the appropriate categories checked for Expedited or Exempt studies?

IRB FOR **APPROVAL**

CRITERIA



45 CFR 46.111 AND 21 CFR 56.111

1(i) - Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.

1(ii) - Risks to subjects are minimized whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2 - Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

3 - Selection of subjects is equitable.

4 - Informed consent will be sought from each prospective subject or the subject's legally authorized representative.

5 - Informed consent will be appropriately documented, in accordance with, and to the extent required by the regulations.

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

7 - There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Additional protections for vulnerable populations - When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

45 CFR 46.111, 21 CFR 56.111: Criteria for IRB Approval - Expanded Guidance

Criterion	Points for Consideration
1(i) - Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.	<ul style="list-style-type: none"> • Risks can include physical, social, legal, and economic risks, etc. • Are the risks fully identified in the research plan? • What are the probability and magnitude of harm from the risks? • Does the research involve greater than minimal risk to subjects? • Can the specific aims be achieved by the proposed research design? • Can the research questions be answered with less risky or fewer procedures or fewer subjects? • What procedures or resources are available to mitigate risk? <ul style="list-style-type: none"> ○ Investigators qualified? ○ Adequate research staffing to conduct study? ○ Adequate training of staff and ongoing contact with PI? ○ Adequate facilities and resources to conduct the research? ○ Do the inclusion and exclusion criteria minimize risk? ○ Is there a data safety monitoring board or plan if > minimal risk or NIH sponsored or clinical trial? ○ Are resources available for participants should they experience an adverse effect? ○ What systems are in place to protect data confidentiality?
1(ii) - Risks to subjects are minimized whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.	<ul style="list-style-type: none"> • Does the study appropriately propose to obtain data from procedures that are already being performed on the subjects for diagnostic or treatment purposes?
2 - Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.	<ul style="list-style-type: none"> • The IRB should only evaluate risk in terms of procedures being done for research and not include risks related to procedures that are being done for non-research purposes • Is there potential for direct benefit to subjects? • What knowledge is expected to result and what is the importance of that knowledge? • Are risks to subjects reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result?
3 – Selection of subjects is equitable.	<ul style="list-style-type: none"> • Who is the target population? • Is this group appropriate for the study and to answer the research question(s)? <ul style="list-style-type: none"> ○ Convenience vs. most appropriate • Are populations being unnecessarily excluded? • Are persons vulnerable to coercion or undue influence? <ul style="list-style-type: none"> ○ Consider recruitment and payment methods • If any vulnerable populations are targeted, are proposed protections adequate?
6 – When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.	<ul style="list-style-type: none"> • If the research involves minimal risk, no DSMP/DSMB is required, but may be beneficial. Greater than minimal risk research requires a DSMP/DSMB per VCU WPP. NIH funded research and clinical trials also require a DSMP/DSMB. • If a DSMP/DSMB is needed: <ul style="list-style-type: none"> ○ What data need to be monitored? ○ Who needs to monitor the data? ○ How often does data need to be monitored? ○ What actions might be taken if monitoring identifies an issue? ○ What will trigger those actions?

45 CFR 46.111, 21 CFR 56.111: Criteria for IRB Approval - Expanded Guidance

<p>7(i) – When appropriate, there are adequate provisions to protect the privacy of subjects.</p>	<ul style="list-style-type: none"> • Privacy relates to the person (not the data about the person) • Is there an expectation of privacy? • What is being done to protect subject privacy? <ul style="list-style-type: none"> ○ In recruitment and consenting processes ○ During study conduct ○ In follow-up contact • Are these provisions adequate to protect the privacy of subjects?
<p>7(ii) – When appropriate, there are adequate provisions to maintain the confidentiality of data.</p>	<ul style="list-style-type: none"> • Confidentiality refers to data about a person • Is there risk of harm should there be a breach of confidentiality? • What protections are in place to adequately safeguard data during collection and storage? <ul style="list-style-type: none"> ○ Coded data ○ Restricted access ○ Encrypted data / equipment • Is a Certificate of Confidentiality needed?
<p>Additional protections for vulnerable populations – When some or all of the subjects, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence additional safeguards have been included in the study to protect the rights and welfare of these subjects.</p>	<ul style="list-style-type: none"> • Are special or different consent procedures needed to reduce the possibility of undue coercion? • Is research subject payment appropriate? • Is consent from a legally authorized representative (LAR) needed in situations where subjects are unable to provide independent informed consent?
Informed Consent Criteria	
<p>4 – Informed consent will be sought from each prospective subject or the subject's legally authorized representative.</p>	<ul style="list-style-type: none"> • Will consent or any elements of consent be waived or altered? If yes, are the criteria met? • Will consent be: <ul style="list-style-type: none"> ○ Legally effective ○ Provide sufficient opportunity for consideration ○ Minimize the possibility of coercion or undue influence ○ In understandable language ○ Exclude exculpatory language ○ Include required and additional elements • Is the process for conducting consent discussions adequate? • Will there be adequate opportunity to read the document before it is signed? • Will there be an opportunity for subjects to ask questions? • Does the consent process minimize the possibility of coercion?
<p>5 – Informed consent will be appropriately documented, in accordance with, and to the extent required by the regulations.</p>	<ul style="list-style-type: none"> • Has waiver of documentation been requested? If yes, are the waiver criteria met? • Will the subject or LAR sign and date the document? • Will a copy be given to the person signing the document? • Will informed consent be appropriately documented (include all required signature lines)?



VCU

Office of Research and Innovation

RAMS-IRB for Expedited Reviewers

Virginia Commonwealth University
Office of Research and Innovation
BioTech 1 Building, Suite 3000
800 East Leigh St.
PO Box 980568
Richmond, VA 23298
(804) 828-0868

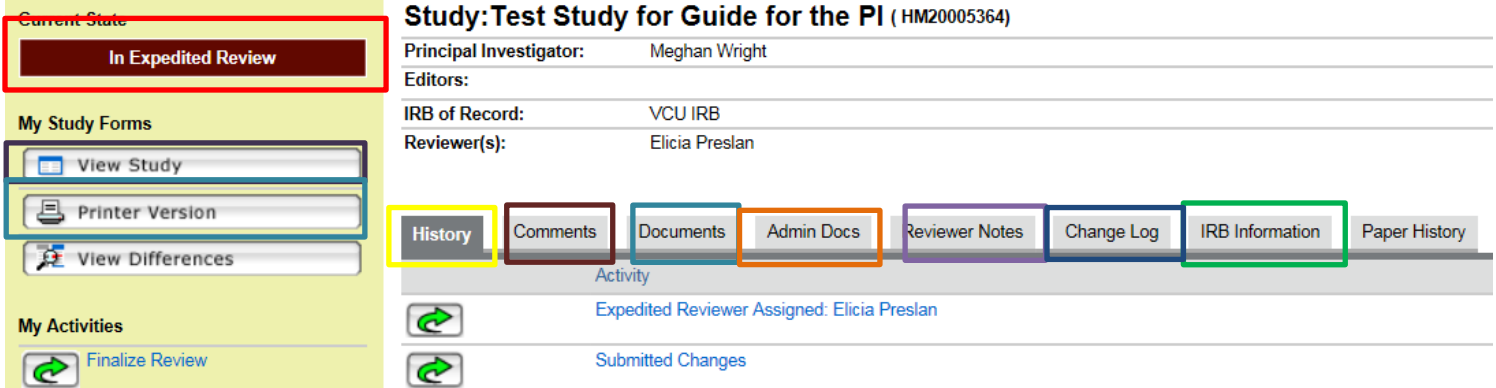
HOME SCREEN

- Connect through RAMS [VPN](#) if off campus
- Log into RAMS-IRB by using your VCU eID and Password at <https://irb.research.vcu.edu>
- Make sure your role says “**IRB Committee Member**”
- Your IRB Committee Member home screen looks like this (see below). Any study needing action from the reviewer will be in your **inbox**. Click on the **name** to access the study. action.

The screenshot displays the VCU IRB Staging Office of Research home screen for Elicia Preslan. The page features a navigation bar with 'Meetings', 'IRB', and 'Help' links. The main content area is titled 'Page for Elicia Preslan' and includes a welcome message and instructions on how to complete reviews and view upcoming meetings. A sidebar on the left shows the user's current role as 'IRB Committee Member' and a list of roles. The main content area has two tabs: 'My Inbox' (selected) and 'Upcoming Meetings'. Below the tabs is a search filter section with a 'Filter by' dropdown set to 'ID', a search input field, and buttons for 'Go', 'Clear', and 'Advanced'. A table below the search section shows a single study entry with the ID 'HM20005364' and the name 'Test Study for Guide for the PI'.

ID	Name
HM20005364	Test Study for Guide for the PI

- Anytime you want to return to your inbox, click “My Home.”



Current State
In Expedited Review

My Study Forms
View Study
Printer Version
View Differences

My Activities
Finalize Review

Study: Test Study for Guide for the PI (HM20005364)
Principal Investigator: Meghan Wright
Editors: VCU IRB
Reviewer(s): Elicia Preslan

History Comments Documents Admin Docs Reviewer Notes Change Log IRB Information Paper History

Activity
Expedited Reviewer Assigned: Elicia Preslan
Submitted Changes

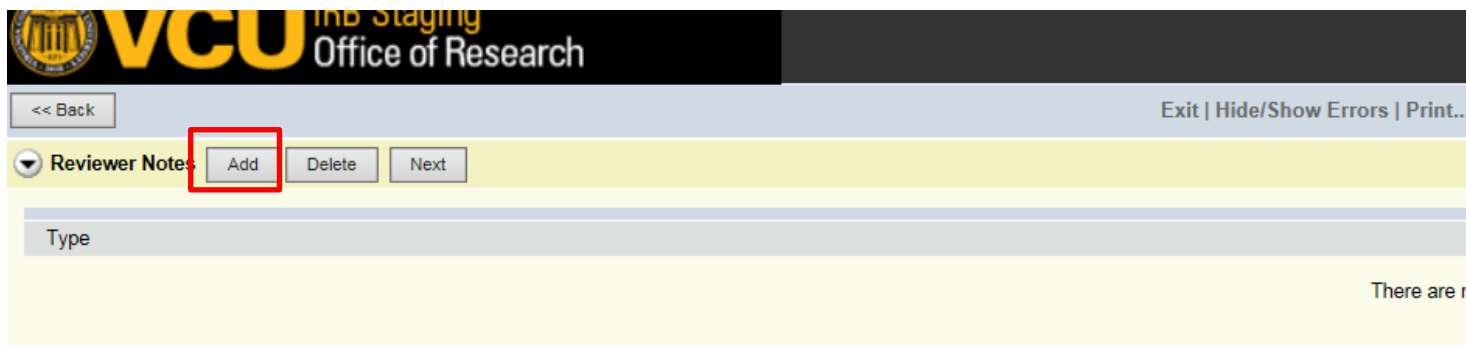
- **Current State** You will see the study is in Expedited Review by the maroon “Current State” box
- Click **“View Study”** to read through the smartform and add reviewer notes. The smartform are the questions answered to create the submission.
- Click **“Printer Version”** to view a printer-friendly version of the smartform (all pages shown as one document without clicking from section to section).
- **History:** All actions through the life of the submission are listed with the most recent actions listed first. The link for each action provides more detail.
- **Comments:** Shows a list of all public and private comments through the life of a submission.
- **Documents:** All uploaded documents related to the study are housed here.
 - Approval status found along right side and who uploaded the document
 - Important to ensure working from the correct/ approved version.
- **Admin Documents:** This tab contains other documents that need to be included for documentation purposes. The PI can’t see these. Examples include COI determinations, email correspondence, etc.
- **Reviewer Notes:** Reviewer Notes are the comments that reviewers enter throughout the smart form where a change is needed. This tab shows a list of all logged reviewer notes.
 - Link takes you directly to the smartform where the change is needed
- **Change Log:** Shows a list of all changes that were made to the smartform during the initial submission.
- **IRB Information:** This tab shows a quick summary of key/important information about the submission.

REVIEWING AN INITIAL SUBMISSION

- Click on the **title of the study** to access the study. Click “View Study” to be able to add reviewer notes.

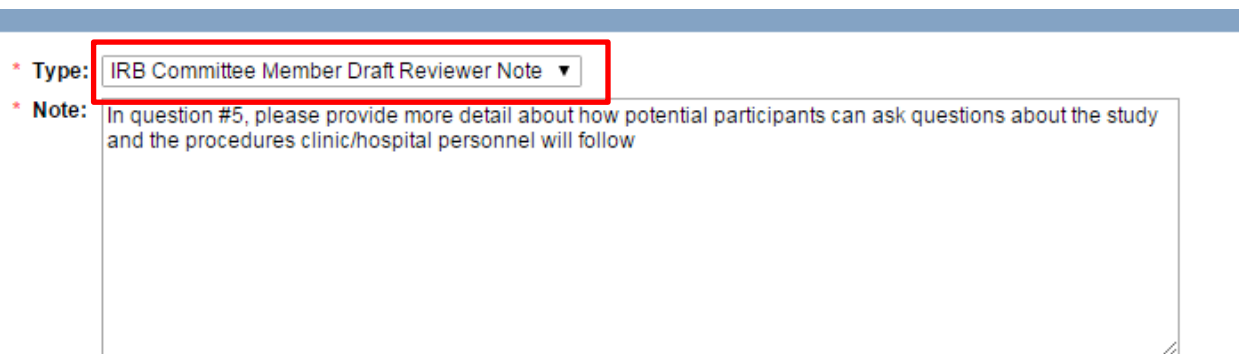
ADDING REVIEWER NOTES

- If you want to request a change, add a reviewer note by clicking “Add”
- You can jump between notes by clicking “Next.”



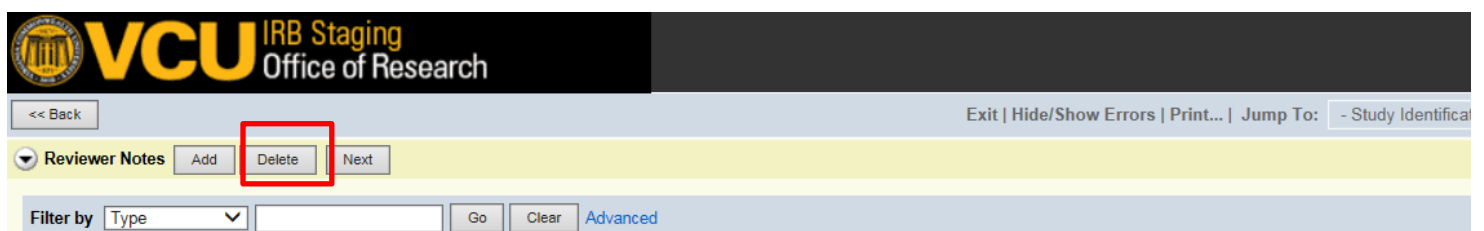
The screenshot shows the top navigation bar with the VCU logo and 'IRB Staging Office of Research'. Below it is a navigation bar with '<< Back' and 'Exit | Hide/Show Errors | Print...'. The main section is titled 'Reviewer Notes' and contains three buttons: 'Add', 'Delete', and 'Next'. The 'Add' button is highlighted with a red box. Below the buttons is a 'Type' dropdown menu and a text area for notes. The text area contains the text 'There are r'.

- In the text box, request the revision or information that you want to have included in the smartform. Remember to be clear and precise about what you want changed, specify where the change should be made in the form, and if appropriate, offer your rationale or context for the request.



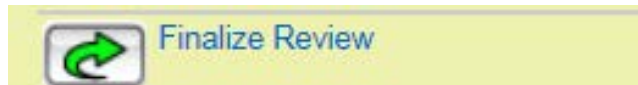
The screenshot shows a 'Reviewer Note' form. The 'Type' dropdown menu is highlighted with a red box and contains the text 'IRB Committee Member Draft Reviewer Note'. The 'Note' text area contains the text 'In question #5, please provide more detail about how potential participants can ask questions about the study and the procedures clinic/hospital personnel will follow'.

- To delete a note, click “Delete” and find the note by time posted.



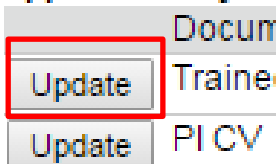
The screenshot shows the top navigation bar with the VCU logo and 'IRB Staging Office of Research'. Below it is a navigation bar with '<< Back' and 'Exit | Hide/Show Errors | Print... | Jump To: - Study Identical'. The main section is titled 'Reviewer Notes' and contains three buttons: 'Add', 'Delete', and 'Next'. The 'Delete' button is highlighted with a red box. Below the buttons is a 'Filter by' dropdown menu and a text area for notes. The text area contains the text 'There are r'.

- When you are done adding reviewer notes, go back to the submission workspace by clicking the “Exit” button.
- Your change requests should be done as reviewer notes, but if you have general questions, you can also contact the PI by logging public comments.
- To send the study back to the PI for changes, and click “Finalize Review” on the left hand side of the submission workspace and choose “Changes Requested” in the drop down menu for question #1.



- Note: Question #5 – An answer is required before the review can be finalized.
- Documents:
 - *Approving Documents:* At this stage, you may approve documents that do not require changes by clicking “Update” and use the drop down menu in question 4 to mark your **approval**.
 - *Documents with Changes:* If a document requires change, make a comment in question 8 to tell the PI that you have uploaded a Red Line document.
 - Click “Update” and upload the redline version.
 - Select “Choose File” and find your redline version on your computer to upload
 - Click “open” and “ok”

9. Approve Upload:
Use the *Update* I
approvable by th

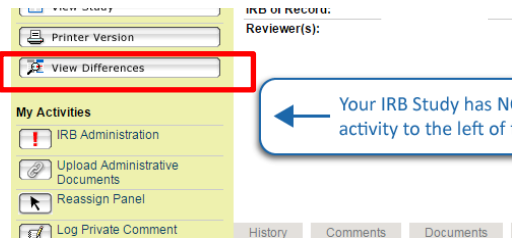


Update Document

- * Document Name:
- * Type:
- * File:
 f(0.01) | History
 No file chosen

VIEWING CHANGES

- Once the PI submits changes, you will get an email notification.
- Go back to the submission and click on “View Differences”



- In the green response to every reviewer note, you will be able to see the PI's comments.
 - Any differences in the smartform responses will appear in **green highlighting** (New/added text) or **red** (Old text) within the form.
- If there were multiple revised pages of the smartform, click >> to go to the next revised page.

View Changes to IRB Study

Show Changes made between Current Version (0.5) and 0.4 8/24/2015 10:40 AM

Changed Steps: Study Identification << >> Limit Steps to Current SmartForm Path

Reviewer Notes Add Delete Next

Filter by Type [] Go Clear Advanced

Type

IRB Staff Change Request

Please make the title more descriptive of the study.

Change Request Completed - Meghan Wright - 8/24/2015 10:43 AM

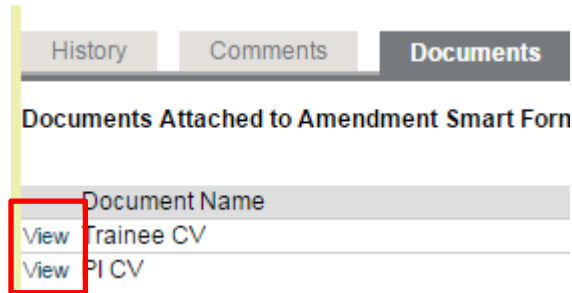
We made the changes.

Study Identification

1. * **Select the Principal Investigator:**
Meghan Wright
2. * **Study Title:**
Test Study for Guide **for the PI**

VIEWING DOCUMENT CHANGES

- Once you've viewed all of the differences in the smartform, click the documents tab to view differences in the documents.
- Click "View" next to each document



- Click "HISTORY" and you will be able to see all revisions, including red-lined documents.

Add Document

1. * Document Name:
Trainee CV
2. * Type:
CV/Biosketch
3. * File:
CV (0.01) History

- If a change was not made appropriately or if you still have questions, log additional reviewer notes and finalize your review again as "Changes Requested." This process of logging reviewer notes and requesting changes may be repeated multiple times until the submission is approvable, but try to identify all the issues on the first round of changes.

FINALIZE REVIEW POP-OUT SCREEN

- Once all changes have been made, click “Finalize Review” again and then choose “**Approve as Expedited**” (or Approve as Exempt or even Not Human Subjects Research) on the drop down menu for question #1.

Finalize Review

Use this activity to finalize your review of this study.

- * Select Your Review Decision:
- Select Exempt Review Categories:
If you have determined this study is exempt, select all applicable exempt review categories from the list below:
 Add
There are no items to display
- Select Expedited Review Categories:
If you have determined this study is expedited, select all applicable expedited review categories from the list below:
 Add
Category Involves the collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding x-rays or microwaves. Remove
- Check each of the approval conditions that you have evaluated and determined to be met. Not all will be applicable, but you must evaluate and check off all the criteria in order to approve.
 Add
There are no items to display
- * If this study involves children and falls into category 404 or 405 where the permission of two parents is optional, indicate what parental signatures are required:
- * Does this study involve greater than minimal risk: Yes No [Clear](#)
- Approve Uploaded Documents:
Use the Update button below to mark all documents as "Approved" if it is approved as is, "N/A" if it is something that is not approvable by the IRB, or "No" if you are withholding approval of the document.

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
<input type="button" value="Update"/>	g	RAMS IRB for Reviewers Expedited.docx	0.01	12/4/2015 11:07 AM	Meghan Wright	Other	
- Comments (will be shown in History Log):



- Question #2 or 3- Categories should be correct already (however they may not be if the PI chose incorrectly) so please verify these selections. You may add or delete categories without sending it back to the PI. The selections in this approval overrides what was submitted in the smart form, so make sure they are accurate.
- Question # 4 is required, even though it doesn't have a *, so be sure to answer that question. Click “Add” and check off all 8 Criteria for IRB Approval (46.111) in the list. **Unless all 8 criteria are met, the study cannot be approved.**
- Question #7 **APPROVE DOCUMENTS** (see next page) – click “Update” for each document, and indicate which documents are approved, and which are not. Make sure redline versions are “Not Applicable.” Refer to the following guidelines about whether or not to approve:
 - In the Comments box, add anything else the coordinator or Panel chairperson needs to know about the study or your determination.
 - Once you click “Ok,” the study goes to IRB staff who will read your review and confirm that all regulatory requirements have been met. If they have questions about your approval, it will be sent back to you for further review. They could also send the study back to the PI if further revisions are necessary.
 - The IRB staff will draft a letter to the PI with your review determination. The letter and the study are then reviewed by the Panel chair (who may have questions or requested changes for IRB staff, reviewer and/or the PI).
- Once the chair approves the letter, documents will be finalized by the IRB staff and the letter with a determination is sent to the PI.**

Approving Documents:

Guidelines to approving, not approving, or not applicable documents:

Approved “Yes”	<ul style="list-style-type: none">○ The IRB approves the content of the document.○ Document or content of document is in the scope of IRB review. <p><u>Examples:</u></p> <ul style="list-style-type: none">▪ Required CVs / Bio-sketches (PI, etc.)▪ Sponsor’s protocols▪ Tables, figures that are referenced in the research description▪ Research measures▪ Case Report Forms when required by the IRB▪ Recruitment materials▪ Funding proposals that had congruency review▪ IND/IDE exemptions approved by IRB▪ All consent documents:<ul style="list-style-type: none">○ Standard consent forms○ Information sheets○ Research measures IF they contain a consent element
Not Approved “No”	<ul style="list-style-type: none">○ The IRB does not approve the content of the document.○ Document or content of document outside of IRB purview.○ Any time any option other than NO could cause confusion to anyone viewing document list. <p><u>Examples:</u></p> <ul style="list-style-type: none">▪ Research plan▪ Study roster▪ Special population forms▪ Appendix A: HIPAA for Research▪ Previous versions of documents that are no longer approved▪ Memos to the IRB or reviewer▪ Redline documents▪ Documents from other IRBs
Not Applicable “N/A”	<ul style="list-style-type: none">○ Considered as part of the review (within scope) but document or content management outside of control of PI or IRB.○ Acknowledged by the IRB. <p><u>Examples:</u></p> <ul style="list-style-type: none">▪ HIPAA standalone authorization forms▪ OSP Approval Form▪ Funding Proposals where congruency not reviewed▪ Required ancillary committee review letters:<ul style="list-style-type: none">○ PRMC○ DSMB reports○ Radiation Safety Committee▪ References/literature, tables, figures▪ FDA documents<ul style="list-style-type: none">○ IND/IDE documentation from FDA/Sponsor○ Forms 1572, 482, 483, 3500, etc.○ Drug/device brochures

AMENDMENTS

- When the PI opens an amendment, it copies the *approved* existing smartform and documents into a new workspace to be edited, and therefore the full edited smartform is submitted as an amendment.
- The approved smartform remains approved as is, until the amendment is approved and changes are applied.

1. First, look at Reason for Changes & Summary of Changes

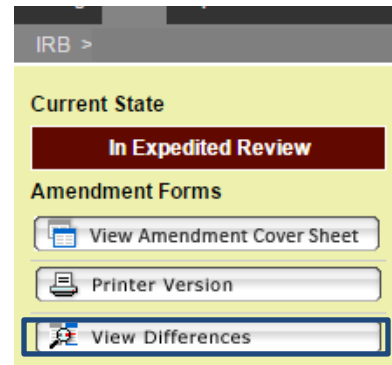
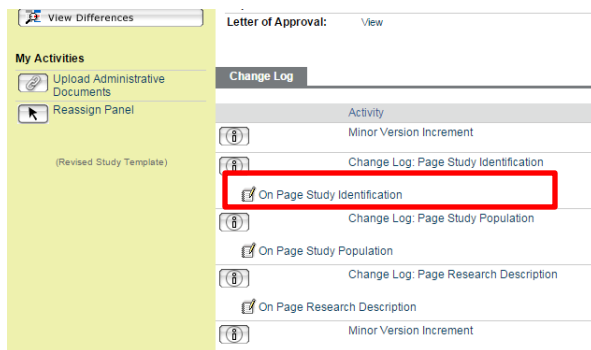
The screenshot shows the IRB system interface. At the top, there is a navigation bar with tabs for ACUP, AIRS, CORES, IRB, SPOT, and REPORTS. Below this is a sub-navigation bar with 'Meetings', 'IRB', and 'Help'. The main content area is titled 'Amendment 4 for IRB Study'. On the left, there is a sidebar with 'Current State' (In Expedited Review), 'Amendment Forms' (View Amendment Cover Sheet, Printer Version, View Differences), and 'Study Forms'. The main form fields include: Principal Investigator, Editors, IRB of Record, Approved Study, Summary of Changes, and Reason for Changes. The 'Summary of Changes' and 'Reason for Changes' fields are highlighted with a red box.

2. Click “View Changes” first

- a. Note: “View Differences” refers to strictly the differences in the amendment *cover sheet*.

The screenshot shows a close-up of the sidebar from the previous image. The 'View Changes' button is highlighted with a red box. The sidebar also shows 'View Modified Study', 'Print-Friendly Study', and 'View Differences' buttons.

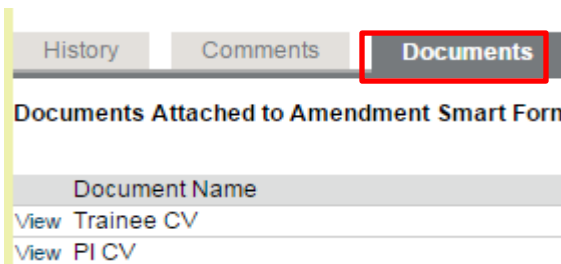
3. To view the specific changes to the smartform, either click **“View Differences”** or click on each individual change in the **change log**. “View Differences” is best used when there are many changes. Those changes will be highlighted, as with an initial submission.



To get back to the Amendment workspace, click “Amendment __” in the top gray bar.



4. Once you’ve reviewed the specific changes they are requesting, click “View Modified Study” or “Print-Friendly” to look at the changes in context of the entire smartform. You should be looking at how those changes affect the rest of the submission and if anything else needs to be changed. (Example, if the recruitment plan changes, the study population of consent process might also need revisions).
- If you have requested changes, log a reviewer note just like reviewing an initial submission.
 - In addition, you should go to the Documents tab and review any modified documents.
 - Click “View” next to each document
 - Click “HISTORY” and you will be able to see all revisions, including redlined



Add Document

1. * Document Name:
Trainee CV
2. * Type:
CV/Biosketch
3. * File:
CV >df(0.01 **History**)

Log reviewer notes with any changes you want to request

→ If you have requested changes, and have logged reviewer notes

→ Finalize your review as Changes Required to Amendment to send it back to the PI

Finalize Review

Use this activity to finalize your review of this amendment. In the bottom section overall.

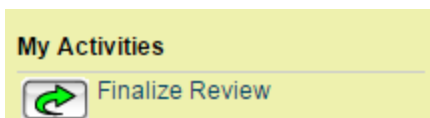
1. * Select Your Review Decision for this Amendment:

Changes Required to Amendment ▼

- Question #2: If changes are requested, then the Criteria for Approval are not met yet and should **skipped**. If the Criteria for Approval are met, the submission is approvable.
- Question #3 – Enter any comments you have for PI, including the fact that you have uploaded any redline documents (if applicable). Otherwise, the PI will not be notified and won't know to look for it.
- Questions #4-8 - Will be automatically filled in from the smart form, these should be checked, but most likely will not require a change. Be very sure you're correct before making a change to these questions.
 - Note: Full board studies remain full board regardless of whether the amendment qualifies for expedited review.
- Question #9 - Upload a redline document to the PI if applicable (refer to initial submission for directions on uploading a redline document)

→ Once the PI has addressed the changes requested, repeat the steps to view differences, and identify if anything else needs to be changed.

→ Once all requested changes have been made and the amendment can be approved, click Finalize review.



Finalize Review

Use this activity to finalize your review of this amendment. In the bottom section overall.

1. * Select Your Review Decision for this Amendment:

Approve Amendment ▼

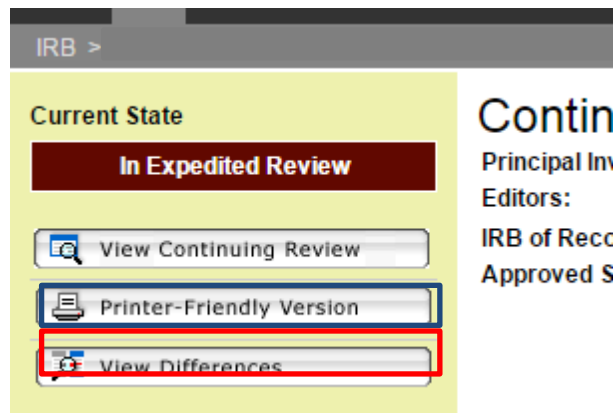
2. Check each of the approval conditions that you have evaluated and evaluate and check off all the criteria in order to approve.

Note: The Finalize Review screen automatically fills with the previous responses, so please make sure to change question #1 to "Approve Amendment." Add all 8 criteria for approval to question #2, and add any comments about your review, or to the coordinator or chair to question #3.

*If new revised documents have been submitted, approve documents as seen in initial submission

CONTINUING REVIEW

1. Initial Read-Through - To read the continuing review submission initially, click **Printer-Friendly Version** – this is easier to read all at one time.
2. If you have questions and need to log a reviewer note, then click **View Continuing Review.** Reviewer Notes: Refer to the process indicated in the Initial Submission directions.



3. Review Documents – Once you're done viewing the form, you will need to look at the documents by clicking on the documents tab of the continuing review workspace.
 - a. Open each document and read them for informational purposes. There is no need for further action unless you have a question, in which case, you would log a reviewer comment.



4. Read through the currently approved smartform (full study submission) to make sure that the Criteria for Approval are still met given the information provided in the continuing review.
5. If you find issues with the **Continuing Review** information, you will need to send it back to the PI for modification.
6. Finalize Review: Click “Finalize Review”
 - a. *Note: Before submitting your finalized review, please refer back to the History Tab for any specific instructions the coordinator may have provide.*
 - b. Fill out the Finalize Review screen.

- c. **Changes Required:** Select that option for question #1, and **skip** question #2.

Finalize Review

- d. Question 3: If you find issues with the **smartform**, outline these changes in the comments box in the finalize review screen. Ask the PI to submit an amendment with these changes.
- e. Question 4: Refer the PI to your final reviewer notes for specific changes. *These may require an amendment to be submitted.*
- f. **No Changes Required:** If everything is complete, and no changes are required, select “Approve Continuation,” for question #1, “Add” and check off all 8 Criteria for Approval in question #2.

Finalize Review

REPORTS

*Reviewers are less likely to see reports – most reports get assigned to chair, but procedures are panel specific.

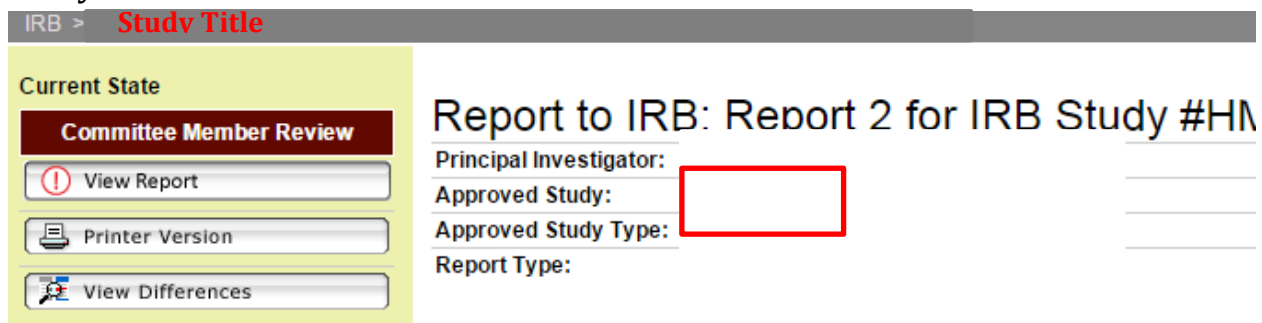
1. Click Printer Version – to view the report all on one page.



2. Read through the printer version and refer to the [WPP VII-6](#) for the procedures about how to review a report. If you have questions, consult your chair.

3. Reviewer Notes: If you have questions about the information in the report, you may log reviewer notes, and/or public/private comments just like any other submission. You may also decide to call the PI.

4. Read Smartform: Go back to the approved smartform (**click on the study title I the gray bar**) and read through the study to make sure that the PI's proposed changes will adequately address the changes that may be needed in the overall study.



5. Finalize Review

* *Before you finalize your review, check to see if the PI already submitted an amendment related to this report. If not, and an amendment **is** required, say “Yes” to question 2.*

- **Changes Required**
Finalize Review

Use this activity to finalize your review of this report.

Review Notes: If this meets the criteria of an Unanticipated Problem, select *Refer to Full Board* as your decision. If it does not meet the criteria of an Unanticipated Problem, select *Acknowledge* as your decision. If you need additional information to make your decision, add Reviewer Notes to the applicable sections and select *Changes Required to Report* as your decision.

1. * Select Your Review Decision:

Changes Required to Report

2. * Is an Amendment to the approved study required before this report is resolved?

Yes No

*Once changes have been addressed, click “View Differences” to see the changes that were made, or look at the reviewer notes tab to see the response the PI provided. *With reports, it is more likely that changes are not made within the report form, but the PI responds to*

The screenshot shows a web interface for reviewing a report. On the left, under the 'Current State' section, there is a 'Committee Member Review' header. Below it are three buttons: 'View Report' (with a red warning icon), 'Printer Version' (with a printer icon), and 'View Differences' (with a magnifying glass icon). The 'View Differences' button is highlighted with a red box. Below this is the 'My Activities' section with a 'Finalize Review' button (with a green refresh icon). On the right, there is a horizontal navigation bar with four tabs: 'History', 'Comments', 'Documents', and 'Reviewer Notes'. The 'Reviewer Notes' tab is highlighted with a red box. Below the navigation bar is a grey bar with the word 'Activity' in blue text.

- **No Changes Required:** Once you’re ready to make a determination of approval, click “Finalize Review” again, read the instructions and WPP to determine if the report should be referred to Full Board*, or “Acknowledge”** and click OK.

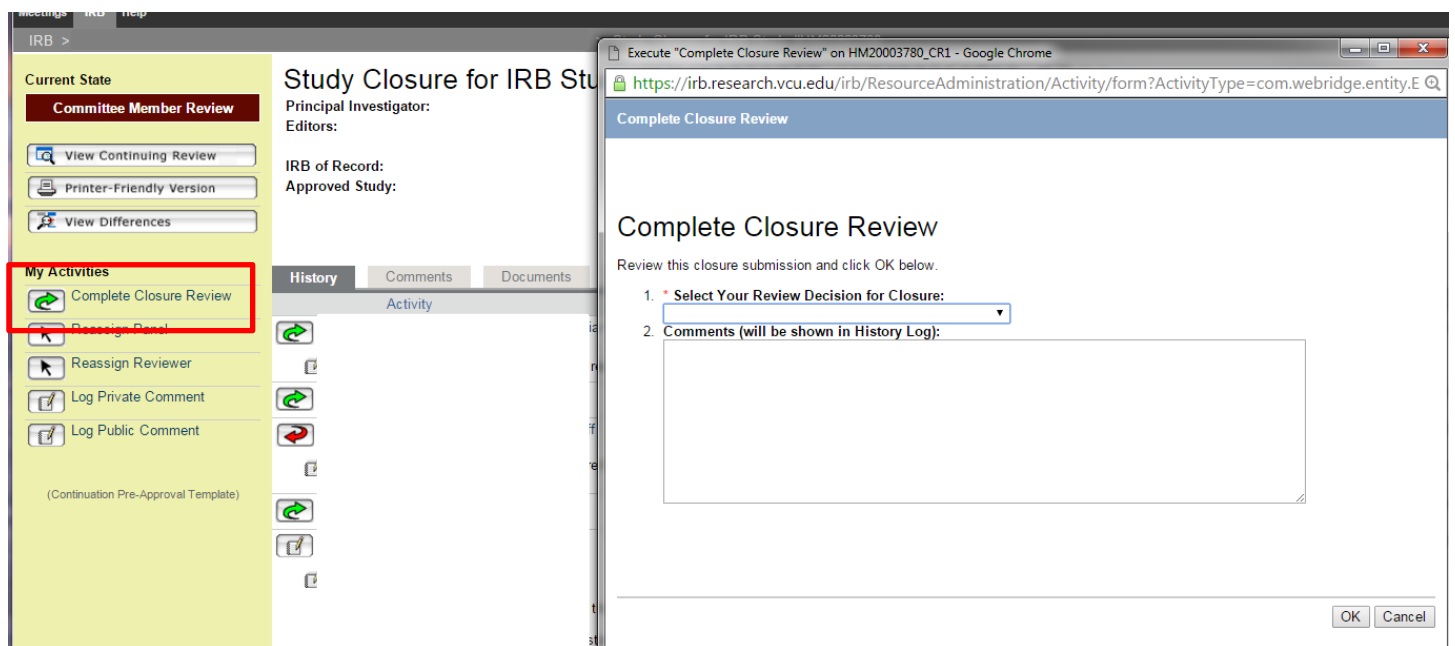
*If you refer to the Full Board, you will likely be assigned as a reviewer, so be prepared to finalize your review again with Full Board comments.

**If a report is “Acknowledged,” the PI will get an automatically generated letter informing them of the determination.

CLOSURE

Before completing a Study Closure, consider if anything needs to be done before the closure to protect human subject. (Example: If the study is closing early, do subjects need to be notified?)

1. Click “Complete Study Closure” and fill out pop-out screen.



- When a closure is acknowledged, the PI gets an automatically generated letter informing them of the closure.
- If a closure should be referred to the full board, consult the Chair & IRB staff for instructions. Do not finalize the review.



VCU

Office of Research and Innovation

RAMS-IRB for Full Board Reviewers

Virginia Commonwealth University
Office of Research and Innovation
BioTech 1 Building, Suite 3000
800 East Leigh St.
PO Box 980568
Richmond, VA 23298
(804) 828-0868

HOME SCREEN

- Connect through RAMS [VPN](#) if off campus
- Log into RAMS-IRB by using your VCU eID and Password at <https://irb.research.vcu.edu>
- Make sure your role says “**IRB Committee Member**”
- Your IRB Committee Member home screen looks like this (see below). Any study needing action from the reviewer will be in your **inbox**. Click on the **name** to access the study. action.

VCU IRB Staging Office of Research

Meetings IRB Help

Page for Elicia Preslan

Page for Elicia Preslan

Welcome to your Personal Page, the central resource for managing IRB submissions. Your Personal Page provides all the tools you need in

- Complete reviews for all items in your inbox. To do this, review the forms and add Reviewer Notes on selected pages. Finalize you
- Meetings for your committee are listed on the Upcoming Meetings tab. You can click on the meetings to view the Agenda and Minute

My Roles

IRB Committee Member

My Inbox Upcoming Meetings

ID	Name
HM20005364	Test Study for Guide for the PI

- Anytime you want to return to your inbox, click “My Home.”

ACUP AIRS CORES IRB SPOT REPORTS

Meetings IRB Help

IRB > Test4354236

Main Study Workspace

Current State

Assigned To IRB Meeting

Study: Test4354236 (HM20005251)

Principal Investigator: Meghan Wright

Editors: Meghan Wright

IRB of Record: VCU IRB

Reviewer(s): Meghan Wright
Christine Davison

View Study

Printer Version

View Differences

My Activities

History Comments Documents Admin Docs Reviewer Notes Change Log

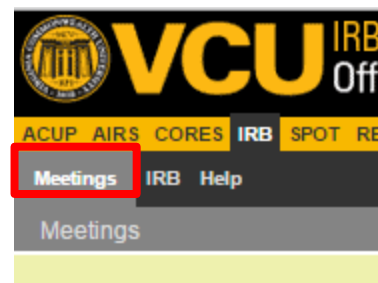
Activity

- **Current State** You will see the study is in full board review when it says “Assigned to IRB Meeting” in the maroon box
- Click **“View Study”** to read through the smartform and add reviewer notes. The smartform are the questions answered to create the submission.
- Click **“Printer Version”** to view a printer-friendly version of the smartform (all pages shown as one document without clicking from section to section).
- **History:** All actions through the life of the submission are listed with the most recent actions listed first. The link for each action provides more detail.
- **Comments:** Shows a list of all public and private comments through the life of a submission.
- **Documents:** All uploaded documents related to the study are housed here.
 - Approval status found along right side and who uploaded the document
 - Important to ensure working from the correct/ approved version.
- **Admin Documents:** This tab contains other documents that need to be included for documentation purposes. The PI can’t see these. Examples include COI determinations, email correspondence, etc.
- **Reviewer Notes:** Reviewer Notes are the comments that reviewers enter throughout the smart form where a change is needed. This tab shows a list of all logged reviewer notes.
 - Link takes you directly to the smartform where the change is needed
- **Change Log:** Shows a list of all changes that were made to the smartform during the initial submission.

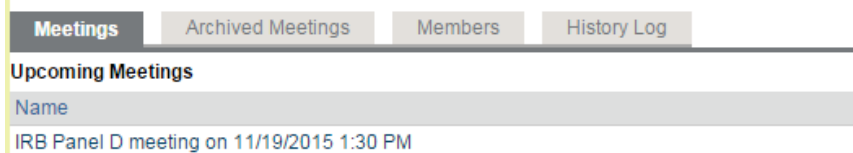
MEETING WORKSPACE & ATTENDANCE

- Before the meeting, you will want to log your attendance and view the electronic agenda.

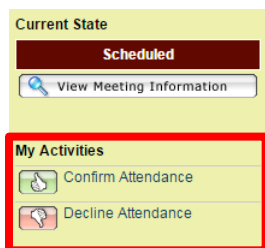
1) Click “Meetings” in upper left hand corner of screen.



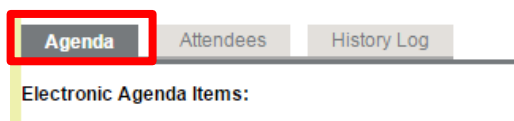
Click the correct upcoming meeting



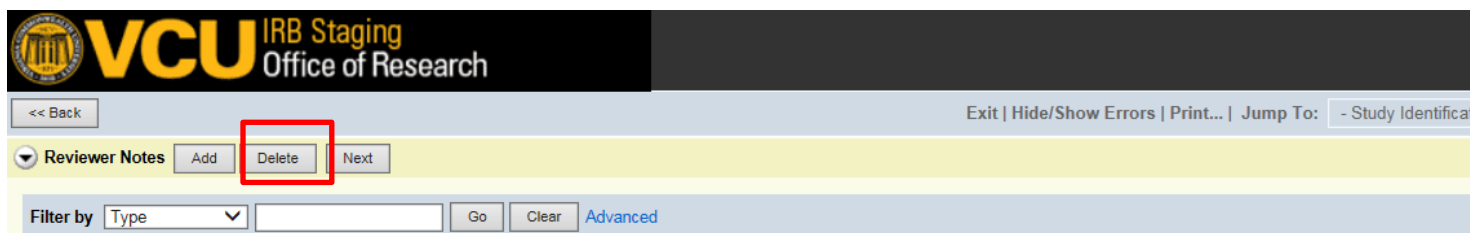
2) To confirm or decline attendance, click the appropriate button on the left hand side of the screen.



3) To view the meeting agenda, click the “Agenda” tab.



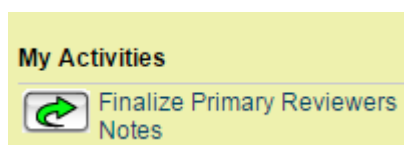
- To delete a note, click “Delete” and find the note by time posted.



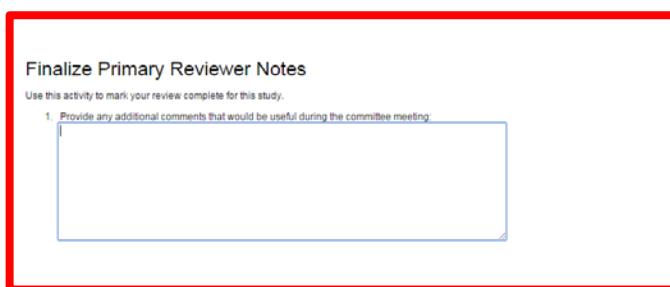
- When you are done adding reviewer notes, go back to the submission workspace by clicking the “Exit” button.
- Your change requests should be done as reviewer notes, but if you have general questions, you can also contact the PI by logging public comments.
- The PI will be able to see your reviewer notes in the “Snapshot” (if they know where to look), however they will not be able to respond or make changes.

FINALIZE REVIEW POP-OUT SCREEN

- Please finalize your review BEFORE the meeting. You may wish to contact the PI to ask questions before you finalize your review.
- For a full board study, you will be making a recommendation to the panel of what action the panel should take, as the study and your findings will be presented to the full panel for review and a vote.



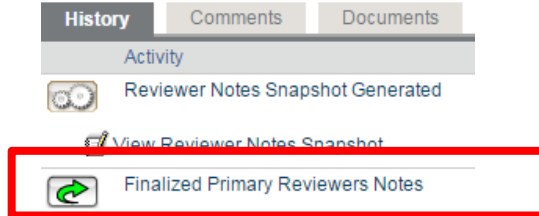
- In the blank box, you should be adding the information to be displayed and discussed at the meeting, such as a summary, if the criteria for approval are met, if the study involves vulnerable populations, risk determination, recommendation etc.



Note: This information should NOT be logged anywhere else such as a private comment, unless something about your review changes after you’ve finalized the review.

VIEWING REVIEWER NOTES (AT MEETING)

- To view your finalized reviewer comments (for example, at the meeting), click on “Finalized Primary Reviewer Notes” under the **History** tab. Do NOT click on the snapshot.



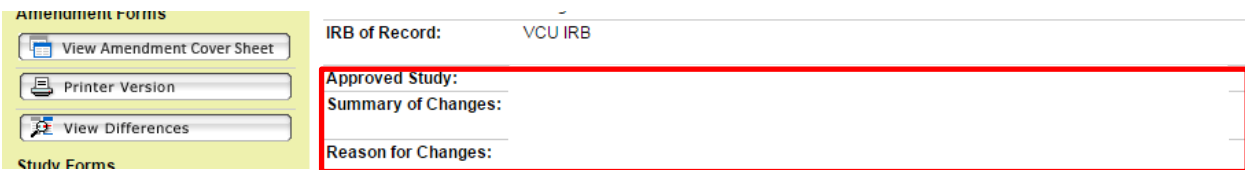
POST MEETING

- M1 (Approval) – the reviewers do not need to do anything further
- M2 (Conditional Approval) –
 - IRB staff will send a letter to the PI with specific changes.
 - Once the changes are submitted, if you are assigned as the designated reviewer, you will need to verify those changes were made as the panel requested.
 - If changes were made *exactly* as the panel requested (no more, no less), then the submission may be approved.
 - If the PI did not make the exact changes requested by the panel, you will need to request changes. If you’re unable to get the PI to make those changes, the submission will be referred back to full board.
- The Letter to the PI will be under the “History” tab

AMENDMENTS

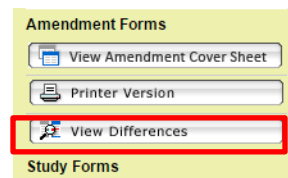
- When the PI opens an amendment, it copies the *approved* existing smartform and documents into a new workspace to be edited, and therefore the full edited smartform is submitted as an amendment.
- The approved smartform remains approved as is, until the amendment is approved and changes are applied.

1. First, look at Reason for Changes & Summary of Changes

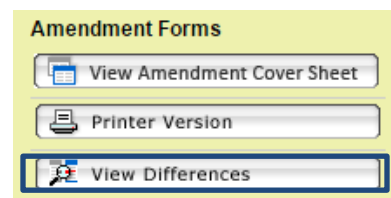
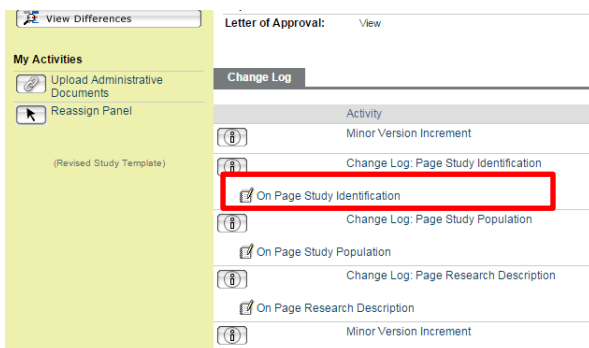


2. Click “View Changes” first

- a. Note: “View Differences” refers to strictly the differences in the amendment *cover sheet*.



3. To view the specific changes to the smartform, either click “View Differences” or click on each individual change in the **change log**. “View Differences” is best used when there are many changes. Those changes will be highlighted, as with an initial submission.



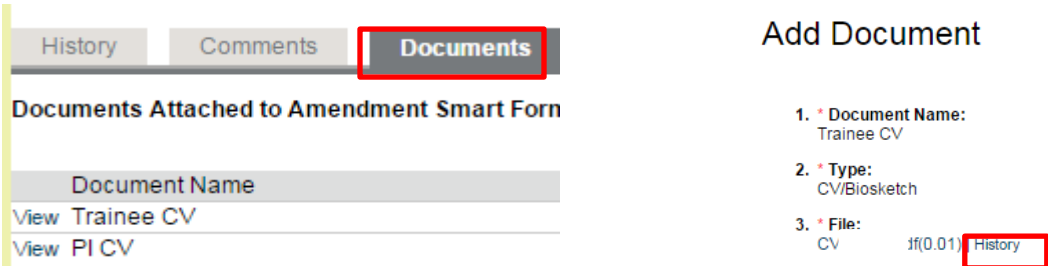
To get back to the Amendment workspace, click “Amendment __” in the top gray bar.



Modified Study:

Principal Investigator:		IRB Coordinator:	
Editors:		IRB Panel:	
Approval Date:			
Expiration Date:		Review Type:	
Letter of Approval:		IRB of Record:	

- Once you’ve reviewed the specific changes they are requesting, click “View Modified Study” or “Print-Friendly” to look at the changes in context of the entire smartform. You should be looking at how those changes affect the rest of the submission and if anything else needs to be changed. (Example, if the recruitment plan changes, the study population of consent process might also need revisions).
 - If you have requested changes, log a reviewer note just like reviewing an initial submission.
 - In addition, you should go to the Documents tab and review any modified documents.
 - Click “View” next to each document
 - Click “HISTORY” and you will be able to see all revisions, including redlined



History Comments **Documents**

Documents Attached to Amendment Smart Form

Document Name
View Trainee CV
View PI CV

Add Document

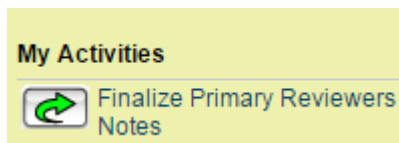
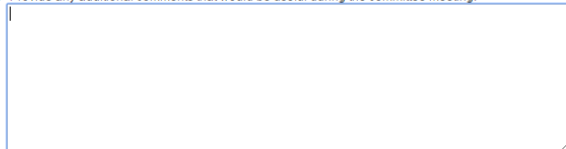
- Document Name:**
Trainee CV
- Type:**
CV/Biosketch
- File:**
CV jf(0.01) [History](#)

- Log reviewer notes with any changes you want to request.
- Finalize your review by clicking “Finalize Primary Reviewer Notes”

Finalize Primary Reviewer Notes

Use this activity to mark your review complete for this study.

- Provide any additional comments that would be useful during the committee meeting:

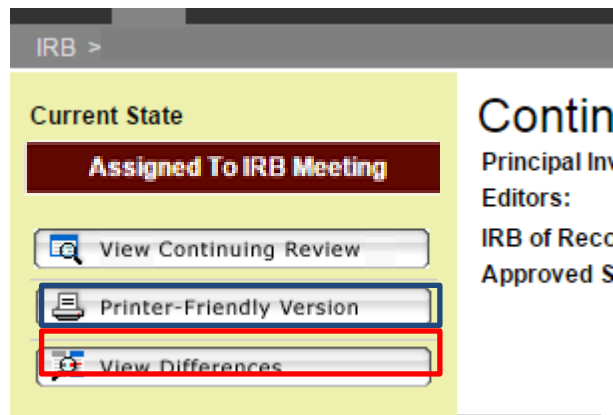


My Activities

[Finalize Primary Reviewers Notes](#)

CONTINUING REVIEW

1. Initial Read-Through - To read the continuing review submission initially, click **Printer-Friendly Version** – this is easier to read all at one time.
2. If you have questions and need to log a reviewer note, then click **View Continuing Review.** Reviewer Notes: Refer to the process indicated in the Initial Submission directions.



3. Review Documents – Once you're done viewing the form, you will need to look at the documents by clicking on the documents tab of the continuing review workspace.
 - a. Open each document and read them for informational purposes. There is no need for further action unless you have a question, in which case, you would log a reviewer comment.



4. Read through the currently approved smartform (full study submission) to make sure that the Criteria for Approval are still met given the information provided in the continuing review.

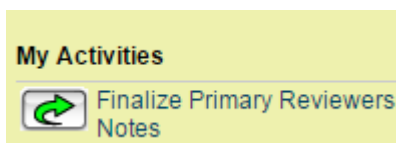
5. If you find issues with the **Continuing Review** information, you will need to send it back to the PI for modification.

6. Finalize your review by clicking “Finalize Primary Reviewer Notes”

Finalize Primary Reviewer Notes

Use this activity to mark your review complete for this study.

1. Provide any additional comments that would be useful during the committee meeting:



REPORTS

*Reviewers are less likely to see reports – most reports get assigned to chair, but procedures are panel specific.

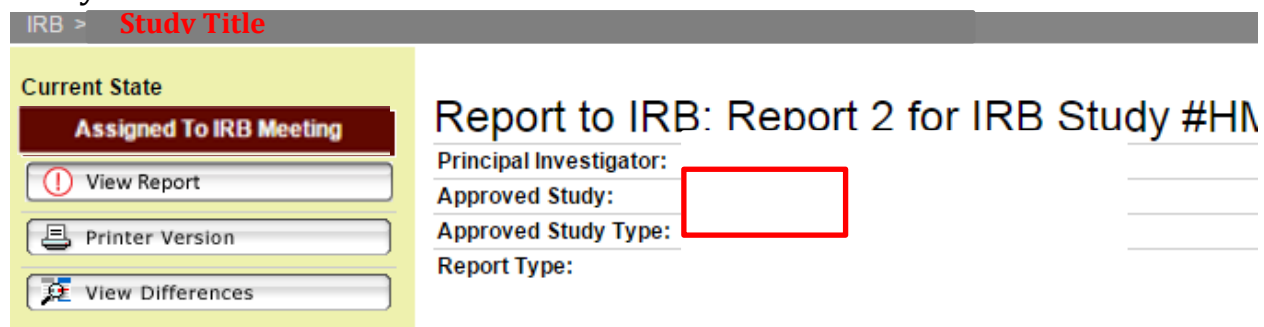
1. Click Printer Version – to view the report all on one page.



2. Read through the printer version and refer to the [WPP VII-6](#) for the procedures about how to review a report. If you have questions, consult your chair.

3. Reviewer Notes: If you have questions about the information in the report, you may log reviewer notes, and/or public/private comments just like any other submission. You may also decide to call the PI.

4. Read Smartform: Go back to the approved smartform (**click on the study title in the gray bar**) and read through the study to make sure that the PI's proposed changes will adequately address the changes that may be needed in the overall study.

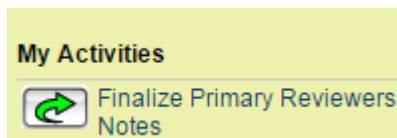


7. Finalize your review by clicking “Finalize Primary Reviewer Notes”

Finalize Primary Reviewer Notes

Use this activity to mark your review complete for this study.

1. Provide any additional comments that would be useful during the committee meeting:



CLOSURE

If a study closure requires a full board decision, the assigned reviewer will be notified by the IRB staff, and may be sent a PDF of the closure request. The reviewer will not see it in their inbox, but can find the closure in the meeting workspace agenda to view and log reviewer notes.

Review comments should be logged as a private comment.

Exempt Categories

Please refer to WPP for more detail and examples of each category.

Note: Exemptions do not apply to research involving prisoners, nor FDA related research EXCEPT Category 6.

- 1. Educational Strategies, Curricula or Classroom Management Methods** - Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- 2. Educational Tests, Surveys, Interviews or Observations of Public Behavior, Not Including Children or Elected Officials** - Research involving use of educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview procedures, or observation of public behavior **unless**: information obtained from these sources is recorded in such a manner that subjects can be identified (directly or through identifiers linked to the subjects), **and** disclosure of the subject's responses outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to his or her financial standing, employability, or reputation.
- 3. Educational Tests, Surveys, Interviews or Observations of Public Behavior of Elected Officials** - Research involving the use of education tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Exemption category (2) (above) of this section if: (i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statutes require, without exception, that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- 4. Secondary Data Analysis of Existing Data, Documents, Records or Specimens** - Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, (a) if these sources are publicly available, or (b) if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. [Identifiers **may** be retained for research related to (a), above. However, identifiers **MAY NOT** be retained for research relevant to (b), above.
- 5. Federal Department or Agency Research and Demonstration Projects for Evaluation of Public Benefit/Service Programs** - Research and demonstration projects which are conducted by or subject to approval of [federal] department or agency heads, and which are designed to study, evaluate, or otherwise examine (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under these programs; (iii) possible changes or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payments for benefits or services under those programs. The program under study delivers a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act). The research is conducted pursuant to specific federal statutory authority. There is no statutory requirement that an IRB review the research. The research does not involve significant physical invasions or intrusions upon the privacy of subjects. [Identifiers may be retained with appropriate protections.
- 6. Taste and Food Quality/Consumer Acceptance Studies (No Additives or Safety Questions)** - Tests and food quality evaluation and consumer studies, (i) if wholesome food without additives is consumed, or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA). [Identifiers may be retained.

Expedited Categories

Please refer to WPP for more detail and examples of each category.

Only *minimal risk* research qualifies for Expedited Review.

1. Is a clinical study of A) drugs that do not require an IND or B) devices where an IDE is not required or the device is being used for an approved use.
2. Involves only the collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from individuals where the amount of blood does not exceed allowable amounts (see help).
3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. NOTE: Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(2\) and \(b\)\(3\)](#). This listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Consent

8 Required Elements of Informed Consent Document

*Consent is an ongoing process

1. Research purpose and procedures
2. Risks and discomforts
3. Potential benefits
4. Alternative procedures or treatments
5. Provisions for confidentiality
6. Management of research-related injury
7. Contacts for additional information
8. Voluntary participation and the right to discontinue without penalty

Information When Applicable

1. Unforeseeable risks
2. Termination of participation by the investigator
3. Additional costs
4. Consequences of discontinuing research participation
5. Notification of significant new findings
6. Approximate number of subjects

Re-consent

- 45 CFR 46.116 (b)(5) and 21 CFR 50.25 (b)(5) state that, when appropriate, the informed consent document include a statement that “significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant.”
- The regulations require notification, but IRB members can require a re-consent process if they deem appropriate. Situations may include:
 - New risk/benefit profile (new risks, an increase in the magnitude of risks, or a decrease in the expected benefit)
 - Study procedures have been added, modified, or removed
 - New alternative treatments become available
 - Minor participant reach the age of 18 and still participating in the research
 - Participant regains decision making capacity
 - Original Informed Consent was obtained improperly (wrong document, not by an authorized person).
 - Unanticipated Problem

In order to approve a study, the IRB must determine:

- That informed consent will be sought from each prospective subject or the subject’s legally authorized representative (LAR) in accordance with the informed consent regulations (45 CFR 46.111(a)(4); 21 CFR 56.111(a)(4)).
- That informed consent will be appropriately documented in accordance with the regulations (45 CFR 46.111(a)(5); 21 CFR 56.111(a)(5)).

The IRB must review & document:

- Informed Consent Form(s) – meet regulatory requirements. Note in minutes any changes made.
- Waivers (see below) – justify in minutes:
 - All elements of consent
 - Some elements of consent
 - Documentation of consent

Waivers of Consent

Waiver of Some or All Elements of Consent

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

****This waiver is not allowed for FDA-regulated research.**

Waiver of Documentation of Consent (only the consent signature)

Circumstance 1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

****This circumstance is not allowed for FDA-regulated research.**

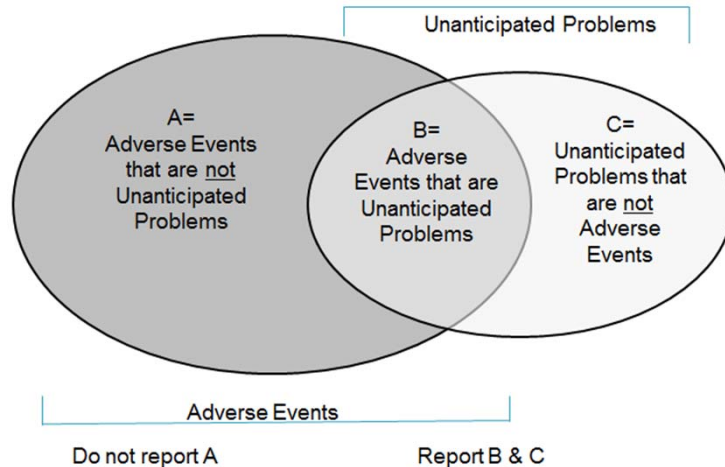
Circumstance 2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Reports

Unanticipated Problems (UP):

An unanticipated problem involving risk to participants or others is defined by meeting ALL 3 of the following criteria:

1. Was **unexpected** or not foreseen;
2. Involves **increased risk or harm** to participants or others than previously known or recognized
3. Was **probably or definitely related** to, or caused by, the research activity in the judgment of the investigator.



How to Review Reports of Ups:

Note: The Chairperson (and/or designated reviewer) may act independently in order to ensure the immediate safety of the research participants.

- Is the event a UP?
- Have any immediate actions taken place?
- Is an amendment required?
 - Should protocol or consent document be revised?
 - Should subjects be re-consented?
 - Should the frequency or nature of continuing review be changed?
- Evaluate risk/benefit profile of research participation
- What revisions and/or corrective actions are required (if any)?
 - o changes to the research protocol prior to obtaining IRB approval to eliminate apparent immediate hazards to subjects;*
 - o modification of inclusion or exclusion criteria;*
 - o implementation of additional procedures for monitoring subjects;*
 - o suspension of enrollment of new subjects;*
 - o suspension of research procedures in currently enrolled subjects;*
 - o modification of informed consent documents to include a description of newly recognized risks; and*
 - o Communication about newly recognized risks to previously enrolled subjects.*
- For protocol violations, is this noncompliance?
- If federally funded, is a report to OHRP needed?

Protocol Deviations & Violations (that caused hard or increased risk) ARE Unanticipated Problems & should be reported:

- **Protocol Deviation:** Any change to the IRB-approved protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant(s)
- **Protocol Violation:** An accidental or unintentional change to the IRB approved protocol that harmed participants or others or that indicates participants or others may be at increased risk of harm.

Noncompliance

Noncompliance

- General – failure on the part of the PI or any member of the research team to adhere to the terms of VCU IRB approval and/or abide by applicable laws, regulations, or policies.
 - General noncompliance may vary in severity based upon the overall risk potential of the noncompliance and its frequency. Noncompliance determined to be general in nature and not serious and/or continuing is not reportable to regulatory authorities or sponsors.
- Serious - failure to adhere to the terms of the VCU IRB approval and/or abide by applicable laws, regulation, or VCU policies when that failure increases risk to participants or adversely affects the rights and welfare of the participants.
- Continuing: repeated noncompliance by an individual investigator either on a single protocol or across multiple protocols, or a pattern of ongoing activities that indicate a lack of understanding of human subjects protection requirements that may affect research subjects or the validity of the research.
 - NOTE: Serious and Continuing Noncompliance is determined by the convened IRB Panel. Must be reported to regulatory authorities and the sponsor.

How to Review Noncompliance:

- Review all documentation, including fact finding by ORSP
- Determine if the noncompliance is serious or continuing based on the above definitions
- Determine whether the noncompliance was resolved successfully by the PI
- Determine if corrective actions are required
 - Research study specific corrective action*
 - Education of the investigator(s) and research team*
 - Modification to the protocol or other study documents*
 - Require that subjects be re-contacted and provided with updated information or re-consent subjects*
 - Notification of current subjects when such information may relate to subjects' willingness to continuing participating in the research*
 - Providing additional information to past subjects*
 - Limit or prohibit publication of data*
 - Discarding data or samples associated with the noncompliance*
 - Suspension or termination of the research*
 - Letter of reprimand to the investigator, which may be copied to the department chair*
 - Disqualify the investigator(s) from conducting research involving human subjects at VCU*
 - Require periodic monitoring or auditing*
 - Enforce more frequent continuing review*

HIPAA

Health Insurance Portability and Accountability Act (HIPAA) – Research involving access or use of *Protected Health Information (PHI)* is subject to compliance with HIPAA and must implement an appropriate **pathway**.

Protected Health Information (PHI): Individually **identifiable health information** that is obtained or used for treatment, payment or health care operations in a **covered entity**.

- Research studies using medical records as a source of person-identifiable research data
- Interventional clinical studies comparing safety and efficacy of treatments

PHI Identifiers

- Names
- All geographic subdivisions smaller than a state
- Some exceptions for 1st 3 digits of zipcode
- All elements of dates (except year) for dates directly related to an individual:
- Birth date
- Admission & discharge dates
- Date of death
- All ages over 89 and all elements of dates (including year) indicative of such age
- Ages 90+ can be categorized into ≥ 90
- Telephone numbers
- Facsimile numbers
- Electronic mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web universal resource locators (URLs)
- Internet protocol (IP) address numbers
- Biometric identifiers, including fingerprints and voiceprints
- Full-face photographic images and any comparable images
- Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification

HIPAA Pathways

- Review preparatory to research
- Signed participant authorization
- Waiver of authorization
- Partial waiver of authorization
- De-identified data
- Limited data set and data use agreement
- Research with decedents

Affiliated Covered Entities (VCU ACE)

- VCU Health System (VCUHS) and all satellite clinics
- School of Medicine
- School of Pharmacy
- School of Nursing
- School of Dentistry
- VCU Employee Health
- VCU Telecommunications
- VCU Audit & General Management
- VCU Police Services
- VCU Office of General Counsel
- VCU Office of Research and Innovation



FDA Regulations



U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

FDA regulated studies must follow all HHS and FDA regulations (some are different)

Reviewing FDA Regulated Studies

1. Confirm if the study is FDA regulated
 - Clinical Investigation of a test article for *safety and effectiveness*
2. If “YES,” determine exempt or non-exempt (flow charts)
 - Exempt: Meets the criteria for exemption – not required to follow 21 CFR 312 (Drugs) or 21 CFR 812 (Biologics) – Exempt from subset of regulations, still follow general FDA regs
 - Non-Exempt: Apply for IND or IDE (only significant risk devices) → follow extra regulations
 - **NOTE: Criteria for IRB Approval must still be met**
3. Consider Waiver Requirements
4. Determine Risk Level (full board vs. expedited)
5. Consider Records/Reporting Requirements
6. Consider Elements of Consent

FDA Regulated Products

- Drug
- Medical Device
- Biologic
- Dietary Supplement
- Food/Food Additive
- Color Additive
- Electronic Product for Human Use
- Other

Differences in HHS & FDA Regulations

HHS	FDA
<u>Research</u> : Systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge	<u>Research</u> : “Clinical Investigation” – any experiment that involves a test article and one or more human subjects
<u>Human Subject</u> : A living individual about whom an investigator conducting research obtains data through interaction or intervention with the individual or private identifiable information	<u>Human Subject</u> : Any individual who is or becomes a participant in research, either as a recipient of the test article or the control – either healthy or a patient.
<u>Data Retention</u> – Participants are allowed to withdraw data if the study allows (noted in IFC).	<u>Data Retention</u> – participants can’t withdraw data that has already been collected
<u>Waiver</u> - Full, some, documentation	<u>Waiver</u> – Only waiver is document of consent or EFIC, no waivers of parental permission/no waiver of doc of PP
Confidentiality will be maintained	Can inspect records
Consent does not need to be dated	Consent must be signed and dated. Waiver of IFC for military personnel

Drug/Biologic Determination Process

1

Describe the drug(s)/biologic(s) being used.

Describe how it is used in the study.

FDA Definition of Investigational New Drug:

- a new drug or biologic that is used in a clinical investigation, defined as...
- “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease...
- articles (other than food) intended to affect the structure or any function of the body of man or other animals...
- compounds intended to affect the structure or function of the body, without regard to whether the compound is intended to influence a disease process“
- Biologics (e.g. bacterial vaccines, allergenic extracts, gene therapy products, growth factors, cytokines, and monoclonal antibodies) applicable to the prevention, treatment, or cure of a disease or condition of human beings (FD&C Act, 201(g)(1))

2

Describe the sponsor/investigator’s assessment of whether the drug would qualify for exemption or need to submit an IND application to the FDA.

Explain whether or not you [the reviewers] agree with the sponsor/investigator’s initial assessment.

This determination should be based on the proposed use of the drug or combination of drugs in an investigation and not on the drug(s) alone.

3

If the IRB decides the drug is IND exempt:

1. State the Panel’s determination of IND exemption, and the rationale for the minutes.

Exemption criteria are listed on reverse side.

If the IRB decides the drug does not meet the exemption criteria:

1. State the Panel’s determination of IND required and the rationale for the minutes;
2. Letter will inform the sponsor/investigator of the IND decision along with any other instructions regarding the IND

IND Application: If the IRB determines that drug does not meet the exemption criteria, the sponsor/investigator must submit an IND application to the FDA

- Documentation of the IND number (or the IND exemption, if applicable) from the FDA must be provided before the protocol can be approved

4

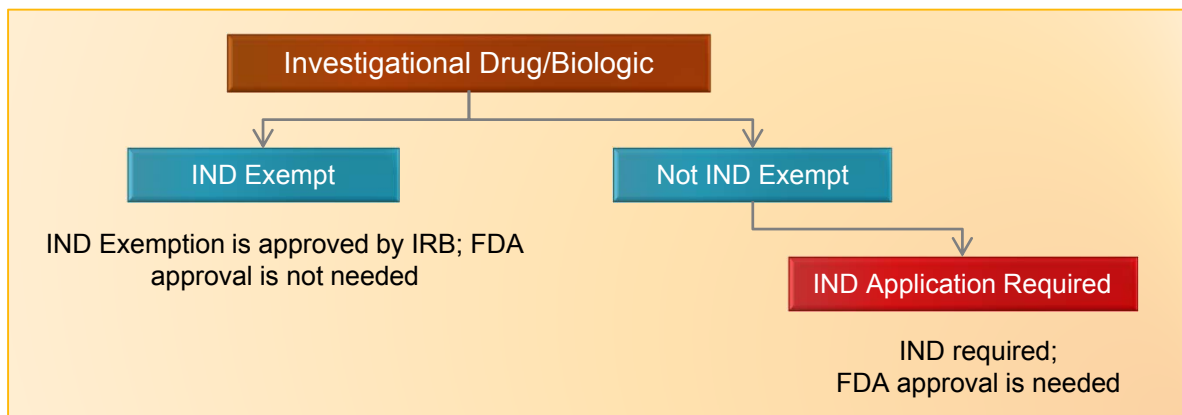
Proceed to review the study applying the criteria within 21 CFR 56.111 (45 CFR 46.111).

IND Exemption Criteria

A clinical investigation of a *marketed* drug is exempt from the IND requirements if all of the criteria for an exemption in § 312.2(b) are met:

- 1) The drug product is lawfully marketed in the United States.
- 2) The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication and there is no intent to use it to support any other significant change in the labeling of the drug.
- 3) In the case of a prescription drug, the investigation is not intended to support a significant change in the advertising for the drug.
- 4) The investigation does not involve a route of administration, dose, patient population, or other factor that significantly increases the risk (or decreases the acceptability of the risk) associated with the use of the drug product (21 CFR 312.2(b)(1)(iii)).
- 5) The investigation is conducted in compliance with the requirements for review by an IRB (21 CFR part 56) and with the requirements for informed consent (21 CFR part 50).
- 6) The investigation is conducted in compliance with the requirements of § 312.7 (i.e., the investigation is not intended to promote or commercialize the drug product).

Regulatory Status of Investigational Drugs



Full Board Device Determination Process

1

Describe the medical device being used.

Describe how it is used in the study.

Medical Device: "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: ...

- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or*
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes." (FD&C Act, 201(h))*

2

Describe the sponsor's assessment of whether the device presents a significant or non-significant risk, or is IDE exempt.

Explain whether or not you [the reviewers] agree with the sponsor's initial assessment.

The risk determination should be based on the proposed use of a device in an investigation and not on the device alone.

3

If the IRB decides the device is IDE exempt:

1. State the Panel's determination of IDE exempt, the category, and the rationale for the minutes.

Exemption categories are listed on reverse side.

If the IRB decides that the device's use in the study is Non-Significant Risk:

1. State the Panel's determination of NSR and the rationale for the minutes.

Non-Significant Risk: A NSR device investigation is one that does not meet the definition for a significant risk study.

If the IRB decides the device's use in the study is Significant Risk:

1. State the Panel's determination of SR and the rationale for the minute;
2. Add a note to the Panel's letter informing the sponsor/investigator of the SR decision along with any other instructions regarding the IDE.

Significant Risk: A SR device study is a study of a device that presents a potential for serious risk to the health, safety, or welfare of a subject and

- 1. is intended as an implant; or*
- 2. is used in supporting or sustaining human life; or*
- 3. is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or*
- 4. otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.*

4

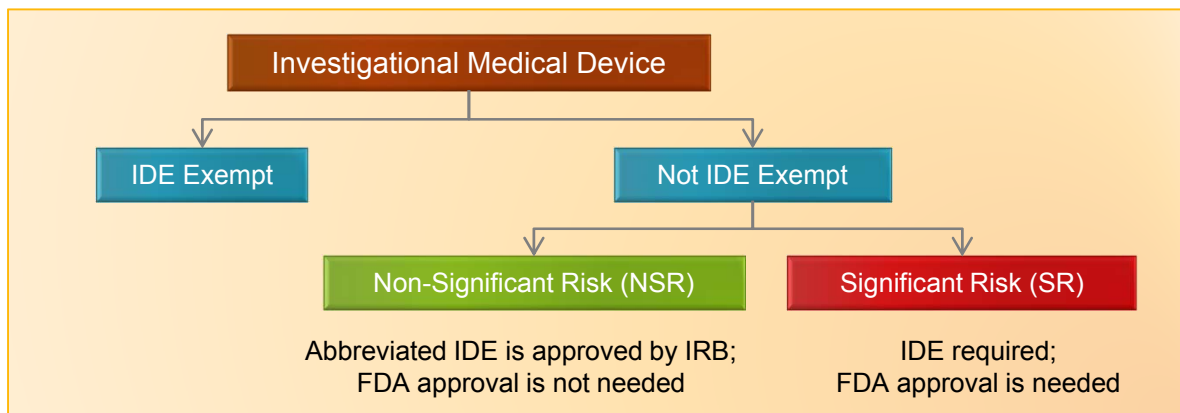
Proceed to review the study applying the criteria within 21 CFR 56.111 (45 CFR 46.111).

IDE Exemption Categories

21 CFR 812(c) provides exemptions from the Investigational Device Exemption (IDE) requirements; meaning 21 CFR 812 and the IDE requirements are not applicable when the device meets one of the criteria below:

- 1) A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.
- 2) A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.
- 3) A diagnostic device, if the sponsor complies with applicable requirements of 809.10(c) and if the testing is:
 - i. Is noninvasive,
 - ii. Does not require an invasive sampling procedure that presents significant risk,
 - iii. Does not by design or intention introduce energy into a subject, and
 - iv. Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
- 4) A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety and effectiveness and does not put subjects at risk.
- 5) A device intended solely for veterinary use.
- 6) A device shipped solely for research on or with laboratory animals and labeled in accordance with 812.5(c).
- 7) A custom device as defined in 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.

Regulatory Status of Investigational Devices



Subpart B: Pregnant Women and Fetuses

Pregnant women or fetuses may be involved in research if **ALL** the following [shaded boxes] are met. If not, the research may **not** be approved under Subpart B.

(a) Pre-clinical Data: Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

No ► [46.204 not met – NOT approvable]



Yes

N/A [not scientifically appropriate]



(b) Risk/Benefit Ratio: Does the research hold out the prospect of direct benefit for the woman or fetus?

No ►

Is the risk to the fetus greater than minimal?

No ►

Yes ► [46.204 not met – NOT approvable]



Is the purpose of the research for the development of important biomedical knowledge which cannot be obtained by any other means?

No ► [46.204 not met – NOT approvable]



Yes

Yes ►

Is the risk to the fetus caused solely by interventions or procedures that hold out the prospect of direct benefit for woman or fetus?

No ► [46.204 not met – NOT approvable]



Yes



(c) Least Possible Risk: Any risk is the least possible for achieving the objectives of the research;

No ► [46.204 not met – NOT approvable]



Yes



(d) Consent of Woman: Consent of pregnant woman is obtained in accord with the informed consent provisions of subpart A.

No ► [46.204 not met – NOT approvable]



Yes



(e) Consent of Father: If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

No ► [46.204 not met – NOT approvable]



Yes

N/A [research benefits woman or direct benefit solely to fetus does not apply]



On Back

(f) **Consent Includes Impact on Fetus:** Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

No ► [46.204 not met – NOT approvable]



Yes



(g) **Pregnant Children:** For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;

No ► [46.204 not met – NOT approvable]



Yes

N/A [children not enrolled]



(h) **Inducements to Terminate:** No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

No ► [46.204 not met – NOT approvable]



Yes



(i) **Termination Decision:** Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

No ► [46.204 not met – NOT approvable]



Yes



(j) **Neonate Viability:** Individuals engaged in the research will have no part in determining the viability of a neonate.

No ► [46.204 not met – NOT approvable]



Yes



If **ALL** of the above [shaded boxes] are met, Subpart B is met for pregnant women and fetuses, and can be approved.

Subpart C: Prisoners

Prisoners* may be involved in research if **ALL** of the following conditions [in shaded boxes] are met. If not, the research may not be approved under Subpart C.

* 45 CFR 46.303(c): "Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(1) Category: The research under review represents one of the categories of research permissible under §46.306(a)(2): [§46.305(a)(1)]

No ▶ None of the permissible categories, A-D, applies to the proposed research §46.305 **NOT** met.



i) study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects. [§46.306(a)(2)(i)]

(ii) study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects. [§46.306(a)(2)(ii)]

(iii) research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research. §46.306(a)(2)(iii)]

(iv) research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research. [§46.306(a)(2)(iv)]

(v) Epidemiological Research Waiver - An additional category of permissible research was added with publication of a waiver in the June 20, 2003 Federal Register as follows: Epidemiological Research - defined as 'public health research that focuses on a particular condition or disease in order to (i) describe its prevalence or incidence by identifying all cases, including prisoner cases, or (ii) study potential risk factor associations, where the human subjects may include prisoners in the study population but not exclusively as a target group [Fed. Reg. June 20, 2003], provided that the study presents no more than minimal risk and no more than inconvenience to the subjects (see definition of minimal risk unique to prisoners, above)



(2) Risk/Benefit ratio: Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired. [§46.305(a)(2)]

No ▶ §46.305 **NOT** met.



Yes



(3) Commensurate risk: The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers. [§46.305(a)(3)]

No ▶ §46.305 **NOT** met.



Yes



(4) Subject & control selection: Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers. [§46.305(a)(4)]

No ▶ §46.305 **NOT** met.



Yes



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Virginia Commonwealth University ♦ Institutional Review Board
Reviewer Checklist ♦ Subpart C: Research Involving Prisoners

(5) Language use: The information is presented in language which is understandable to the subject population. [§46.305(a)(5)]

No ► §46.305 NOT met.



Yes



(6) Parole status: Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole. [§46.305(a)(6)]

No ► §46.305 NOT met.



Yes



(7) Follow-up care: Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact. [§46.305(a)(7)]

No ► §46.305 NOT met.



Yes [i.e. follow-up care needed & adequate provisions have been made] ► **Subpart C: §46.305 met.**

N/A [i.e. follow-up care not needed] ► **Subpart C: §46.305 met.**



If **ALL** of the above [shaded boxes] are met, Subpart C is met for prisoners, and research can be approved.

Subpart D: Children

Children* may be involved in research if **ALL** the following [shaded boxes] are met. If not, the research may **not** be approved under Subpart D.

*HHS regulation 45 CFR 46.402 (a) and FDA regulation 21 CFR 50.3 (o): "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

**HHS regulation 45 CFR 46.402 (a) and FDA regulation 21 CFR 50.3 (n): "Assent" means a child's affirmative agreement to participate in a clinical investigation. Mere failure to object may not, absent affirmation agreement, be construed as assent.

When both parents were alive, known, competent, reasonably available, and is legal responsibility for the care or custody of the child, the IRB is required to determine whether the permission of both parents was required or whether the permission of one parent is sufficient. Please address this requirement.

1) Level of Risk

None of the permissible categories apply to the proposed research – Subpart D not met



No greater than minimal risk

Greater than minimal risk **with** prospect of direct benefit.

More than minimal risk to children is presented by:

- An intervention or procedure that holds out the prospect of direct benefit for the individual subject
- OR
- A monitoring procedure which is likely to contribute to the well-being of the subject

Is the permission of one parent sufficient?

No Yes



In addition, the IRB has found:

- (a) the risk is justified by the anticipated benefits to subjects
- (b) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.

Greater than minimal risk **with NO** prospect of direct benefit, but likely to yield generalizable knowledge about the subject's disorder or condition. More than minimal risk to children is presented by:

- An intervention or procedure that holds out the prospect of direct benefit for the individual subject
- OR
- A monitoring procedure which is NOT likely to contribute to the well-being of the subject

In addition, the IRB has found:


- (a) the risk represents a minor increase over minimal risk
- (b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social educational situations.
- AND
- (c) The intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding of amelioration of the subject's disorder or condition.

Both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.



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2) Parental Permission: Adequate provisions under [HHS 46.116] [FDA 50.55] are made for soliciting the permission of each child's parents or guardian.

No ► [HHS 46.116] [FDA 50.55] **NOT** met  Yes




3) Waiver of Parental Permission

Is the research regulated by the FDA?

Yes ► FDA **DOES NOT** allow waiver of parental permission



No 

Yes – Parental permission waived under [HHS 46.408 (c)]. Parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), provided an appropriate mechanism for protecting children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State or local law.

Yes – Parental permission waived under [HHS 46.116]

No – [HHS 46.408 (c)] or [HHS46.408] **NOT** met



4) Documentation of Parental Permission: Permission by parents or guardians shall be documented in accordance with and to the extent required by [HHS 46.117 of Subpart A] & [FDA 50.27 & 56.109 (c)]



5) Assent of Children: In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgement may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate.

The IRB has determined that some or all of the children involved in the research are capable of assenting.

➔ **Can the assent be waived?**

Yes: All 4 conditions are met. [May only be waived when research is no more than minimal risk as determined by section 1]

- No more than minimal risk
- Waiver will not adversely affect rights/welfare of subject
- Research could not be practicably be carried out without waiver
- Pertinent information provided later, if appropriate

No: The IRB has determined that assent is required and adequate provisions are made for soliciting the assent of children.

Must Assent be documented?

No: Provide justification

Yes: Specify how assent will be documented

Assent is not required because the IRB has determined that the capability of some or all of the children is so limited that they cannot reasonably be consulted.

Assent is not required because the IRB has determined that the intervention or procedure involved in the research holds out a prospect for direct benefit that is important to the health or well-being of the children AND is available only in the context of the research.



If **ALL** of the above [shaded boxes] are met, Subpart B is met for pregnant women and fetuses, and can be approved.

Written Policies and Procedures Part I

For specific Policies and Procedures, please view the most up to date list on the [ORSP Website](#).



VCU

VIRGINIA COMMONWEALTH UNIVERSITY

Panel Meeting Guidance

Meeting Procedures

Regular Meeting Schedule:

- 1) The panel Chair will call meeting to order when quorum (majority +1) is met
- 2) Panel Education
- 3) Other panel business (reminders, updates, etc.)
- 4) Review and vote of previous meeting's minutes – those who were not present at that meeting abstain from voting
- 5) Review Research Studies
 - 1) Study will be projected on screen
 - 2) Primary reviewer summarizes the study
 - 1) During this time, you should address the checklist
 - 3) Reviewer discusses findings/ concerns
 - 1) May call PI at this time with questions
 - 4) Secondary reviewer discusses findings/concerns
 - 5) Reviewer makes a recommendations
 - 6) Discussion (Other panel members should be familiar with the study and ready to discuss)
 - 7) Chair will ask "Do we have a motion?"
 - 1) Someone will make a motion (see next page)
 - 2) Someone else will "second" the motion
 - 3) The Chair will then ask for the votes

Meeting Procedures

Member Responsibilities: Pre-Meeting

- *All members* (even without official reviewer duties), should read and be familiar with all proposed research being discussed, in order to fully participate in discussion at the meeting.
- *Primary & Secondary Reviewer:*
 - Conduct a timely, thorough review of all materials related to the assigned protocol
 - Contact the Panel Administrator/Chair if additional expertise is necessary
 - Conduct informal queries of the PI and/or other experts in order to provide a thorough review
 - Write your final reviewer comments*

****Final Reviewer Comments:***

Final reviewer comments submitted for full board studies should be based on the Criteria for IRB Approval. See the page titled “Reporting on Your Review” for all items that should be included.

Member Responsibilities: During the Meeting

- *All members* should fully participate in discussion and decision making
- *Primary Reviewer:*
 - Provide a brief summary of the study, lead the discussion of any issues or concerns with the study, determine whether the study meets criteria for approval, and make a motion
 - Coordinate review comments with the secondary reviewer
 - Present specific recommendations for panel action, including changes and/or questions in written form to the Panel Coordinator
- *Secondary Reviewer:*
 - Lead discussion of the informed consent document, requests for waivers, and recruitment procedures, focus on disagreements with primary reviewer
 - Present specific recommendations for panel action, including changes and/or questions in written form to the Panel Coordinator.
 - NOTE: Secondary reviewer is asked to record any scripted (specific) changes requested/required directly on his/her copy of the documents and provide the marked copy to the Panel Coordinator following the final vote.

Member Responsibilities: Post-Meeting

- Follow up on any unfinished business, such as approval with condition

Motions & Voting

How to Make a Motion

“**I move that this** (study / amendment / CR / report) **be** (approved / conditionally approved / tabled / disapproved / deferred).”

• Possible Motions

- **Motion 1 - Approval:** The study can be implemented under the approved submission. Motions to approve should note:
 - *Criteria for Approval 46 CFR 111*
 - Risk Determination
 - HIPAA Pathways used (if applicable)
 - Special Population Criteria (See Subpart Documents)
- **Motion 2 - Approval with Conditions-** There is enough information to determine that all *Criteria for Approval 46 CFR 111* are met, and only directive changes are needed.
- **Motion 3 - Table:** There is NOT enough information to determine that all *Criteria for Approval* are met. Significant changes or clarifications are required, and the study will be reviewed again at the full board. All *Criteria for Approval 46 CFR 111* are NOT met.
- *Rarely Used: Disapproval, Suspended, Termination*

Amending Your Motion

- Amending a motion lets you... Add or take away conditions or requested changes and/or change elements of the review (i.e., a children’s category or that conditions for a waiver of consent are met.)
- The person who made the motion says, “**I amend my motion to** ____ “

Withdrawing Your Motion

- The person who made the motion says, “**I withdraw my motion.**” This opens the floor for someone else to propose a new motion.

•

Voting Options

Yes	In favor of the motion
No	Against the motion
Abstain	Decline to vote
Recuse	Decline to participate

***It’s OK to Vote “No”**

Voting does not have to be unanimous. If you do not agree with the proposed motion, it is OK to vote “No.”

Who Votes?

- Only members and alternates (if regular member is not voting)
- Chair usually abstains from voting unless necessary to break a tie
- Anyone with a conflict of interest may not vote
- Votes by proxy are not allowed
- *Note: A favorable vote of the **majority** of members is required to approve research*

Reporting on Your Review

Initial Review

- Criteria for Approval (46.111)
- Risk Level of Study
- Period of Approval
- PI's Qualifications
- Review all criteria for inclusion of any vulnerable populations
 - Children/wards, pregnant women/fetuses, neonates of uncertain viability, nonviable neonates, prisoners, decisionally impaired adults, Limited English Proficiency subjects

Continuing Review

- Criteria for Approval (46.111)
- Risk Level of Study
- Period of Approval
- Confirm all criteria for inclusion of any vulnerable populations
 - Children/wards, pregnant women/fetuses, neonates of uncertain viability, nonviable neonates, prisoners, decisionally impaired adults, Limited English Proficiency subjects

Amendment

- Criteria for Approval (46.111)
- Risk Level of Study
- Confirm all criteria for inclusion of any vulnerable populations
 - Children/wards, pregnant women/fetuses, neonates of uncertain viability, nonviable neonates, prisoners, decisionally impaired adults, Limited English Proficiency subjects

Additional IRB Requirements

- Grant Congruency
- New PI's qualifications
- Criteria for waivers of consent
- IND or IDE requirements
- Requirements if funded by:
 - Dept. of Defense/Navy
 - Dept. of Education
 - Dept. of Justice