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1. Reviewer Worksheets

HRPO worksheets are used to document consideration of and adherence to local and federal policies and regulations. There are worksheets to be completed as part of the general submission review (such as the Initial, Modification, and Renewal worksheets) and there are worksheets to address specific regulatory determinations (such as a waiver of HIPAA/Consent, or inclusion of subparts B, C, or D).

LOCATION: The most recent versions of all worksheets are available on the HRPO website:

<https://www.hhrinstitute.org/researcher-resources/ohsr/hrpo-worksheets/>. The direct link can be found on the *IRB & CRC member resources* page.

The general submission worksheets are used at all review levels (Exempt, Expedited, and Full Committee). Instructions are provided at the top of each worksheet describing which sections must be completed for each review level.

Hennepin Healthcare

HUMAN RESEARCH PROTECTION Initial review

Number 709 Version Date 14 FEB 2021

Resource type WORKSHEET <https://www.hhrinstitute.org/researcher-resources/ohsr/hrpo-worksheets/>

Complete this worksheet in accordance with the review type:

	REVIEW TYPE		
	EXEMPT	EXPEDITED	CONVENED IRB
required sections	1 and 9	1-8	1-7
optional sections	10	10	10
completed by (Reviewer)	analyst/reviewer	designated reviewer	primary reviewer

This worksheet must be finalized and saved electronically in accordance with 203 SOP Using worksheets with Cayuse HE

1. General considerations

HE ID: Click or tap here to enter text. Principal Investigator: Click or tap here to enter text.

1.1 Serving as Reviewer for this submission. I attest that I have reviewed. True False **STOP—contact HRPO**

708 WORKSHEET – REVIEWER WORKSHEET LIST: The 708 Worksheet is completed by the IRB analyst before assigning a submission to a Primary Reviewer. The 708 captures general regulatory oversight but also indicates what worksheets must be completed in the review. If a box is checked under the “Required reviewer WORKSHEET” column, the worksheet must be completed as part of the submission review. A submission type review document will also be indicated on the 708 (Initial, Modification, or Renewal).

The **primary reviewer** should consult this document to ensure all required worksheets are completed in their review. Other IRB members may find it helpful to review the regulatory oversight indicated on the 708, but do not need to consult this document as part of a general review.

2. Guidance Documents

In addition to revised reviewer worksheets, there are several new or revised guidance documents to be referenced by the IRB and research community. Guidance documents are not completed or saved as part of a submission review, but can be referred to, as necessary, for additional support or clarity. You may notice certain reviewer worksheets refer to guidance documents. For example, 197 GUIDANCE- Criteria for IRB Approval may be referred to for additional detail regarding the criteria of approval for a submission.

LOCATION: Guidance documents are available on the HRPO website: <https://www.hhrinstitute.org/researcher-resources/ohsr/>.

3. Navigating Cayuse for review of Initial submission

The initial submission is where all of the study information and attachments are collected. From the Submission Details page, click Review (under the study title) to view the smartform.

NOTE: The Attachments tab does not display submission documents until after the submission is approved. The Attachments tab can be used to view documents on a submission *after* it has been approved, but it will not display documents for pending review items.

Under Review

Initial
IRB-FY2021-31-TEST_1.6_jb

Review PDF Delete Checklist

PI: Erin Venegoni
Current Analyst: Jennifer Boe
Decision: N/A
Policy: Post-2018 Rule
Required Tasks: N/A

Review Type: Full Board
Review Board: IRB
Meeting Date: [02-25-2021](#)

Approvals Task History Meetings Attachments

Research Team

Name	Role	Result	Date
Erin Venegoni	Principal Investigator	Certified	02-19-2021 4:38 PM
Erin Venegoni	Primary Contact	Completed by Erin Venegoni	

Once in the submission, click on SUBMISSION DETAILS to return to the submission details page. You can click on each smartform page to go to the different sections or you can use the arrows to the right of the screen to move through each page.

NOTE: The submissions have built in logic. Different questions and pages will appear depending on the response to each question. Depending on the details of the study, you will not always see the exact same submission structure.

Dashboard Studies Submissions Tasks Meetings

IRB NUMBER: IRB-FY2021-31
TEST_1.6_jb - Initial

SHOW CHECKLIST CREATE PDF COMPARE SAVE

Getting started

Submission Intro

COI attestation

Sponsor info

Site info

Study personnel

Study protocol

Study activities

Risks and benefits

Recruitment

Informed consent

HIPAA

Study data

List of attachments

Getting started

Consider questions carefully

Cayuse HE is a SmartForm web application - as you proceed to answer questions, additional questions may appear based on your responses; you may also see additional sections added on the left as you proceed. If you answer a question not as intended, the appropriate sections may not appear or inappropriate sections may appear. You may revise sections at any time prior to IRB approval.

As you complete the application, your information can be saved; you don't have to finish all sections in one session.

For tips or technical support, you may refer to the [Cayuse Help Center](#) or contact [HREO](#) for assistance.

IMPORTANT - Attachments

All attachments submitted for IRB approval must have a file name that includes a version number and date for the IRB to reference for approval. In addition, the version and date must be present in the body of the attachment (e.g., title page, header, and/or footer) that corresponds to the file name version and date.

Principal Investigator responsibilities

- Certifying submissions
- Ensuring that all Institutional approvals have been obtained, as appropriate
- Maintaining oversight of study activities to ensure scientific integrity and regulatory compliance
- Reviewing and accepting Hennepin Healthcare [Principal Investigator responsibilities](#)

Hennepin Healthcare IRB oversight

Comments in Cayuse HE

The **analyst** and **primary reviewer** may add **RESTRICTED** or **UNRESTRICTED** comments to almost any item in the smartform. Restricted comments are not visible to the study team. If you are not assigned as the primary reviewer of an item, you will not need to add or respond to any comments in the submission.

Click Expand Comments to view previous comments left by the analyst, study team, and/or reviewer. These comments could be internal notes/ reminders or comments to request clarification from the study team. Any unrestricted comment requesting clarification would also be noted as “resolved” once the analyst or reviewer marked it as resolved.

Submission intro

* Hennepin Healthcare Principal Investigator/Project Director (PI/PD)

If you do not find the person you are looking for listed, please contact [HRPO](#) for assistance

Name	Organization	Address	Phone	Email
Erin Venegoni	HRPO			evenegoni@hhrh

Expand Comments

* Status

Is the PI/PD a resident or fellow?

- NO
 YES

+ Add Comment

* Primary Contact (PC)

The PC may be the PI/PD or another person to manage this submission. By default, the PC is the person initiating the

IMPORTANT: If a PC is also conducting human research activities, s/he must be listed in the Study personnel section

You may add more than one PC using the FIND PEOPLE button; the PI and PC(s) will receive all notifications regarding

For ALL sponsored research: use the FIND PEOPLE button to add Grants and Contracts Team as a Primary Contact.

If you do not find the person you are looking for listed, please contact [HRPO](#) for assistance

Name	Organization	Address	Phone	Email
Erin Venegoni	HRPO			evenegoni@hhrh

+ Add Comment

Once you click Expand Comments, you will see the name of who left the comment, the date/time, and visibility.

NOTE: Restricted comments cannot be seen by study team members (Image 1). UNrestricted comments were visible to the study team as initial clarification requests and should be marked as resolved (Image 2).

Image 1 on intro

* Hennepin Healthcare Principal Investigator/Project Director (PI/PD)

If you do not find the person you are looking for listed, please contact [HRPO](#) for assistance

Name	Organization	Address	Phone	Email
Erin Venegoni	HRPO			evenegoni@hhrh

Collapse Comments

Jennifer Boe Today at 2:04 PM Visibility: Restricted
INSTRUCTIONS for PRIMARY REVIEWER:
708 attached for reference. 720 completed and provided for reference. Please complete the 709 worksheet. Once complete, reply to this comment and attach the final document.

- 708-WORKSHEET-Reviewer-worksheet-list-2021-31.docx
- 709-WORKSHEET-Initial-review_2021-31.docx
- 720-WORKSHEET-Informed-consent_2021-31.docx

Reply

JBoe Reviewer Today at 5:23 PM

- Final Reviewer Worksheets attached.
- 709-WORKSHEET-Initial-review_2021-31_JB.docx
- 720-WORKSHEET-Informed-consent_2021-31_JB.docx

Image 2 Healthcare other personnel

Is there Hennepin Healthcare personnel who may carry out study activities involving human subjects (e.g., clinic providers/s

- NO
 YES

Collapse Comments

Jennifer Boe Today at 1:47 PM Visibility: Unrestricted
Clarification to the study team (UNrestricted / visible to study team). No actual change necessary - please reply with DONE and return :)

Reply

Resolved Today at 5:19 PM by Jennifer Boe

Rich text editor toolbar

Reply text input field

SAVE COMMENT

Viewing Study Documents

Various pages of the smartform will solicit certain documents from the study team. Any document uploaded in the smartform will also be visible on the final LIST OF ATTACHMENTS page. For example, a protocol uploaded on the PROTOCOL page is the same document which appears under the protocol section of the LIST OF ATTACHMENTS page. The LIST OF ATTACHMENTS page will be an easy way to download all study documents from one page; however, it is still important to review the smartform since some information is collected in the responses and not necessarily provided in the documents attached.

The screenshot shows the 'Study protocol' section of the smartform. The left sidebar lists sections from 'Getting started' to 'List of attachments', with 'Study protocol' highlighted. The main content area is titled 'Study protocol' and contains the following text:

A poorly written protocol can contribute to substantial delays in IRB approval, especially for Investigator-initiated studies. The primary basis for the proposed research; it defines the study objectives, the population to be studied, the procedures to be followed, the evaluation and the plan for analysis. It also describes the administrative aspects of the study such as safety management and regulatory issues.

It is the responsibility of the PI/PI/D to ensure that the protocol serves as a robust, stand-alone document that fully describes the overall study to the external audience, and that all information provided in the sections of this submission are consistent with the attached protocol, a document that is IRB processed and approved.

Attach study protocol

IMPORTANT: Attachments must include a version number and date for the IRB to reference in the approval letter. In addition, a version number must be present in the body of the protocol (e.g., title page, header, and/or footer) and correspond to the file name version and date.

If this is a Modification submission with a previously approved protocol showing, delete it (click the X next to it) and then click the 'Add' button to upload a modified version to be approved.

Protocol v1.docx

Add Comment

Resources for protocol development

The screenshot shows the 'List of attachments' section of the smartform. The left sidebar lists sections from 'Getting started' to 'List of attachments', with 'List of attachments' highlighted. The main content area is titled 'List of attachments' and contains the following text:

Review this section after you've completed your submission (i.e., when all the other sections on the left have a checkmark).

IMPORTANT:

The ATTACH icons with files listed below them show the attachments that have been added as you completed each section. Attachments submitted for IRB approval must have a file name that includes a version number and date for the IRB to reference. In addition, a version and date must be present in the body of the attachment (e.g., title page, header, and/or footer) and correspond to the file name version and date.

No attachment will be shown under the ATTACH icon if it was not requested as part of the submission - you do not need to request attachments.

If this is a Modification submission to approve a revised attachment, the file listed should be the modified version of the attachment.

Study protocol

Protocol v1.docx

Expand Comments

Consent/assent document(s)

4. Finding completed Primary Reviewer worksheets

The primary reviewer's completed worksheets will be available to all IRB members in order to assist in their own review. To find the worksheets for a new INITIAL submission, go to the Submission Intro page and click Expand Comments under the PI name.

Submission intro

Henepin Healthcare Principal Investigator/Project Director (PI/PD)

If you do not find the person you are looking for listed, please contact [HRPO](#) for assistance

Name	Organization	Address	Phone	Email	Trainings
Erin Venegoni	HRPO			evenegoni@hhrinstitute.org	View

Expand Comments

Status

Is the PI/PD a resident or fellow?

NO
 YES

+ Add Comment

Primary Contact (PC)

The PC may be the PI/PD or another person to manage this submission. By default, the PC is the person initiating the submission.

IMPORTANT: If a PC is also conducting human research activities, s/he must be listed in the Study personnel section.

You may add more than one PC using the FIND PEOPLE button; the PI and PC(s) will receive all notifications regarding the submission.

NOTE: Be sure to view the most recent copy of the worksheet. Clicking on the attachment from an older comment will not bring up the complete/final version of the worksheet.

Submission intro

Henepin Healthcare Principal Investigator/Project Director (PI/PD)

If you do not find the person you are looking for listed, please contact [HRPO](#) for assistance

Name	Organization	Address	Phone	Email	Trainings
Erin Venegoni	HRPO			evenegoni@hhrinstitute.org	View

Collapse Comments

Jennine Roe Today at 2:04 PM Visibility: Restricted

INSTRUCTIONS for PRIMARY REVIEWER:
708 attached for reference. 720 completed and provided for reference. Please complete 709 worksheet. Once complete, reply to this comment and attach the completed document.

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Reply

Jboe Reviewer Today at 5:23 PM

Final Reviewer Worksheets attached.

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