HUMAN RESEARCH PROTECTION

Serving as a Designated Reviewer

Resource type IRB Member Job Aid

Version Date 11 NOV 2021

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1. Role of a Designated Reviewer

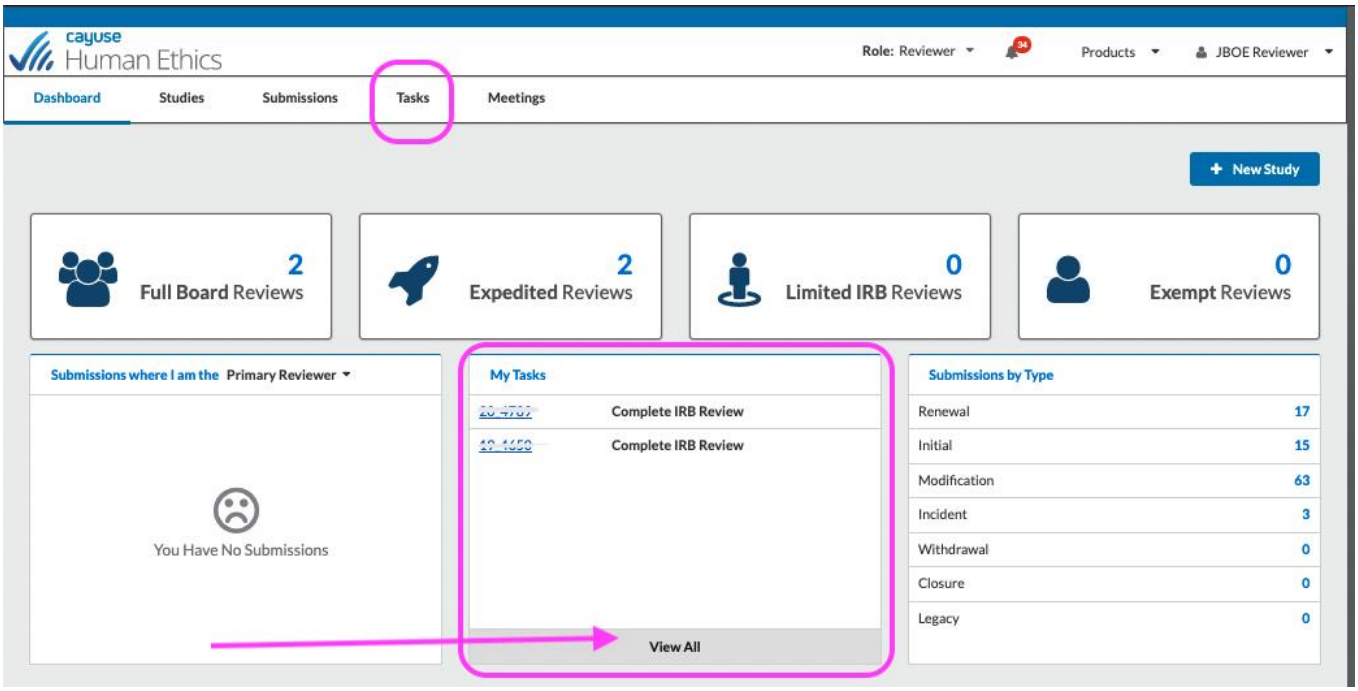
A designated reviewer is an IRB member who completes non-convened IRB reviews. Designated reviewers are assigned submissions to be completed on their own and will complete all the required reviewer worksheets, as well as the Make Decision function in Cayuse HE. Submissions assigned to a designated reviewer are in addition to convened IRB meeting agendas.

Designated reviewers should complete their reviews **within 7 days** of being assigned. They must communicate with the IRB analyst, as soon as possible, if they anticipate any delay or if they are not available to complete the review.

2. Notifications & Finding tasks assigned in Cayuse HE

When a submission has been assigned, the designated reviewer will receive an email notification (from Cayuse) and the submission will appear under their tasks in Cayuse HE. An IRB analyst will also email the designated reviewer.

The My Tasks square on the dashboard view will only display a limited number of tasks. To see a complete list of tasks (or submissions ready for your review), click the **Tasks** tab at the top of Cayuse HE. Or click *View All* at the bottom of the My Tasks square.



REMINDER: Tasks assigned to you as a designated reviewer AND those assigned to the convened IRB will appear under *My Tasks*. When you are assigned as a designated reviewer the email notification from Cayuse will say that the submission has been assigned to you for *expedited* review. The IRB analyst will also clarify this in their email.

3. Conducting your review

Similar to a primary reviewer of a submission assigned to the convened IRB, the designated reviewer must complete all required reviewer worksheets. The IRB analyst will attach the reviewer worksheets as a restricted comment before assigning you as a designated reviewer in Cayuse HE.

Where to find reviewer worksheets:

For **INITIAL** and **MODIFICATION** submissions → the Submission Intro page, *under the PI name*

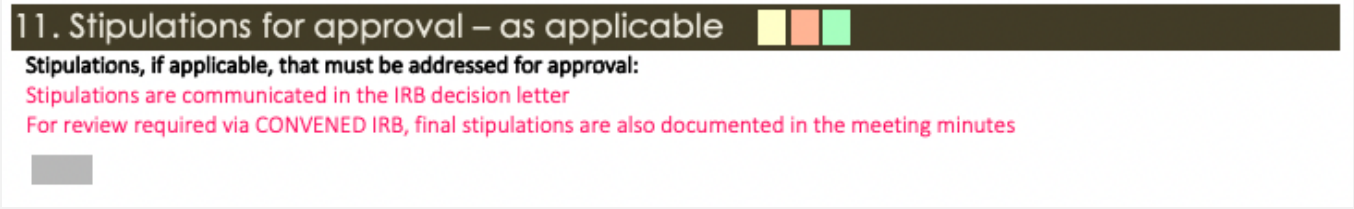
For **RENEWAL** submissions → the Criteria Check page, *under the study status question*

For **INCIDENT** submissions → the Incident/New Information page, *under the incident type question*

FIRST, the designated reviewer should review the 708 WORKSHEET to see a regulatory overview of the study and the type of worksheets to be completed for the submission. The designated reviewer should also open and review all the required reviewer worksheets attached, starting with the submission type worksheet (709, 724, 727, or 713 WORKSHEETS). Then The IRB analyst typically adds notes in the worksheets and it is best to review these notes before starting your own review.

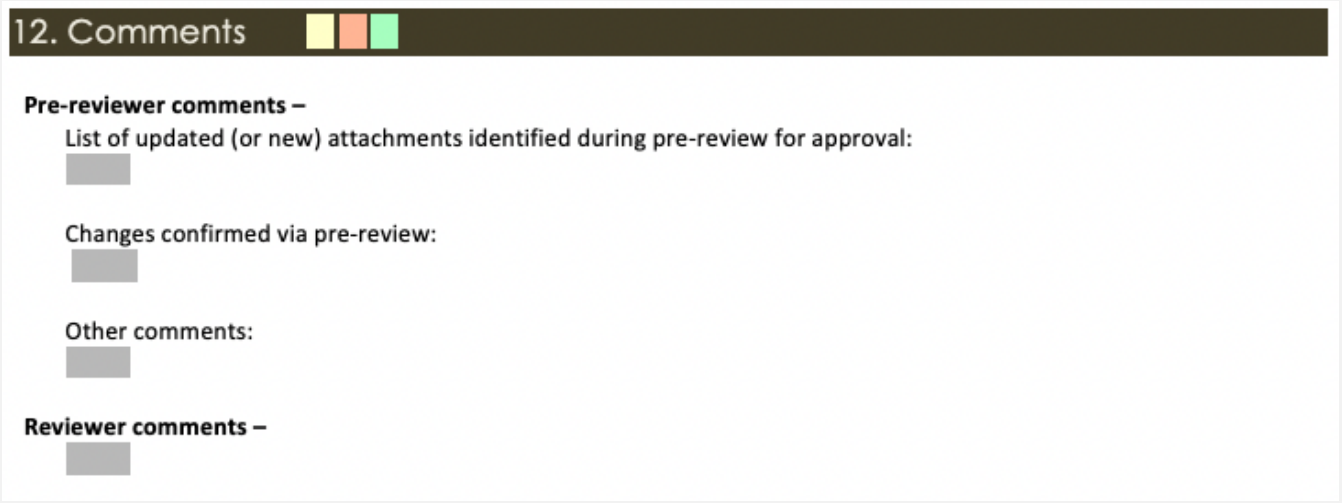
If the IRB analyst notices stipulations (during the pre-review) which should be required, they will list them in the ***Stipulations for approval*** section* of the worksheet. The designated reviewer may list additional stipulations in this section as well.

**Please note that the number and information in these sections vary slightly depending on the submission type.*



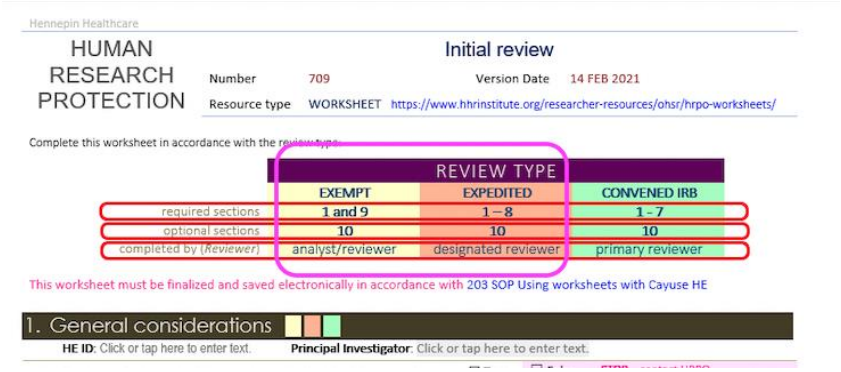
The IRB analyst will summarize relevant information in the ***Comments*** section* of the worksheet under *Pre-Reviewer comments*. This section will not be used to summarize the submission; the IRB analyst will summarize any information or additional context that may be helpful for the designated reviewer to know in advance.

**Please note that the number and information in these sections vary slightly depending on the submission type.*



SECOND, the designated reviewer should review the smartform, review any new or revised study materials, and complete the required reviewer worksheets. Additional resources and job aids for completing certain types of reviews are available on the IRB Member Resources page of the HRPO website.

> **REMINDER:** You may not need to complete all sections of the submission type worksheet (709, 724, 727, or 713 WORKSHEETS), depending on the type of review and overall study level determination (exempt or expedited). Review the instructions at the top of the worksheet (see below) or contact the IRB analyst for clarification, if you are not sure which sections need to be completed. Also, please note that this information will vary depending on the submission type and necessary worksheet.


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.

Once the review is complete, the designated reviewer will reply to the restricted comment where the IRB analyst originally attached the worksheets and attach the final versions.

> **REMINDER:** Designated reviewers should save final reviewer worksheets with their initials in the file title (for example, *709_WORKSHEET_IRB-FY2021-123_**jb**.doc*).

THIRD, the designated reviewer must complete the **Make Decision** function in Cayuse in order to finalize their review. Completing the Make Decision function is what returns the submission to the IRB analyst and removes it from the designated reviewer's *Tasks*. See section 4 below for additional instructions on this step.

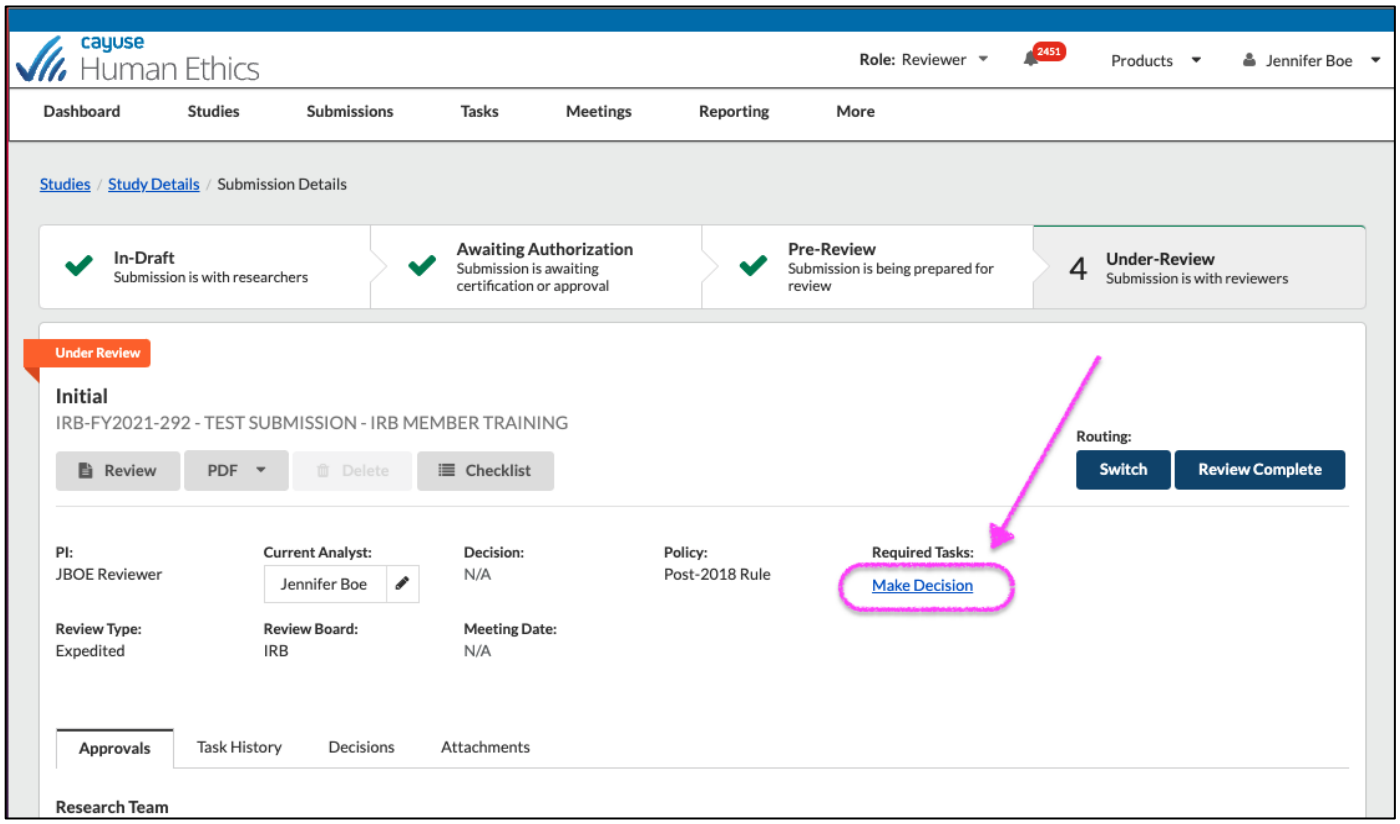
4. Completing the Make Decision function

Once the reviewer worksheets have been attached, the designated reviewer must complete the Make Decision function in Cayuse. Completing this step will return the submission to the IRB analyst, so the worksheets must be attached ***before*** the Make Decision step is complete. Once the submission is returned to the IRB analyst, the designated reviewer will have *view only* access and will no longer be able to comment in the submission.

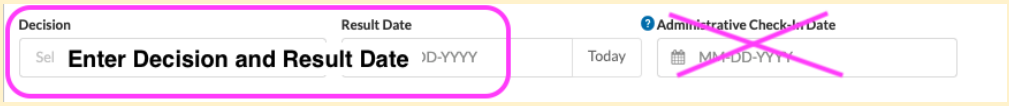
The IRB analyst will review the reviewer worksheets and the information provided in the Make Decision function; if there is any clarification necessary, the IRB analyst will follow up with the designated reviewer. The IRB analyst will clean up the Make Decision function and add in any other additional language necessary (for example, stock language for any regulatory determinations approved).

On the *Submission Details* page, you will see the **Make Decision** function under **Required Tasks**. After you have completed your review and attached all required worksheets, click Make Decision to enter a determination and return the submission to the IRB analyst.

NOTE: You will not see the Make Decision function on submissions assigned to the convened IRB.



STEP 1: Complete the **Decision** and **Result Date**. Leave the Administrative Check-In Date empty.



DECISION:

There are several options in the Decision menu, but the common selections are described below:

- **APPROVED:** Select this option when the submission is approved as is, without any additional stipulations.

- **MINOR STIPULATIONS:** Select this option when the submission has conditional approval, with minor revisions required. Remember that Minor Stipulations must be prescriptive in nature; Minor Stipulations are not requests for clarification. If the necessary stipulations prevent the IRB from confirming the criteria for approval (see 197 GUIDANCE), the submission cannot be approved with Minor Stipulations.

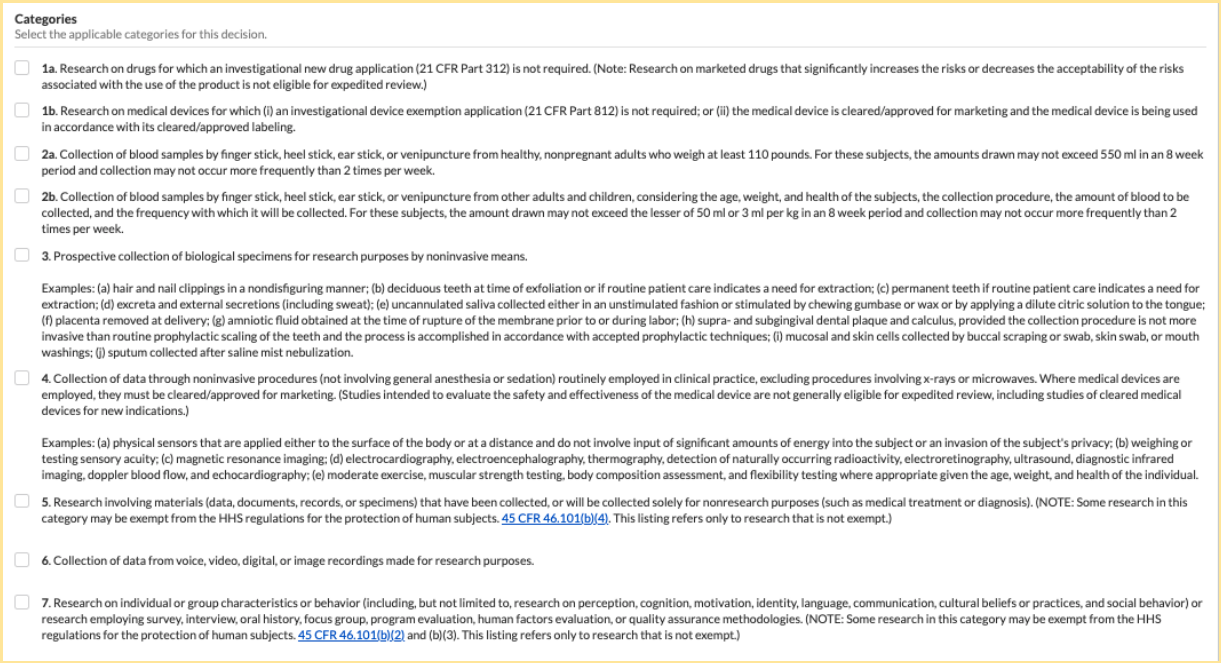
  NOTE: *When a submission is approved with Minor Stipulations, the IRB analyst will review the PI's response. The submission will not be returned to the designated reviewer, unless the IRB analyst requires assistance in evaluating the appropriateness of the PI's response.*

- **RETURN TO PI:** Select this option when you are not able to approve the submission but require additional clarifications from the PI. The clarification requests must be added as comments within the smartform or described in the INTERNAL NOTES section (see more about this in **STEP 3** below).

  NOTE: *When selecting Return to PI, the submission will be returned to the designated reviewer once the PI has responded to the clarifications requested. Return to PI is not a conditional approval.*

RESULT DATE:
The result date will always be the date you are completing the review. You can click on *Today*, to automatically enter today's date.

STEP 2: Select the appropriate categories for the submission under review.



Categories
Select the applicable categories for this decision.

- ☐ **1a.** Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
- ☐ **1b.** Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- ☐ **2a.** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.
- ☐ **2b.** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- ☐ **3.** Prospective collection of biological specimens for research purposes by noninvasive means.

  Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
- ☐ **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. 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.)

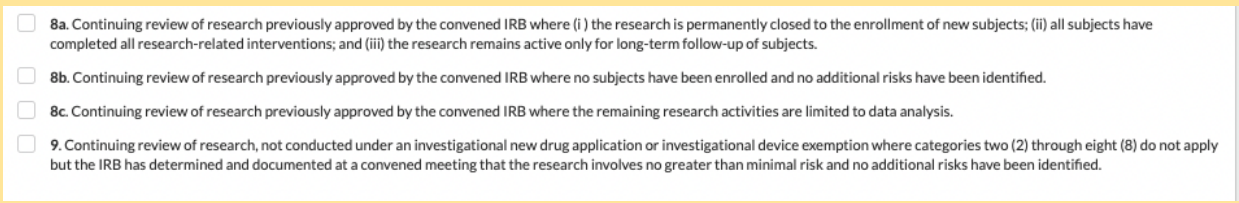
  Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- ☐ **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.)

For an **INITIAL** submission, check all categories which apply to the new study. These must match the categories selected on the Expedited Categories page of the smartform.

For a **MODIFCIATION** submission, do not select any categories. Leave all categories UNchecked.

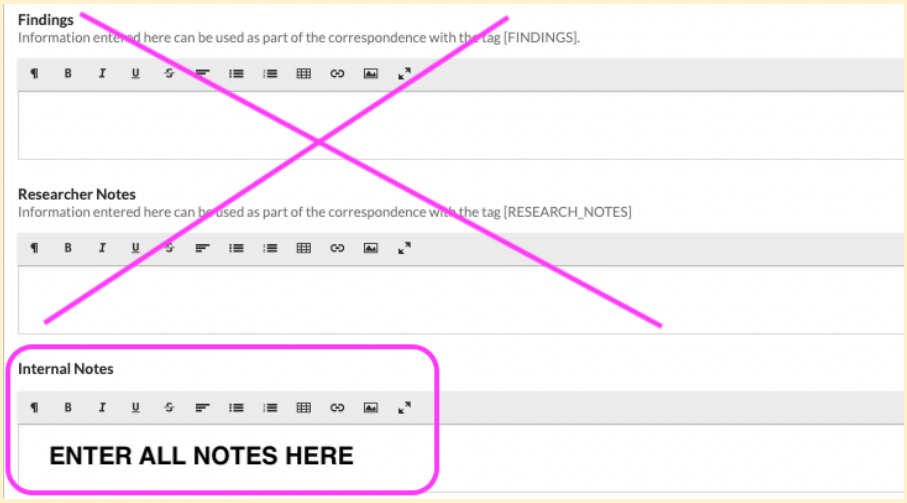
For a **RENEWAL** submission on a study originally approved under Expedited Review Categories, check all categories that apply to the overall study.

IMPORTANT: Categories 8(a-c) and 9 (see below) only appear for Renewal submissions and only apply to studies originally approved by convened IRB. These categories are not used to for studies originally approved under Expedited Review. The original review level can be found at the top of the 708 WORKSHEET.



- ☐ **8a.** Continuing review of research previously approved by the convened IRB 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.
- ☐ **8b.** Continuing review of research previously approved by the convened IRB where no subjects have been enrolled and no additional risks have been identified.
- ☐ **8c.** Continuing review of research previously approved by the convened IRB 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.

STEP 3: Complete the **INTERNAL NOTES** section. Leave the **FINDINGS** and **RESEARCHER NOTES** sections empty.



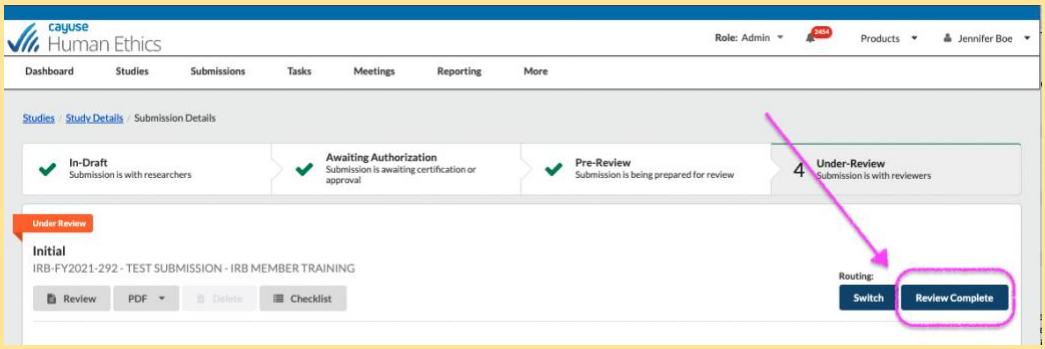
The **INTERNAL NOTES** section will never pull into the IRB letter and will not be shared with the PI. Formatting is not important in this section. You do not need to add notes here; you provide your reviewer comments in the submission type reviewer worksheet and you indicate your determination in the DECISION section of the Make Decision. However, if you have additional notes to provide, you may enter them in here.

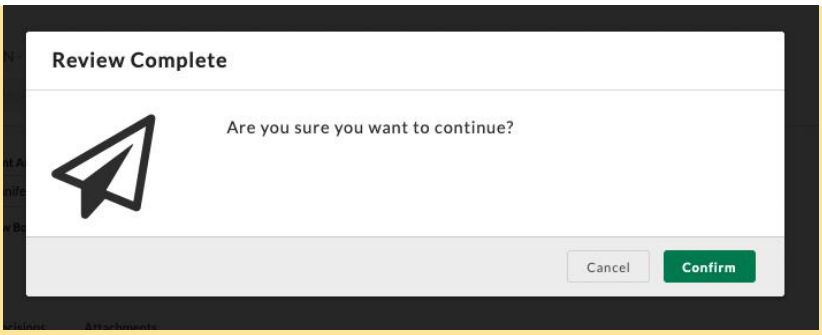
If selecting RETURN TO PI as the decision, the clarification requests must be added as comments in the smartform or you can describe them in the **INTERNAL NOTES** section. When adding clarification requests to the INTERNAL NOTES section, the IRB analyst will add the information in the appropriate section.

If selecting MINOR STIPULATIONS as the decision, the stipulations being requested should be added to the submission type worksheet (under section titled "Stipulations for approval"). However, you could use the **INTERNAL NOTES** section add any other helpful information or context.

STEP 4: Once you have completed the Make Decision with all relevant information, click **SAVE** in the top right hand corner of the Make Decision function. After clicking **SAVE**, you must click **REVIEW COMPLETE** (on the Submission Details page) and **CONFIRM** in order to complete your review.

IMPORTANT: If you click SAVE but do not click REVIEW COMPLETE / CONFIRM, the submission will not be returned to the IRB analyst and will cause delay in subsequent review. If you have completed the Make Decision but continue to see the submission ID under My Tasks (on your Dashboard view), it probably means that you did not click REVIEW COMPLETE / CONFIRM.



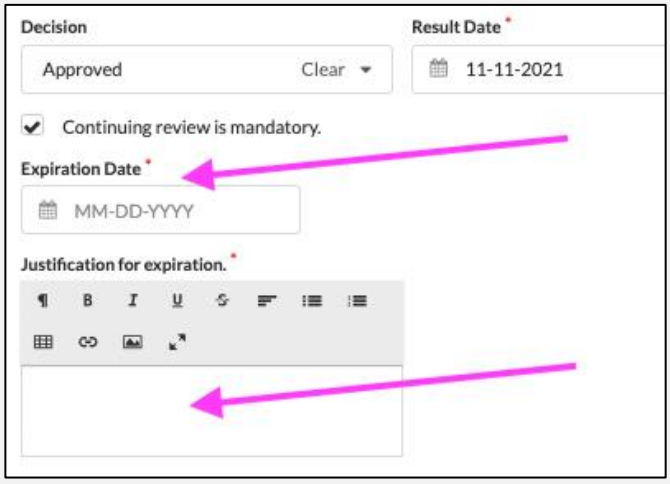


5. Continuing Review and Expedited Review

When reviewing an Initial submission for a study to be approved under Expedited Review, an additional section will appear in the Make Decision function asking if Continuing Review is mandatory. Continuing Review is mandatory for all Initial submissions reviewed by the convened IRB; however, the continuing review requirement *may* not apply to studies approved under expedited review, under the revised Common Rule (see 45 CFR 46.109 (f)(1)). However, certain types of research approved under expedited review still require continuing review (see 197 GUIDANCE). For example, FDA regulated research approved under expedited review requires continuing review.

When a submission requires continuing review, check the box below the decision options. This box appears after the decision has been entered and is not a part of the default view of the Make Decision function.

After checking the box, enter the **Expiration Date** and provide **Justification** for requiring Continuing Review.



IMPORTANT: The IRB/designated reviewer may require continuing review, even if it meets the regulatory criteria for not requiring continuing review. This determination must be documented in the Make Decision function, with appropriate rationale.