


## Reviewer Sheet Completion Instructions

After completing your review of an IRB submission, using the various tools available, such as the [IRB reviewer reference sheets](#), you are now ready to document your findings on the submission reviewer sheet.

1. Upon opening the reviewer sheet in BuckeyeBox, type your name and date on the very bottom section of the reviewer sheet. A "wet" signature is not required as your identity is authenticated in BuckeyeBox.

Jane Smith	8/1/2016
IRB Reviewer	Date

2. The study number and PI name will be pre-filled for you at the top of the reviewer sheet.

 THE OHIO STATE UNIVERSITY	Office of Research Office of Responsible Research Practices Biomedical Sciences Institutional Review Board
<b><u>IRB Protocol Review Sheet for Convened Initial Review</u></b>	
Protocol Number: 2016H1234	PI: Jones

Other reviewer sheet sections (see picture below):

3. Determinations:

Once you complete your review, you will make a proposed determination based on your findings. You should place an "x" next to the appropriate determination. For convened review, if you prefer, you can wait until the discussion is completed at the meeting before marking your determination.

4. Populations:

The requested populations for the study will be listed either on the *Participant Population* page (for initial and amendment submissions) or on the *Number of Participants* page (for continuing review submissions). If you determine through your review that the population is appropriate for the study, you will place an "x" next to the appropriate population on the reviewer sheet. If no special populations were requested, place an "x" next to the "No Special Populations" box.

5. Consent/HIPAA:

The requested informed consent and HIPAA authorization waiver and alteration requests will be found on the *Informed Consent Process* and *HIPAA Research Authorization* pages, respectively. If you determine through your review that the waiver or alteration is appropriate for the study, you will place an "x" next to the

appropriate waiver on the reviewer sheet. If no special waivers or alterations were requested, place an "x" next to the "No Waivers, Alterations, or LAR Consents" box.

6. Level of Risk:

Depending on the risk level of the research, an "x" should be placed next to the appropriate option in this section. This option will be present on initial and continuing review reviewer sheets only.

7. Next Review Date:

The appropriate review date should be selected for both initial and continuing review submissions. Research must be reviewed and approved within one year intervals; however, the IRB can determine that more frequent review is required. If a different interval is recommended, the specific time (e.g., 6 months) should be noted in the blank provided.

8. Noncompliance:

The noncompliance section is present on the reviewer sheet for all submission types. If noncompliance was discovered by you during your review or you were provided information regarding the noncompliance, the appropriate determination and required actions should be noted on the reviewer sheet by placing an "x" next to the specific options.

DETERMINATIONS	CONSENT/HIPAA (check all that apply)
<input type="checkbox"/> Approved	<input type="checkbox"/> No Waivers, Alterations, or LAR Consent
<input type="checkbox"/> Requires Modifications – *provide comments	<input type="checkbox"/> Waiver of Consent
<input type="checkbox"/> Deferred – *provide comments	<input type="checkbox"/> Alteration of Consent
<input type="checkbox"/> Disapproved – *provide comments	<input type="checkbox"/> Waiver of Consent Documentation
	<input type="checkbox"/> Waiver of Parental Permission
	<input type="checkbox"/> Alteration of Parental Permission
POPULATIONS (check all that apply)	
<input type="checkbox"/> No Special Populations	<input type="checkbox"/> Waiver of Parental Permission Documentation
<input type="checkbox"/> Approval for Pregnant Women/Fetuses	<input type="checkbox"/> Waiver of Assent
<input type="checkbox"/> Approval for Children	<input type="checkbox"/> Consent by Legally Authorized Representative
<input type="checkbox"/> Approval for Prisoners	<input type="checkbox"/> Waiver of HIPAA Research Authorization
<input type="checkbox"/> Approval for Adults with Decisional Impairment	<input type="checkbox"/> Partial Waiver of HIPAA Research Authorization
<input type="checkbox"/> Approval for Non-English Speaking Subjects	<input type="checkbox"/> Alteration of HIPAA Research Authorization
<input type="checkbox"/> Approval for Non-Viable Neonates	
<input type="checkbox"/> Approval for Neonates of Uncertain Viability	
LEVEL OF RISK	NONCOMPLIANCE (check all that apply)
<input type="checkbox"/> Minimal risk	<input type="checkbox"/> N/A
<input type="checkbox"/> Greater than minimal risk	<input type="checkbox"/> Unsubstantiated
	<input type="checkbox"/> Minor (not serious, not continuing)
	<input type="checkbox"/> Serious
NEXT REVIEW DATE	
<input type="checkbox"/> One year	<input type="checkbox"/> Continuing
<input type="checkbox"/> Other – specify:	<input type="checkbox"/> Refer to IRB Investigative Committee
	<input type="checkbox"/> Refer to another university review process
	<input type="checkbox"/> Determination pending/ Further information required
	<input type="checkbox"/> Corrective actions(s) required – *provide comments

9. If you have questions which will result in required modifications, deferral, or further action required (for an event report), the questions/concerns should be clearly stated in the comments/modifications section of the reviewer sheet.

Instructions specific to convened review:

- a. You can also use this space to list issues for which you need input from others on the board
- b. Concerns that are resolved during the convened meeting discussion should be deleted or otherwise denoted as no longer applicable.
- c. If you are not an assigned reviewer during convened review, but have additional comments, please retrieve a blank reviewer sheet in the convened meeting folder under the specific submission and save in your named box folder and/or email your comments to ORRP staff.

**\*COMMENTS/MODIFICATIONS:**

## Tips for writing required modifications:

### *What is a modification?*

A modification is a question or issue with the submission requiring clarification or revision prior to the IRB issuing approval of the submission.

### General guidelines:

- Requested revisions should be meaningful, conveying questions or concerns which will result in an improved study submission.
- Concerns noted on the reviewer sheet should be *clear* and *specific* with rationale for the change provided. An ORRP staff person must translate the information from the reviewer sheet to action items for the PI. To assist, you should note exactly where in the document(s) that an issue or discrepancy exists and why the change is important.

Examples of clear and specific modifications:

- Insert study calendar in section #3 of the consent document to help the subject understand what is required for study participation and follow the study schedule.
- Revise the protocol to describe the randomization method.
- Page 4, Line 5 of the **tracked** protocol: Remove blood draw that is no longer performed.
- Revise Buck-IRB, *Participant Identification* section to describe the process to determine eligibility.
- Revise the recruitment letter to provide accurate study team contact information.
- Before requesting a change, ask yourself if the change will improve the welfare of subjects, will provide significant clarity to a specific issue, or will resolve a regulatory concern. If not, do not request the change.
- Typographical error correction or formatting changes should be requested to improve the meaning of the specific document or help with readability rather than to improve grammar.
- If multiple responses by the investigator will satisfy an IRB member's regulatory concern, specify the alternatives and the associated actions.

Example:

"If written informed consent will be obtained from subjects, please provide the informed consent document. If a waiver of documentation is being requested, indicate in Buck-IRB and complete the newly revealed section."

- Use an administrative note to convey suggestions that are not associated with the criteria for approval.

Example:

- It is recommended that a co-investigator from radiology be added to the study team to provide imaging guidance.

## **Specific submission guidelines:**

### Continuing review

- Investigators are *not* able to edit many sections of the continuing review application as this information was previously approved. The following Buck-IRB application pages *cannot* be edited by the investigator:
  - Location of Research, Summary of Research, Approved number of participants (though they can request an increase in accrual and do provide updates on current accrual), Informed Consent Process, HIPAA Research Authorization
  - IRB members should not request changes to the above sections as modifications to the continuing review because the investigator cannot perform the change.
- Significant revisions beyond study documents' revisions to include changes in personnel, minor risk changes, participant numbers, or obvious errors which cause confusion for subjects should not be requested at the time of continuing review. Instead, the investigator should be instructed to submit an amendment after approval of the continuing review to correct these items within the Buck-IRB application and/or study materials.

Example:

- Following approval of the continuing review, the investigator must submit an amendment to request a partial waiver of HIPAA research authorization as study coordinators are reviewing clinic schedules for screening purposes.

### Amendment

- When submitting an amendment, an investigator can change any page in the study. You will receive a tracked version of Buck-IRB application pages as well as study documents.
- Your main focus with an amendment is the change being requested as represented in the submission materials. All approved materials are available in the submission folder within the "Approved docs" sub-folder to ensure consistency between materials.
- When completing the reviewer sheet, you should only place an "x" next to populations or waivers which were added with the amendment. If the study is already approved for a specific population or waiver (that was not added through the amendment) or has no special approvals, no "x" is needed.

## Event report

- Event report submissions only include information regarding a potential unanticipated problem involving risks to subjects or others (UPIRSO) and/or potential noncompliance.
- The investigator does not have access to all Buck-IRB study pages when submitting the report.
- After reviewing an event report, if you see that study documents need to be revised based on the information included in the event report, you should instruct the investigator to submit an amendment to make the change. This cannot be changed within the event report submission.
- You can request changes to the event report application pages.

Examples of event report further action comments:

- Provide a specific action plan to ensure that this type of breach of confidentiality will not occur again.
- Confirm that this type of breach of confidentiality has not occurred with other participants.
- Clarify when and how the participant will be informed of the drug dispensing error as the participant would need this information in order to make an informed decision about continuing study treatment.