Guidance for Preparing an eIRB Application that will be Reviewed and Approved under the Revised Common Rule

As of January 21, 2019, all human subjects research activities submitted to the JHM IRB must comply with the revisions to the U.S. Department of Health and Human Services (DHHS) human subjects research regulations [known as the Common Rule]. To comply with the Revised Common Rule, the eIRB application has been updated in several sections. This document serves as a reference guide for study teams preparing a new eIRB application or a response for a new application that will now be subject to the Revised Common Rule. All new applications that have not received initial approved prior to January 21, 2019 are required to address the updates in the eIRB application. This includes new applications returned with pre-review issues and new applications tabled or approved with administrative changes but not granted final approval prior to January 21, 2019.

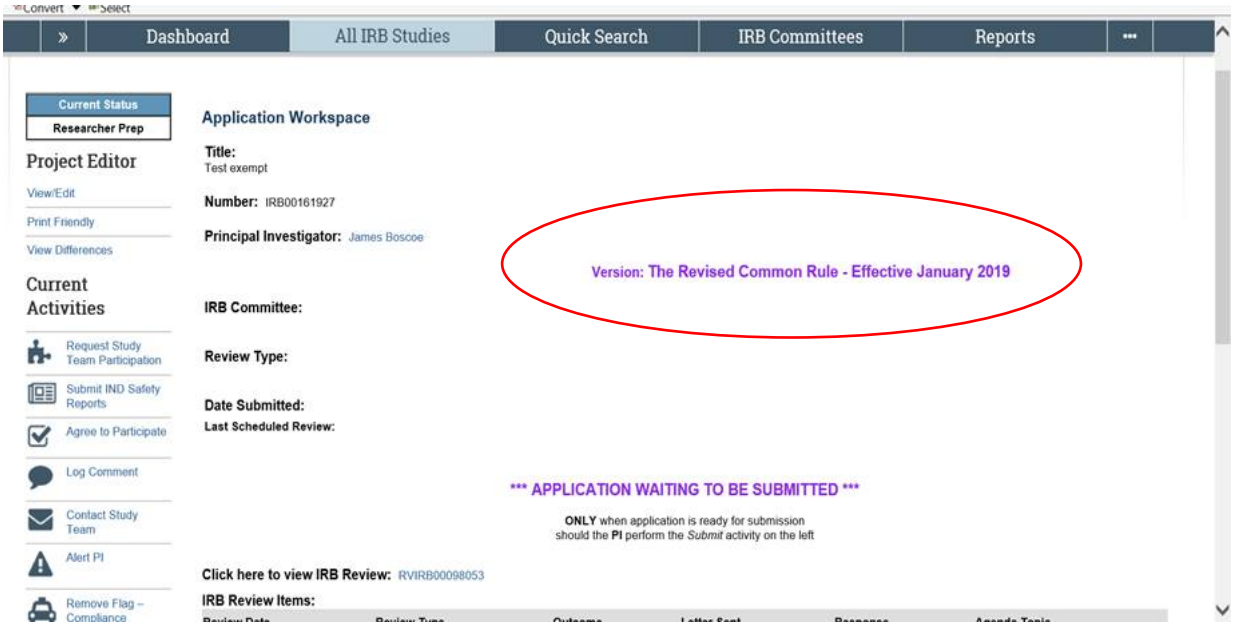
This guidance outlines changes made to the eIRB application and associated documents. If you are submitting a response to issues for a new application, please pay close attention to any requests to update the review type of your application and follow the corresponding instructions. The review type is an item which you select in Section 1, Item 7.

This guidance document is divided into three parts. Please click on the applicable section header or sub-header to see the related guidance.

PART 1: Changes Impacting <u>All</u> Applications

A. Common Rule Version Identifier Added to the Application Workspace

To help identify whether an application is subject to the requirements of the Revised Common Rule, a new "Version" identifier has been added to the Application Workspace. The version identifier appears in purple at the top right of the Application Workspace and will either say "Version: The Common Rule" or "Version: The Revised Common Rule-Effective January 2019". All new applications not initially approved by January 21, 2019 will automatically be identified as The Revised Common Rule version of the application.



B. Changes to eIRB Section 1, Section 2, the Add Study Team member screen and the Agree to Participate screen related to the physician consent policy.

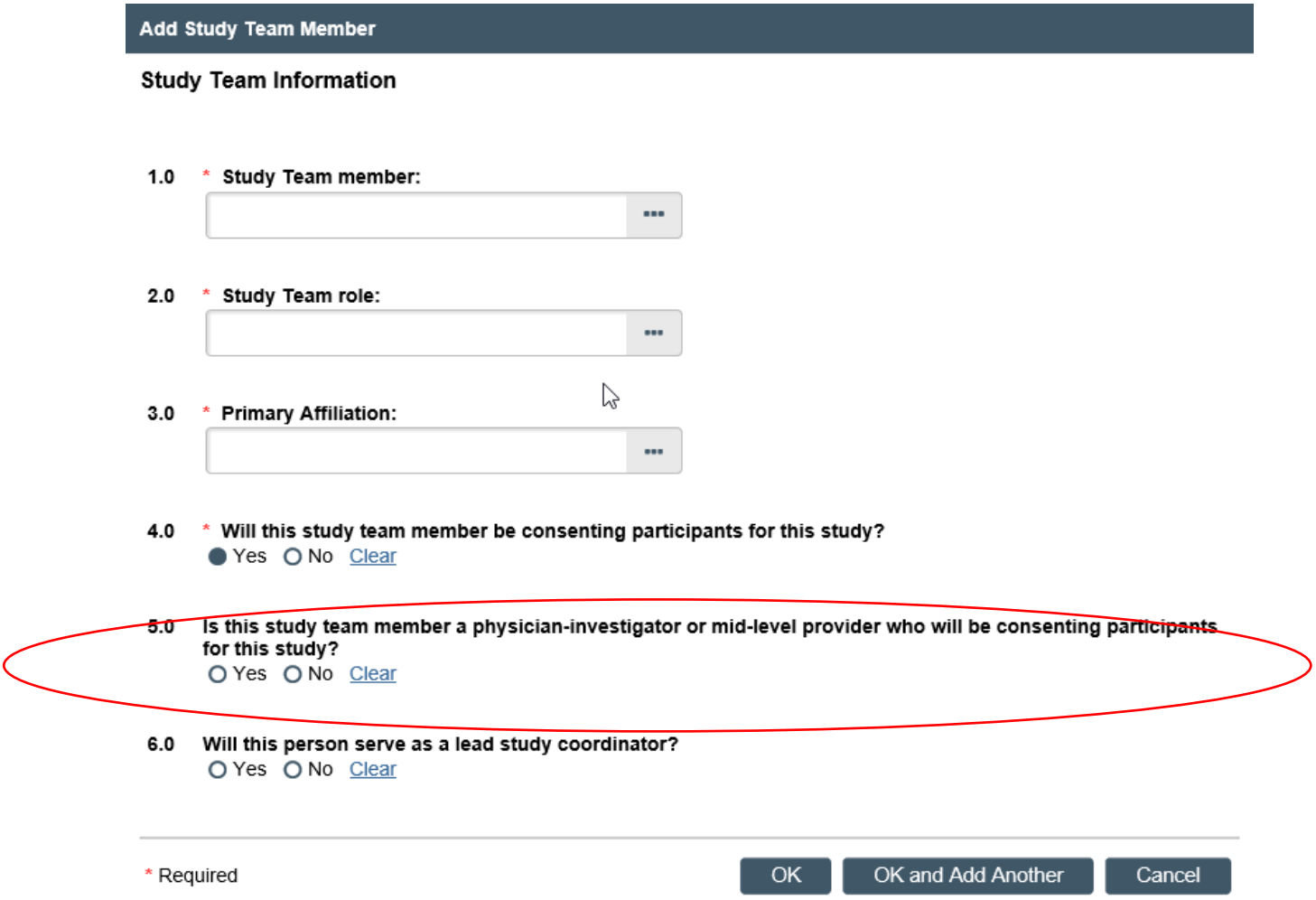
To streamline the tracking of information about whether the physician consent policy applies to an application, and who will be consenting in accordance with this policy, the following changes have been made:

1. **The following question has been moved from Section 15 to Section 1**:

   Does the institutional policy on physician consent require that a physician-investigator or mid-level provider obtain informed consent for this research?

   This question now appears in Section 1 as Item 22.

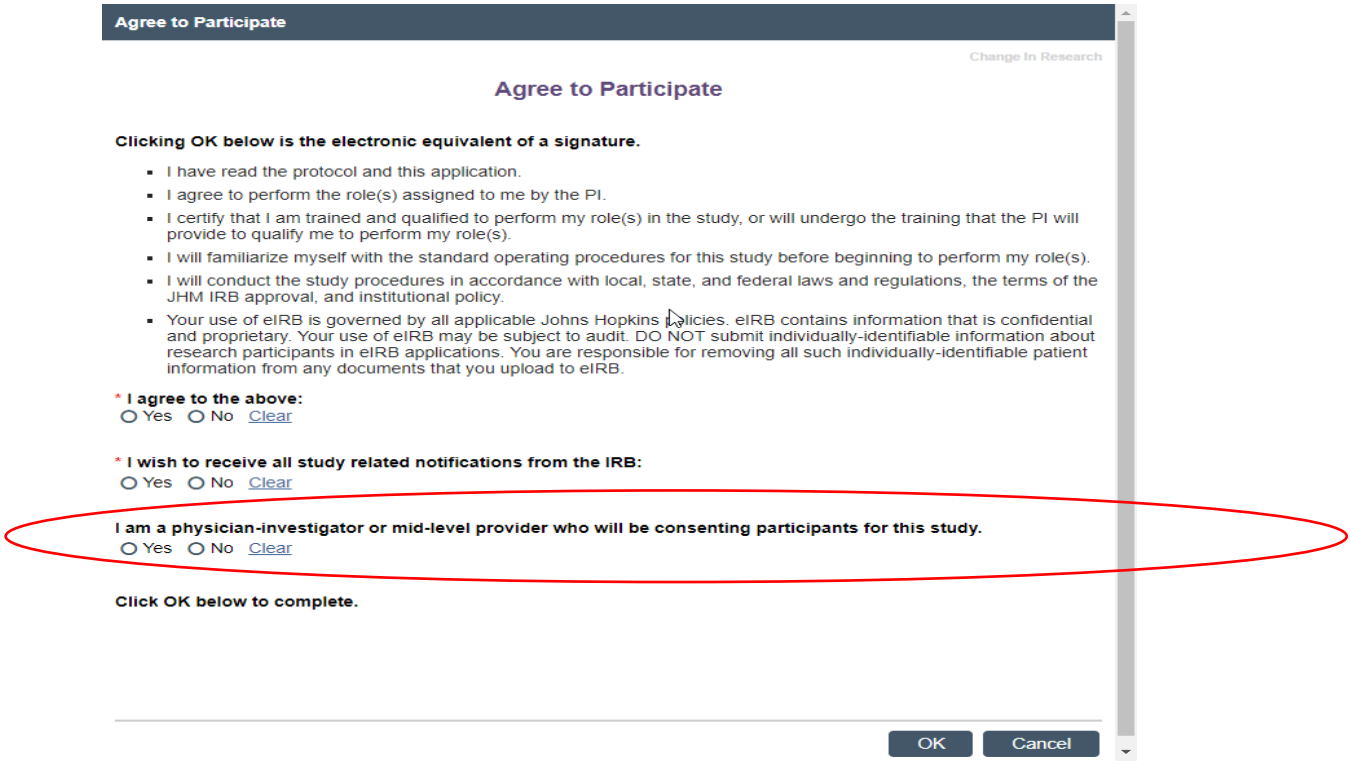
2. **When adding study team members, a new question is asked to affirm whether those team members reported to be involved in consenting qualify as either a physician or mid-level provider who will obtain consent in accordance with the physician consent policy.**



The response will automatically populate in the study team member table in Section 1.

3. Additionally, at the time of agreeing to participate, study team members will now be asked to verify their role in the consent process.

Please note: The response to the physician consent item at "Agree to Participate" must be consistent with the response to the physician consent item when the study team member is "Added" to the study team list in Section 1. If the responses are inconsistent, (i.e. one says "Yes" and the other says "No") an error message will appear at time of submission and submission cannot proceed until the inconsistency is corrected. This logic will also apply to all changes in research adding new study team members.



4. **PIs will now be asked to verify whether they are a physician or mid-level provider if they report involvement in the consent process.**
   If the answer is YES, to Section 1, Item 2 "Will the PI obtain consent for this study?" a new question [Item 2b] will appear that asks:

   2b. Is the PI a physician-investigator or mid-level provider who will be consenting participants for this study? [Answer Options: Yes/No]

C. Addition of a question on Public Health Surveillance (PHS) activities.

Under the Revised Common Rule, certain activities, deemed to qualify as a PHS activity are not considered research. It is possible that a researcher may be engaged in a project where the entire project or a component of the project qualifies as a PHS activity. The IRB will make this assessment. If you believe your project or a portion of your project qualifies as a PHS activity, please answer Yes to the following new question added to Section 1:

13. Is there a component of your proposed project that is a public health surveillance activity?
    Yes No Clear

If you respond "Yes" you will be prompted to upload the new Public Health Surveillance Determination Worksheet, accessible here.

14. Please Upload the PHS Determination Worksheet:
    Click Add to upload a new document. Click Update to upload a revision version of the existing document. (Click History to see all uploaded versions of an existing document.)

Please review the new guidance on Public Health Surveillance Activities for assistance in answering this question.

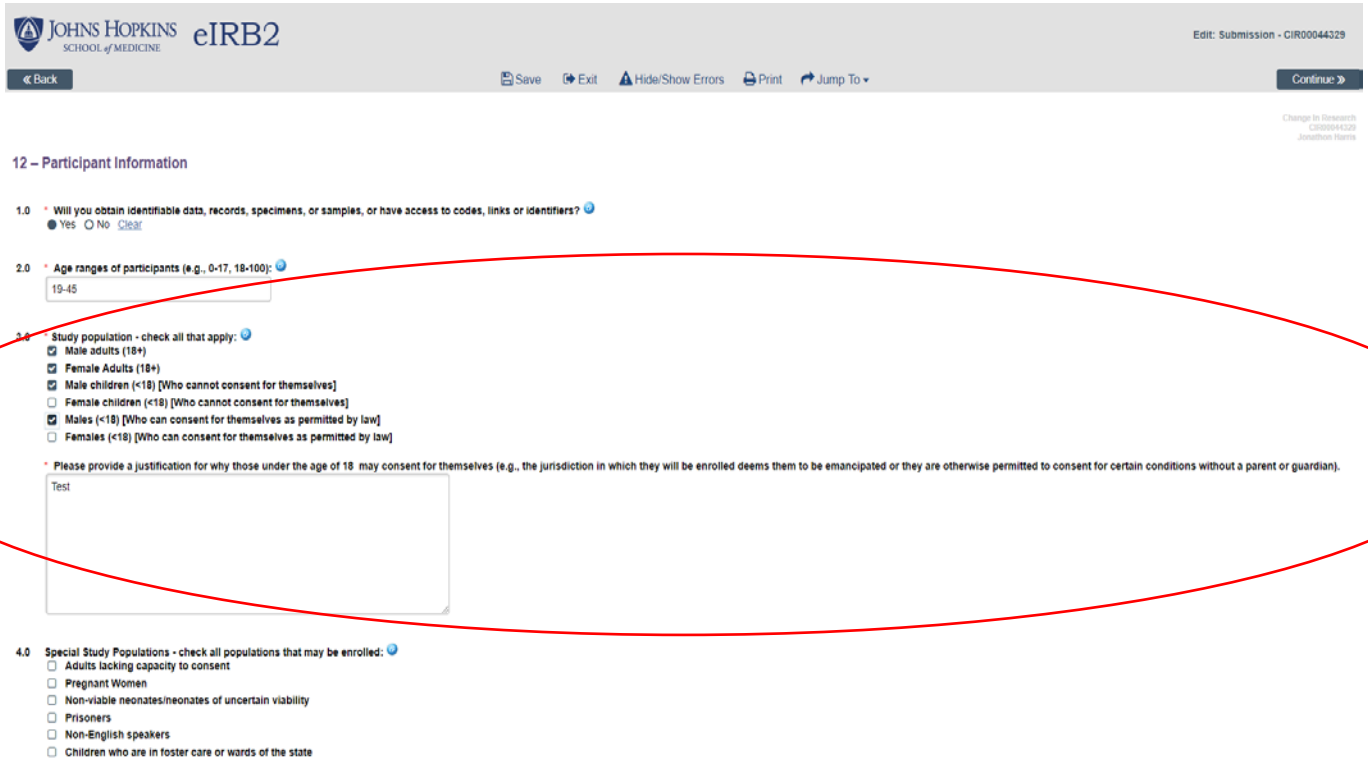
D. Revisions to the Participant Information Section: eIRB Section 12

1. Requirement for Completion of Section 12 for All Applications

Moving forward, Section 12 will be visible for all application types including exempt and not human subjects research applications. This section was previously not visible for select application types. For all research, it is important for the JHM IRB to understand information about the study participants, even if the investigators are only interacting with participant data or biospecimens.

2. Change to the Study Population Section to Identify Minors who can Consent for Themselves

In addition to Section 12 now being required, Item 3 of Section 12 has been revised to differentiate children who are being enrolled for whom parental permission is required and those children who are minors but because of the nature of the research, may consent for themselves. This may be true in cases where the research involves a certain condition, like sexual health, where minors may make their own health decisions as permitted by law. For more information about Maryland State law outlining when minors may provide consent for themselves, click here. If you intend to enroll minors who can consent for themselves, a new text box will appear asking for justification as to why this is permissible.

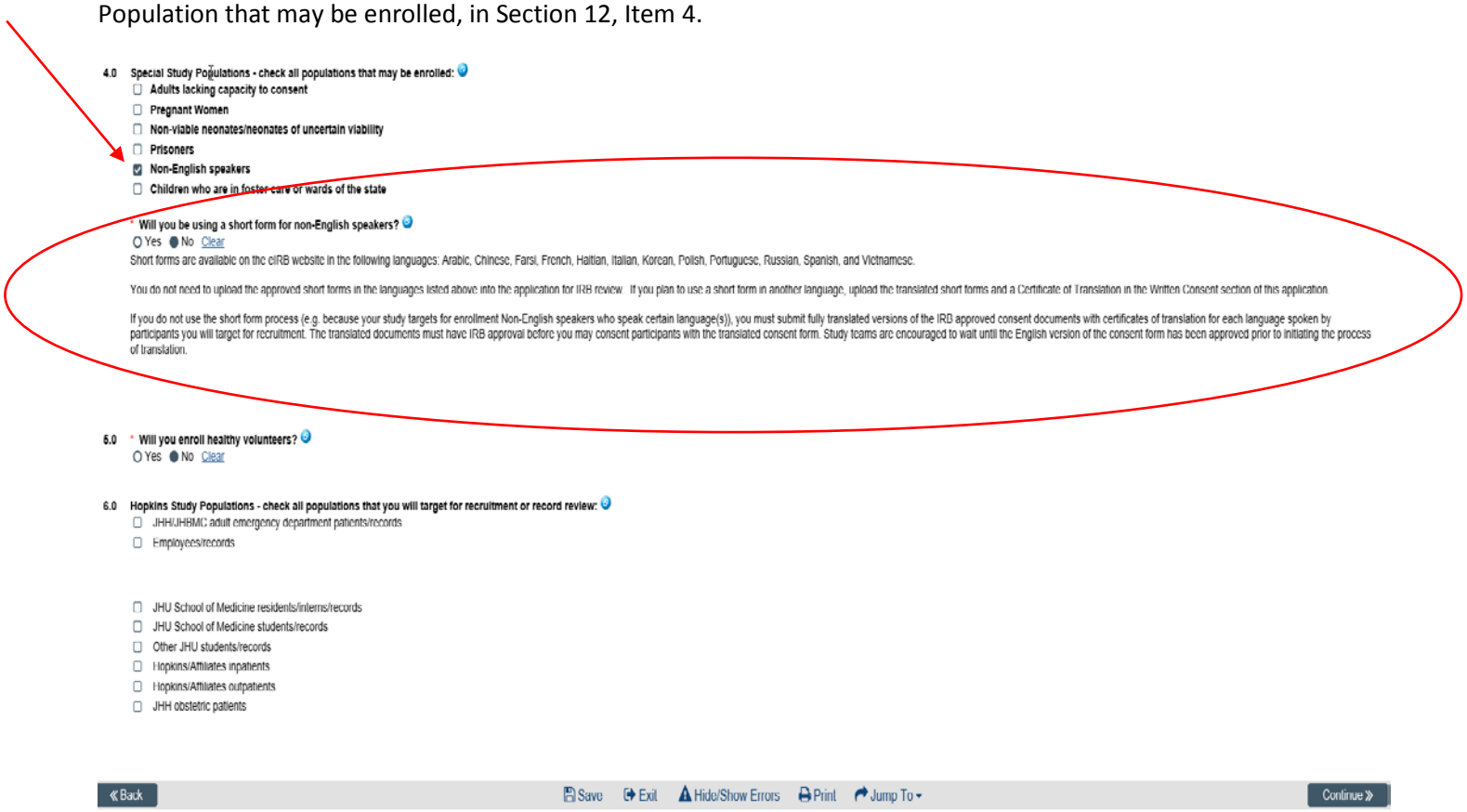


3. Confirmation about Plans for Use of the Short Form in the consent process.

To avoid discrepancies across multiple sections of the eIRB application, Section 12 has been updated to include the following question [previously located in Section 14]:

Will you be using a short form for non-English speakers?

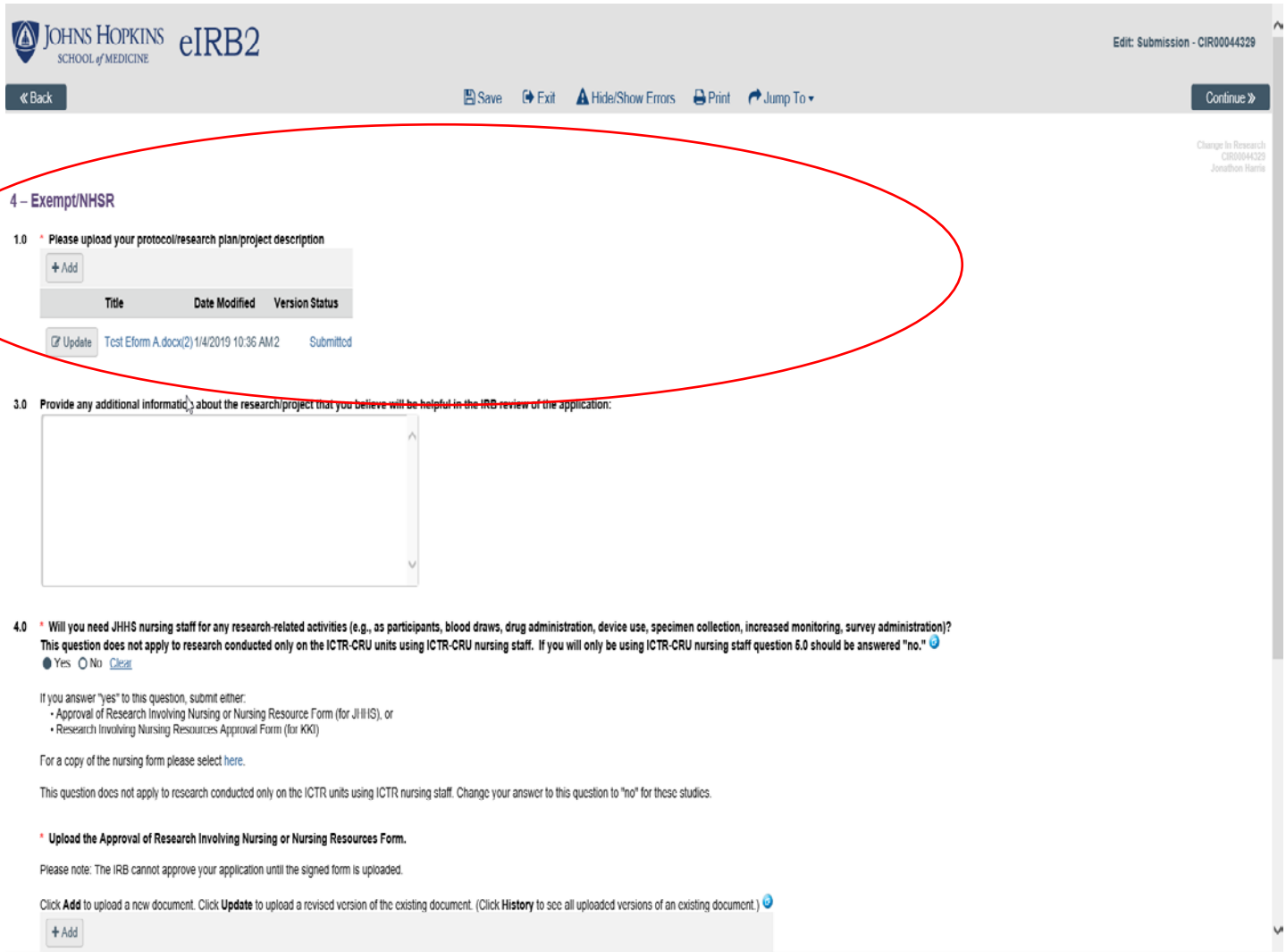
This question will only appear for individuals who have selected "Non-English Speakers" as a Special Study Population that may be enrolled, in Section 12, Item 4.



PART 2: Changes Impacting New Applications Qualifying as Exempt/Not Human Subjects Research

The eIRB application for research projects that may qualify as not human subjects research or may qualify for exemption has been substantially simplified. Many sections of the eIRB application are no longer required for these review types.

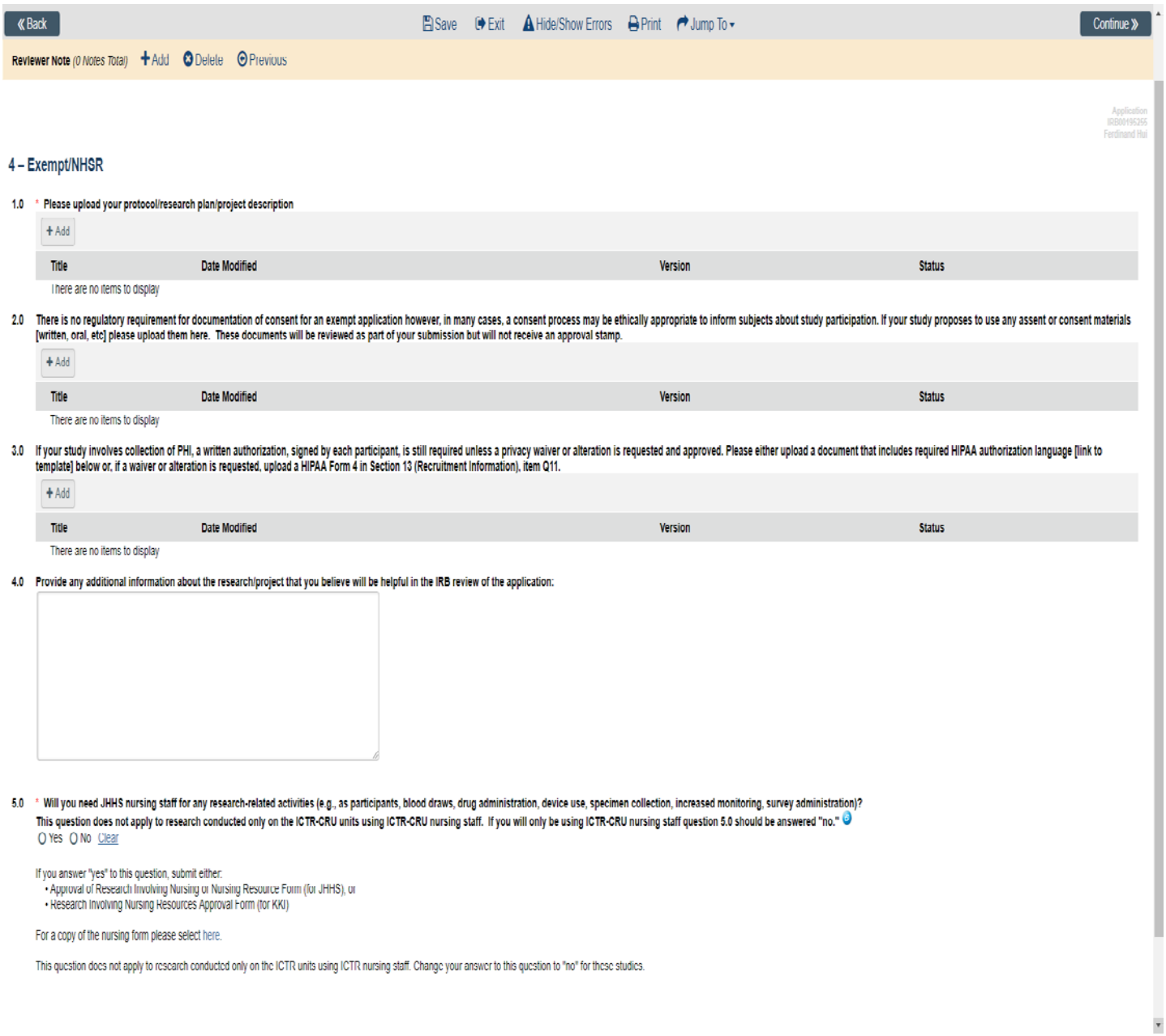
For projects that qualify as **Not Human Subjects Research**, a new question has been added requesting an upload of a project description. The study team may upload their own project description or use the eForm N as a template to build the project description/plan.



For projects qualifying as **Exempt**, Section 4 has been revised to request three primary items:

- A project description. For exempt projects any of the following templates may be used:
  - eForm A
  - eForm S- Now permissible for any projects involving secondary use of data/biospecimens that were originally collected for a different primary purpose
  - eForm E- New template designed for use by investigators submitting an exempt application

- A description of any planned consent process including any written consent forms, consenting scripts or text [e.g. that may be introduced at the beginning of a web-based survey] that may be used. Applicable materials must be uploaded. Please note: These documents are reviewed but do not receive an IRB approval stamp for projects qualifying for exemption.
- A written authorization if the study involves the collection of protected health information [PHI] from participants. Even where a consent document may not be required, if the study involves collection of PHI, written authorization for use of that health information is still required unless a waiver or alteration of authorization is requested and granted. For exempt applications involving the collection of PHI you must either upload a written authorization OR confirm you are requesting a waiver/alteration and upload a HIPAA Form 4 in Section 13.



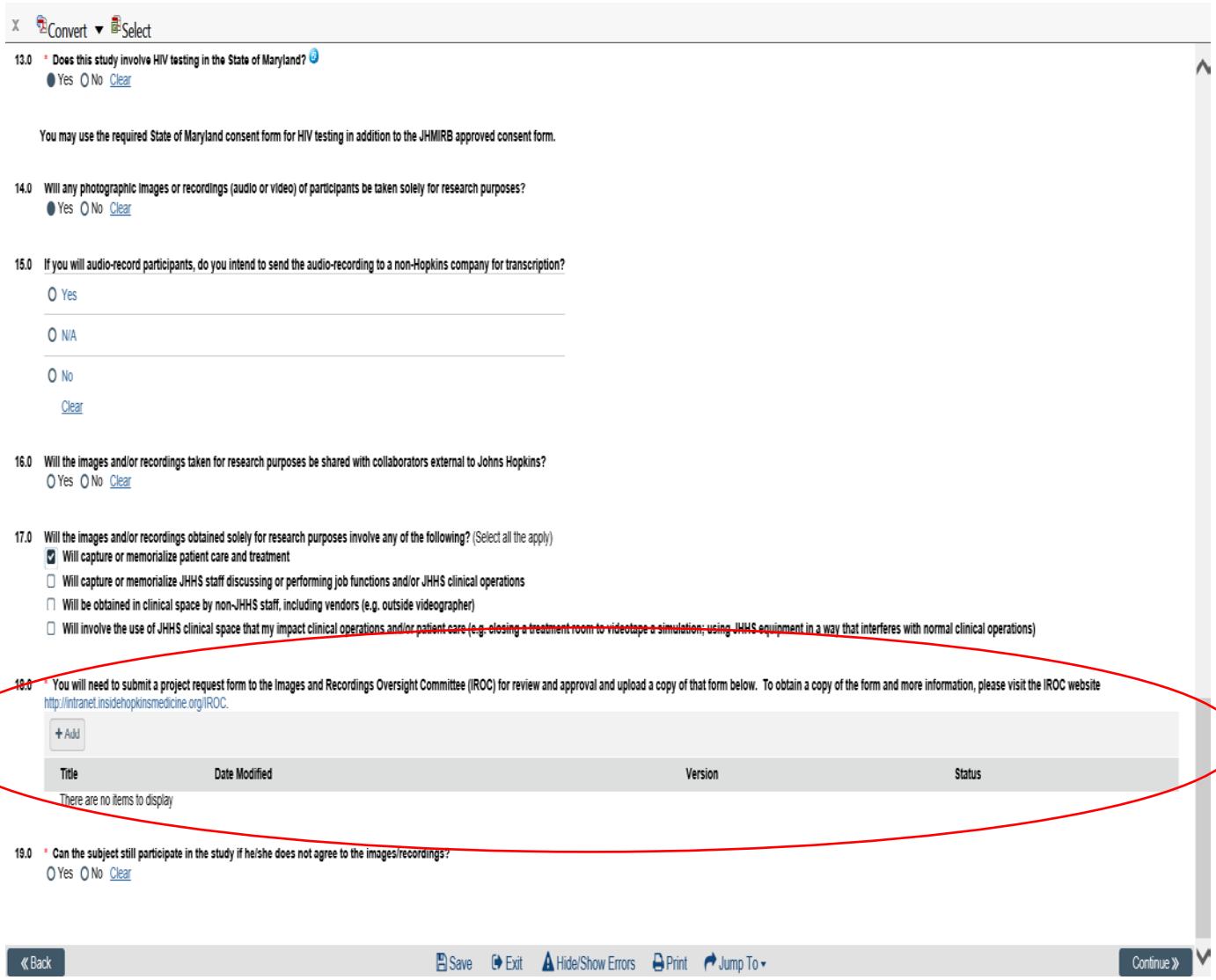
PART 3: Changes Impacting Applications Where the Review Type is Expedited/Convened:

A. Changes to move select questions regarding study procedures to eIRB Section 6

Two items previously located in Section 15 have been relocated to Section 6, as they relate primarily to study procedures and not specifically to the consent process. The following questions have been moved to Section 6:

12. *Does this study involve HIV testing in the State of Maryland?*
13. *Will any photographic images or recordings (audio or video) of participants be taken solely for research purposes?*

Please Note: If your response to Item 13 is "Yes" additional questions will appear. Based on your responses, review by the Images and Recordings Oversight Committee (IROC) may be required. While these questions have not been updated in relationship to the Revised Common Rule, they were recently updated [in November 2018].



B. Changes Related to Informed Consent and Consent Waivers

There are several changes to the eIRB application related to informed consent. These changes have been made to better align the eIRB application with the terminology of the regulations and to make revisions required by the Revised Common Rule.

It is important to note that Sections 14, 15 and 16 of the eIRB application, as further described below are utilized to describe the type and manner of consent for adults and/or minors who are able to consent for themselves. This includes adults with limited decision-making capacity. Parental permission and assent for children who are unable to consent for themselves are separately addressed in Section 17 [See details below].

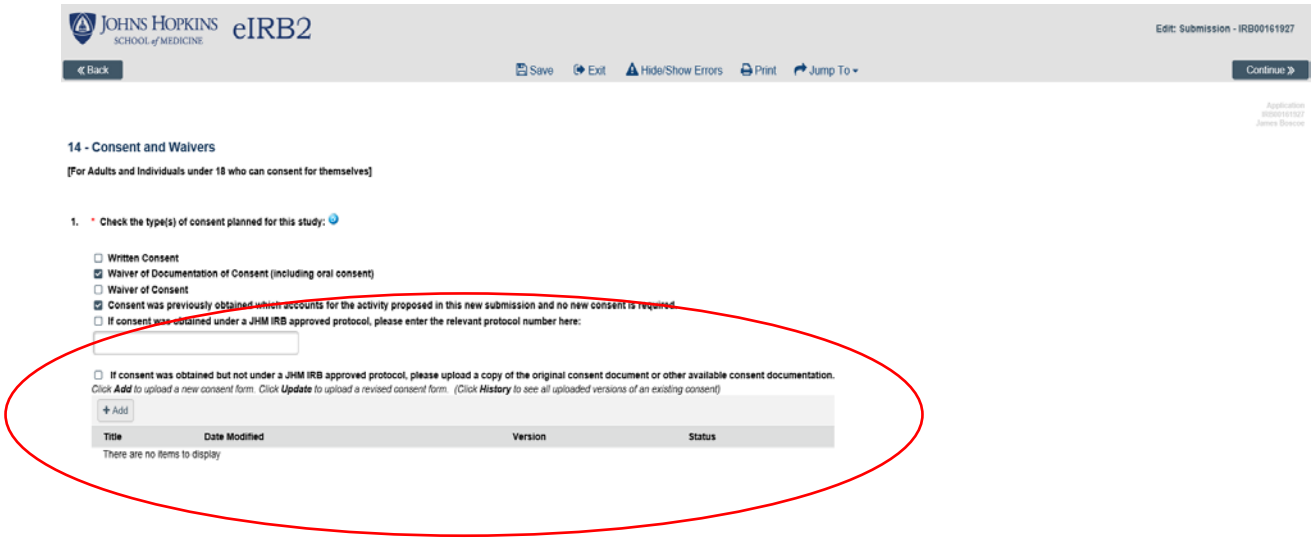
The following changes have been made to the eIRB application related to research with adults and minors who are able to consent for themselves.

1. Changes to the Consent Types that May be Selected [eIRB Section 14]

In Section 14, study teams are asked to identify which types of consent apply to the study. More than one type of consent may be used/selected for your study. There are now four options- a) written consent, b) waiver of documentation of consent (including oral consent), c) waiver of consent and d) consent was previously obtained which accounts for the activity proposed in this new submission and no new consent is required.

There are a few important things to note about these options:

- Waiver of written documentation of consent was previously called oral consent. Since consent documentation may be waived in circumstances when the consent process is not conducted orally [e.g. where consent is obtained via an online platform] the terminology was revised to make it clear that this consent type is not limited to the use of oral consent.
- The fourth option [where consent was previously obtained] is new and is meant to account for the cases in which consent may have been obtained through a prior study or some other activity for the activity that is being proposed in the new eIRB application. If the prior consent was obtained in a study approved by the JHM IRB, the study number must be identified so the JHM IRB may verify the prior consent form was sufficient to cover this new activity. If the prior study or other activity (for example, consent obtained by a commercial entity to obtain and market biospecimens for research) was not reviewed by the JHM IRB, a copy of the original consent form must be uploaded.



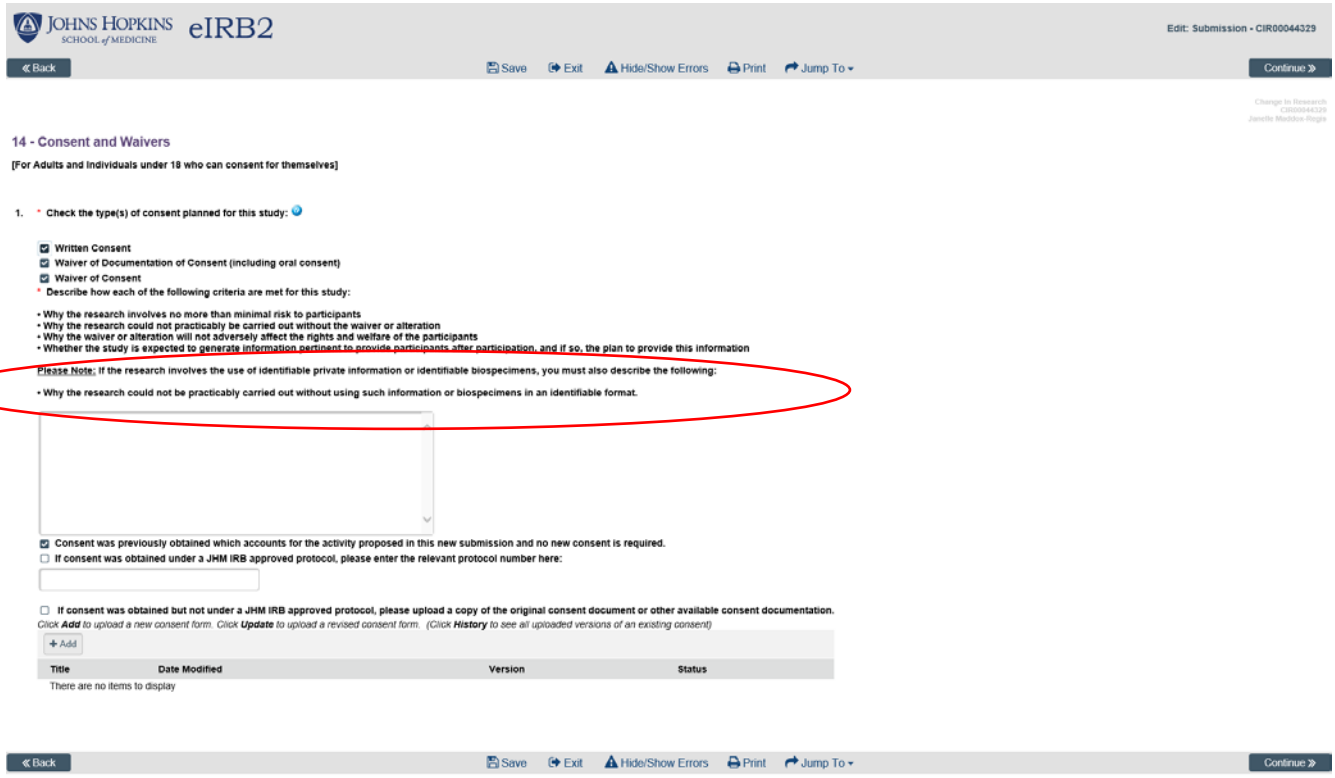
2. Addition of New Consent Waiver Criterion [eIRB Section 14]

A waiver of consent may be granted by the IRB if select criteria, outlined in the Revised Common Rule are met. For applications requesting a consent waiver be applied to some or all of the proposed research activity, Section 14 has been revised to include a new criterion introduced in the Revised Common Rule for projects involving the use of identifiable private information or identifiable biospecimens.

For these types of research, the following additional criterion must be met in order for the IRB to grant a waiver of consent:

- *The research could not practicably be carried out without use of the information and/or biospecimens in an identifiable format*.

Please ensure all applicable criteria are addressed if you are seeking a waiver of consent as part of your eIRB application.



3. Requirement for use of the New Consent Form Template [Version 16]- [eIRB Section 15]

All studies that must comply with the Revised Common Rule (new applications approved after 01/21/2019) are required to utilize the latest version of the IRB's informed consent template [Version 16].

A study-specific consent form, created using the new template, must be uploaded in Section 15. New applications containing a consent form written using an older version of the consent form template will be returned. A revised consent form, using the new template, will be required before the study is scheduled for IRB review. The new template and associated guidance on key information can be found here.

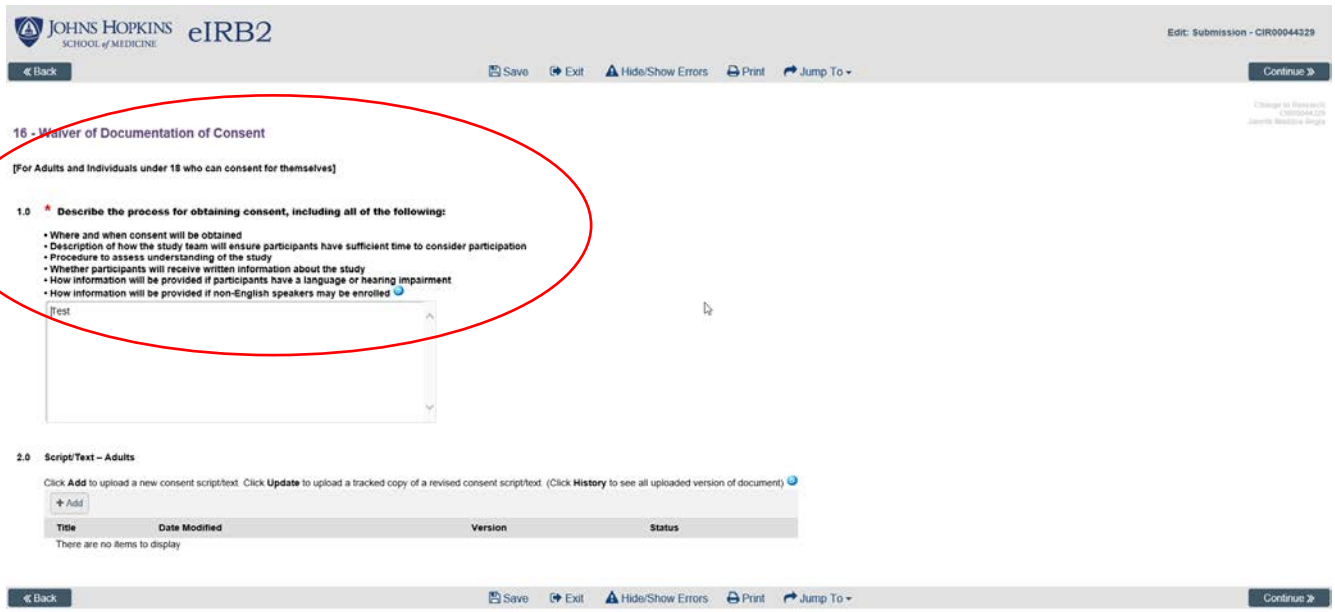
Please Note: Applications approved under the old Common Rule (approved on or before 1/20/2019) should continue to use the Version 15 consent template. There is no requirement to transfer to the Version 16 template and requests to transfer to the Version 16 template will not be processed.

4. New Options for Waiver of Documentation of Consent [eIRB Section 16]

As noted above, the concept of "oral consent" has been replaced with the regulatory term "waiver of documentation of consent". There are three options when the requirement for a signature [documentation] may be waived:

- The only record linking the participant and the research is the consent document and the principal risk is loss of confidentiality.
- The research involves no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context.
- The research involves no more than minimal risk and the participant or representative are members of a distinct cultural group or community in which signing forms is not the norm. There is an appropriate alternative mechanism for documenting that informed consent was obtained.

When requesting to waive the consent signature requirement, consider which of the above criteria may apply to the study. Please note, even when waiving the signature requirement, all other required consent elements must still be included in the consent script/text. Please see the IRB's Guidance on Waiver of Documentation of Consent.



C. Changes Related to Research with Children [eIRB Section 17]

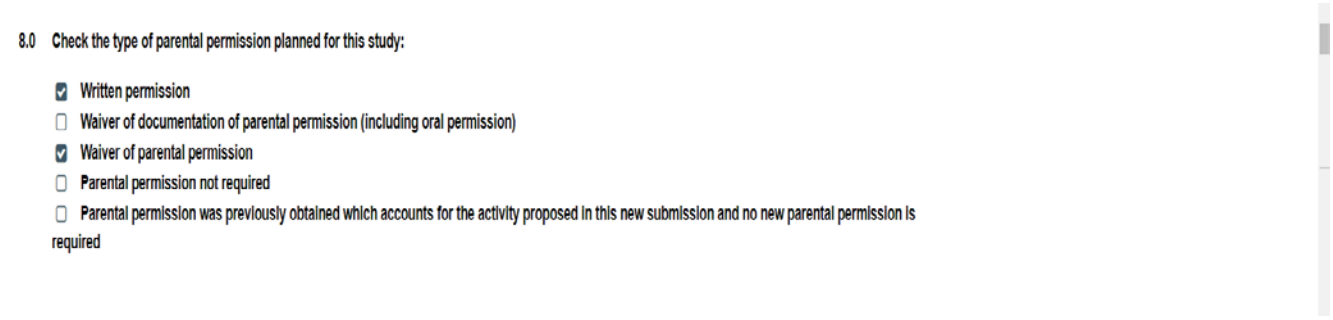
1. Addition of New Questions Regarding Parental Permission

A decision to participate in research is generally referred to as informed consent. For research involving children who are legally unable to consent for themselves, there are two requirements- a) the parent or legal guardian must give **permission** for the child to participate in the research and b) where appropriate, the child must be given an opportunity to express his or her choice, a process called **assent**. In these cases, where the study will not enroll children capable of choosing for themselves whether or not to participate in the research, the process through which a child agrees to join the study is not referred to as "consent".

Often studies target multiple populations. A study may include both adults over the age of 18 for which consent may be sought and children for whom parental permission/assent may be sought. To account for this, Section 17 of the eIRB application has been revised to focus on the requirements for research with children, including the requirements for both parental permission and assent.

The questions regarding assent were always included in Section 17 and remain unchanged.

New questions have been added to Section 17 to identify, similar to consent for adults, the type of parental permission that will be obtained for the study.

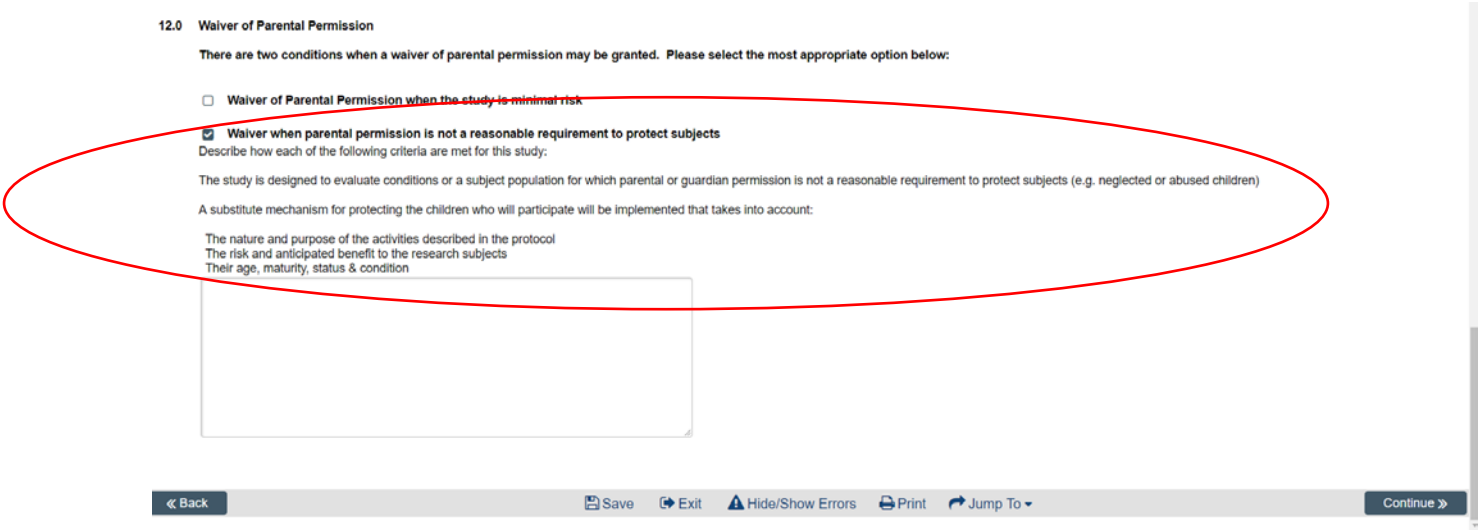

8.0 Check the type of parental permission planned for this study:

- [x] Written permission
- [ ] Waiver of documentation of parental permission (including oral permission)
- [x] Waiver of parental permission
- [ ] Parental permission not required
- [ ] Parental permission was previously obtained which accounts for the activity proposed in this new submission and no new parental permission is required

2. Addition of Option for Waiver of Parental Permission

Although most of the options for parental permission [and applicable criteria] are similar to the options for consent, there is one distinction.

There is an additional option to waive parental permission in cases when permission is not a reasonable requirement to protect subjects [e.g. for studies that target neglected or abused children]. Although this waiver option previously existed under the old Common Rule, the eIRB application has now been updated to reflect that this is an option.


12.0 Waiver of Parental Permission

There are two conditions when a waiver of parental permission may be granted. Please select the most appropriate option below:

- [ ] Waiver of Parental Permission when the study is minimal risk
- [x] Waiver when parental permission is not a reasonable requirement to protect subjects

Describe how each of the following criteria are met for this study:

The study is designed to evaluate conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect subjects (e.g. neglected or abused children)

A substitute mechanism for protecting the children who will participate will be implemented that takes into account:

The nature and purpose of the activities described in the protocol
The risk and anticipated benefit to the research subjects
Their age, maturity, status & condition

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3. Upload of Parental Permission Form Using the New Consent Form Template

All studies that must comply with the Revised Common Rule (new applications approved after 01/21/2019) are required to utilize the latest version of the IRB's informed consent form template [Version 16]. Rather than create a separate template for parental permission, Version 16 of the template has been adapted to also serve as a parental permission form.

A study-specific parental permission form, created using the new template, must be uploaded in Section 17 for studies involving children. Applications containing a parental permission form built using an older version of the consent template will be returned. A revised parental permission form, using the new template, will be required before the study is scheduled for IRB review. The new template and associated guidance on key information can be found here.

Please Note: If your study targets both adults or children able to consent for themselves and children unable to consent for themselves, the same form may be used as both a consent form and parental permission form. In these cases, the form must only be uploaded once and should reside in Section 15.

Please Note: Applications approved under the old Common Rule (approved on or before 1/20/2019) should continue to use the Version 3 parental consent template. There is no requirement to transfer to the Version 16 template and requests to transfer to the Version 16 template will not be processed.