IRBIS changes, effective June 5, 2026

IRBIS System Update:

Summary of Changes
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Exempt Application

The Exempt application has been updated to function more like a simplified version of the full application. You will only be prompted to describe your study and the study procedures, rather than select the appropriate Exempt category. This should decrease the number of stipulations since you will not be asked to guess which categories apply.

We have moved the consent process description to Section D.1 when you are interacting with participants either directly during an interview or focus group or indirectly in an online questionnaire. You will also describe any deception or withholding of information in this section.

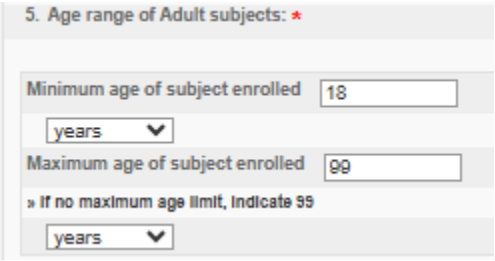
We have also included an Exempt Research Information Sheet template builder. Selected sections will populate based on your responses in the application.

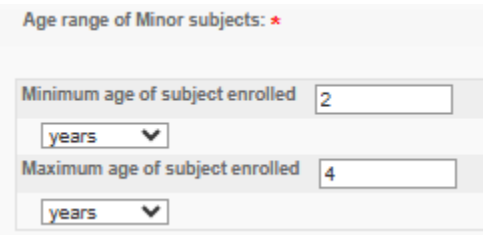
We think you will find this application very similar to the Full Form.

Updated Sections for Both Exempt and Full Form Applications

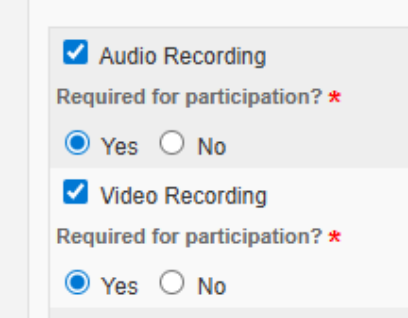
In updating the Exempt application to be more consistent with the Full Form, we have addressed issues in both forms that tend to solicit the most stipulations. We have updated some questions to gather more specific information.

Section A.2: Subjects has been updated so that when Children are selected as participants, there is a separate collection of the age range.

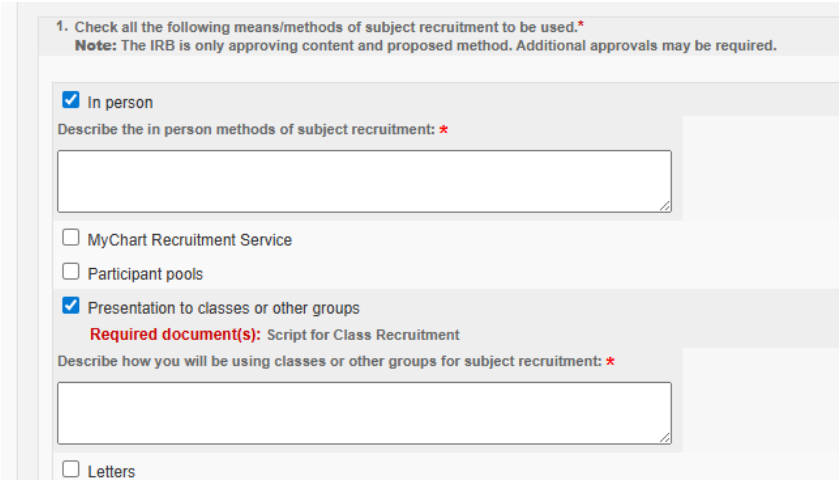




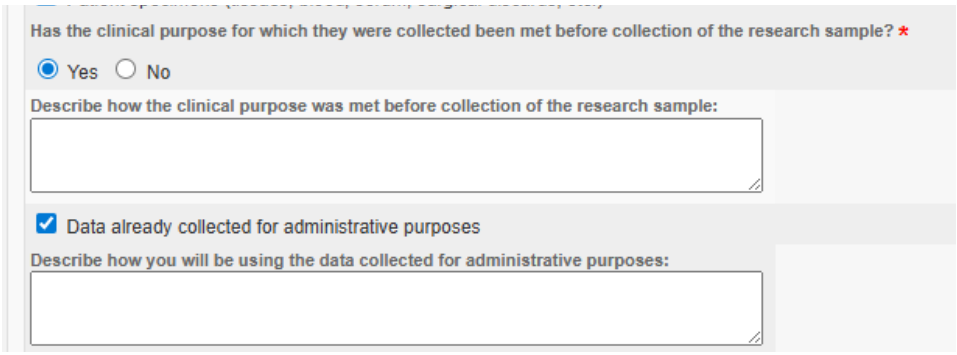
Section A.4: Includes options for when audio and/or video are or are not required for participation. This will populate specific information in the consent template.



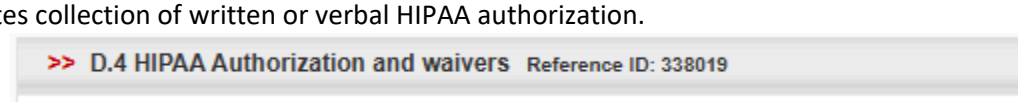
Section B.1: each selection allows for the description of just that method of recruitment.



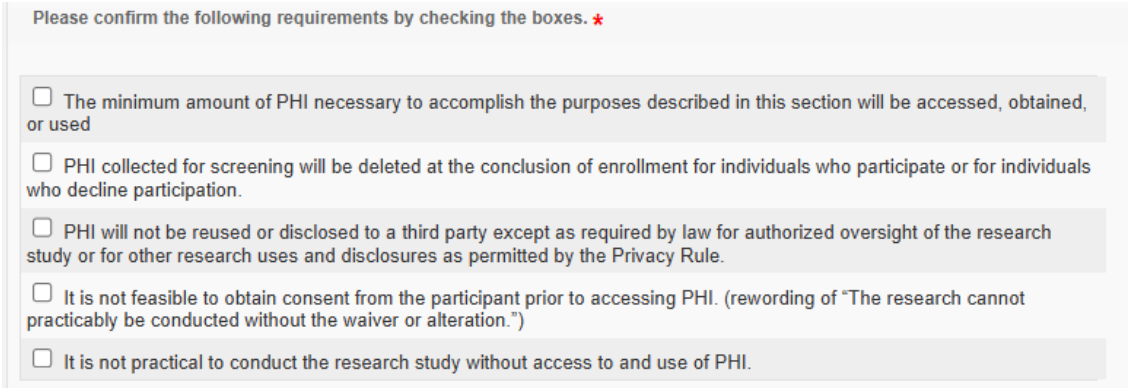
C.1: Similar to the recruitment section, each selection of existing data has a text box to describe that data source.



We have a new section for both forms that collects requests for a partial or full waiver of HIPAA as well as indicates collection of written or verbal HIPAA authorization.



With the waiver request, the specific requirements for the waiver have been updated for investigators to confirm the requirement is met rather than typing out a description confirmation.

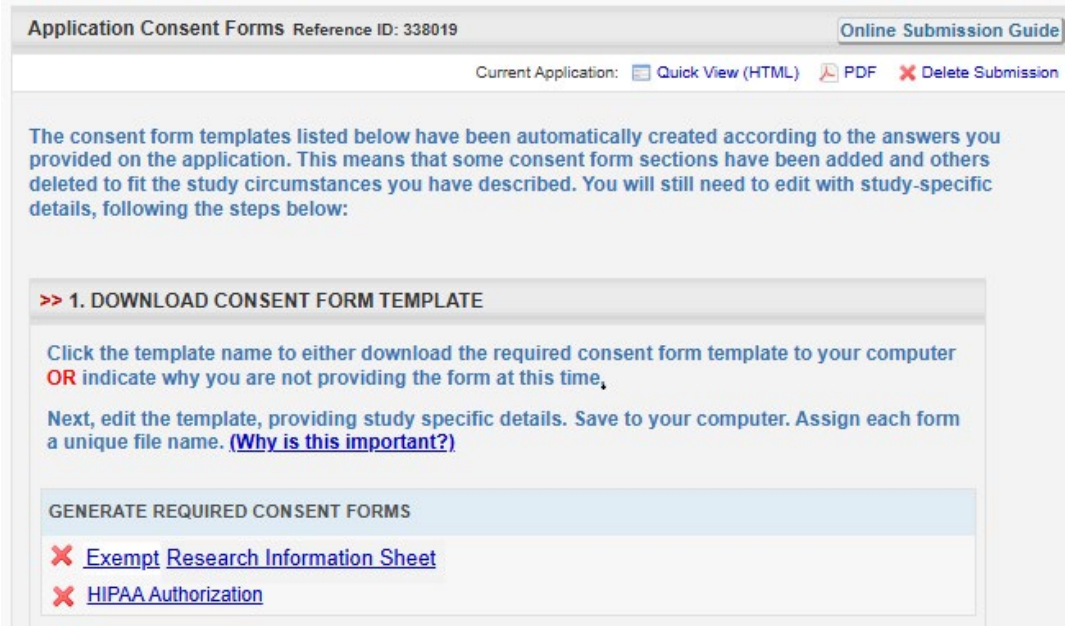


If you are interacting with the participant through interview or questionnaire and abstracting medical record data, you are expected to obtain signed or verbal HIPAA authorization. Your intent to collect that information is gathered in this section and will trigger the requirement for a HIPAA authorization form.

Consent Section for Exempt

The consent section in the Exempt form will have a link to a downloadable exempt consent form that will contain all of the needed information based on the responses in the application. This functions very similar to consent builder in the Full Form.

This section will also populate the HIPAA Authorization form when needed.



Exemptions and HIPAA

The new section D.4 will collect requests for HIPAA authorization or waiver to access and abstract medical record data even for most Exempt submissions.

This will allow Chart Reviews, CDW pulls and on-going reviews of Medical Records to be Exempt in most situations. Note the following will continue to require a Full Form:

- Chart review targeting prisoners
- Interaction with minors that does not meet Exempt criteria. This includes interviews or surveys of minors where the focus is not on educational curriculum or instruction.
- Development of a medical device, even if studying feasibility.

Studies that have been previously approved will be assessed for exemption during their next annual review. If they are found to meet the new Exempt requirements, they will be transitioned to exemption. Please note this feature may not be available until July.

Current Multi-site or Rely-on applications cannot be transitioned to Exempt.

Funding Sources

Once funding has ended for a study, you do not have to remove it from the application. Just add the end date in the funding table.