

IRBIS changes, effective June 5, 2026

IRBIS System Update:

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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.

5. Age range of Adult subjects: *

Minimum age of subject enrolled
years ▾

Maximum age of subject enrolled
» If no maximum age limit, indicate 99
years ▾

Age range of Minor subjects: *

Minimum age of subject enrolled
years ▾

Maximum age of subject enrolled
years ▾

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.

Audio Recording
Required for participation? *

Yes No

Video Recording
Required for participation? *

Yes No

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

1. Check all the following means/methods of subject recruitment to be used.*
Note: The IRB is only approving content and proposed method. Additional approvals may be required.

In person
Describe the in person methods of subject recruitment: *

MyChart Recruitment Service

Participant pools

Presentation to classes or other groups
Required document(s): Script for Class Recruitment
Describe how you will be using classes or other groups for subject recruitment: *

Letters

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

Has the clinical purpose for which they were collected been met before collection of the research sample? *

Yes No

Describe how the clinical purpose was met before collection of the research sample:

Data already collected for administrative purposes
Describe how you will be using the data collected for administrative purposes:

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.

>> **D.4 HIPAA Authorization and waivers** Reference ID: 338019

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.

Please confirm the following requirements by checking the boxes. *

- The minimum amount of PHI necessary to accomplish the purposes described in this section will be accessed, obtained, or used
- PHI collected for screening will be deleted at the conclusion of enrollment for individuals who participate or for individuals who decline participation.
- PHI will not be reused or disclosed to a third party except as required by law for authorized oversight of the research study or for other research uses and disclosures as permitted by the Privacy Rule.
- It is not feasible to obtain consent from the participant prior to accessing PHI. (rewording of "The research cannot practicably be conducted without the waiver or alteration.")
- It is not practical to conduct the research study without access to and use of PHI.

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.

Application Consent Forms Reference ID: 338019 [Online Submission Guide](#)

Current Application: [Quick View \(HTML\)](#) [PDF](#) [Delete Submission](#)

The consent form templates listed below have been automatically created according to the answers you provided on the application. This means that some consent form sections have been added and others deleted to fit the study circumstances you have described. You will still need to edit with study-specific details, following the steps below:

>> 1. DOWNLOAD CONSENT FORM TEMPLATE

Click the template name to either download the required consent form template to your computer **OR** indicate why you are not providing the form at this time.

Next, edit the template, providing study specific details. Save to your computer. Assign each form a unique file name. [\(Why is this important?\)](#)

GENERATE REQUIRED CONSENT FORMS

- [Exempt Research Information Sheet](#)
- [HIPAA Authorization](#)

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.

1. Funding Source(s) and/or Sponsor(s): Please list all entities that are providing monetary support or supplies (e.g., study drug, gifts, devices at no cost, or others that provide in-kind services).

Please search for and select your RAMSES proposal number. If you do not have a proposal number or cannot locate it, click the 'Currently Not Available' link and then proceed to select the sponsor of your project below.

UNC Ramses Number *	<input type="text" value="25-1829"/>
	Currently Not Available Clear
Sponsor Name *	<input type="text" value="National Institutes of Health (NIH)"/>
	Clear Sponsor
Sponsor Type *	<input type="text" value="Federal"/>
Prime Sponsor Name	<input type="text"/>
Prime Sponsor Type	<input type="text"/>
Sponsor/Grant Number	<input type="text"/>
Funding End Date	<input type="text" value=""/> Remove Date