IRBIS changes, effective 4:00 PM, December 5, 2019

IRBIS 5.09.19 Update:

New Common Rule – Part 1 changes:

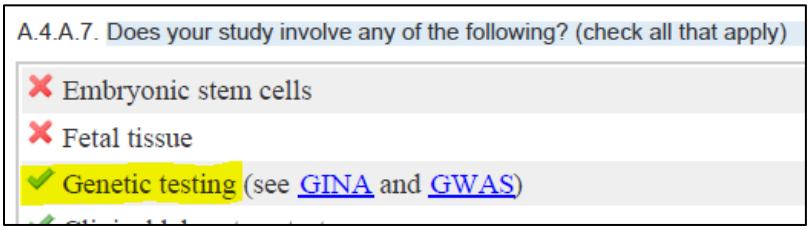
In preparation for studies to be approved after January 21, 2019, we are launching the new consent form templates. Changes include:

Addition of a Concise Summary to Consent Form Templates

1. A Concise Summary section has been added to the beginning of all IRB consent form templates. New language reads:

> CONCISE SUMMARY
>
> The revised Common Rule requires that consent forms contain a concise presentation of key information. The intention of this section is to provide potential research participants with a better understanding of the project's scope, including major risks and benefits, so they can make a more fully informed decision about whether to participate.
>
> This section should include a summary of the purpose of the study, duration of participation, major requirements of the study and any potential benefits. This section should also contain any significant risks of participating in the study. The information presented in this section may be discussed in greater detail later in the consent form.
>
> Examples of model summary statements are available on the IRB website. Click here to view examples.

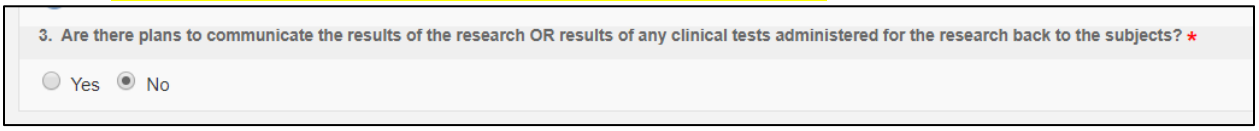
2. When "Genetic testing" is selected in A.4.A.7.:



The following language has been added to the IRB Consent templates (in the "What will happen if you take part in the study?" section:

> **For Whole Genome Sequencing (WGS)**: A statement on whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). (may be omitted if not applicable)

3. The wording in A.5.3. has been updated to: "Are there plans to communicate the results of the research OR results of any clinical tests administered for the research back to the subjects?"



4. If "Yes" to A.5.3. the following language has been added to the consent forms **after** the "What if we learn about new findings or information during the study?" section under new heading titled, "Will I receive any clinical results":

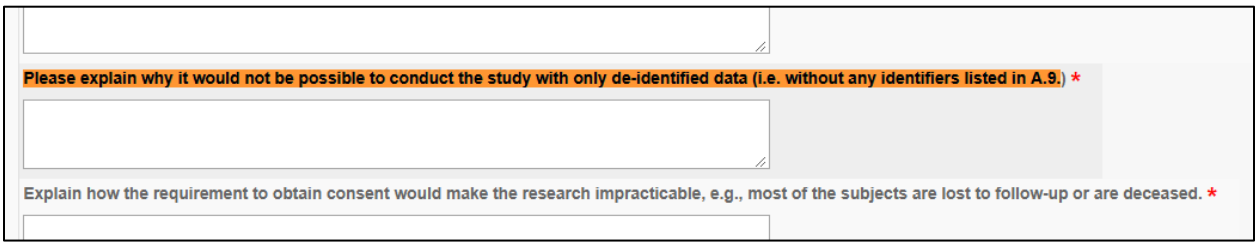
Will I receive any other clinical results?
Other clinically relevant results of this research will be communicated with you (describe which test results, when, and under what conditions). (if applicable)

5. A second paragraph stating, "The use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form" has been added to the "Will you receive results from research involving your specimens?" section of the consent form templates:

Will you receive results from research involving your specimens?
[Delete if separate consent for specimens]
Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally. There are no plans to re-contact you or other subjects with information about research results.

The use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form.

6. An additional element has been added to section D.3. (Full or partial waiver of consent), which states: "Please explain why it would not be possible to conduct the study with only de-identified data (i.e. without any identifiers listed in A.9.)." An explanation is required.



7. The following sentence has been added to the "How will information about you be protected?" section of the consent form template, "We may use de-identified data and/or specimens from this study in future research without additional consent."

How will information about you be protected?

Indicate how privacy and confidentiality will be protected. Briefly but as clearly as possible describe the key procedures for protecting the privacy and confidentiality of the individual's data, such as:

- How records will be secured.
- Who will have access to individually identifiable data (e.g. research collaborators, sponsors, etc.).
- Whether names or ID numbers will be used (if codes or numbers are assigned, describe how the linkage file will be secured).

Participants will/will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

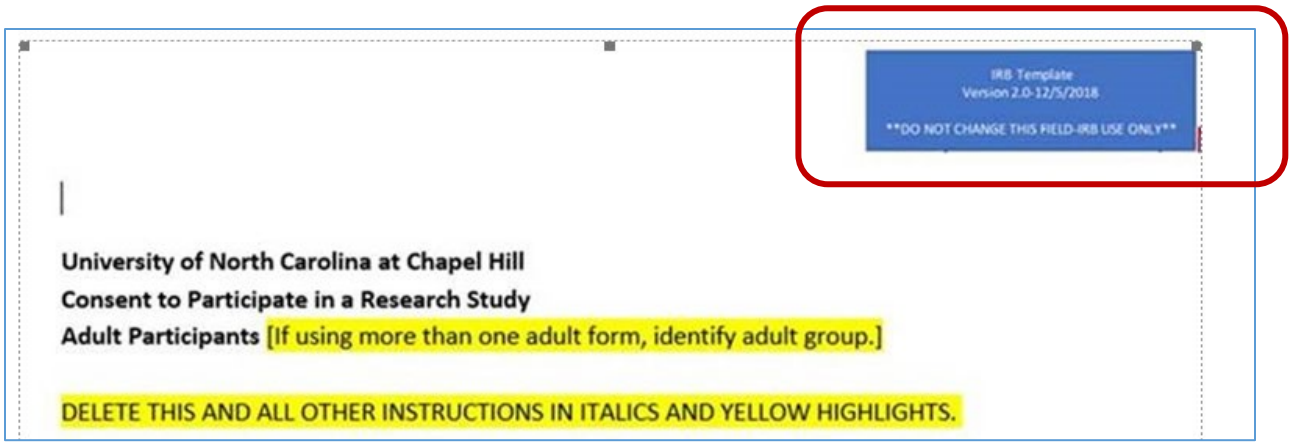
Where applicable, advise participants that they must agree not to reveal anything they learn from interviews, group discussions or other activities.

A copy of this consent form will go in to your medical record. This will allow the doctors caring for you to know what study medications or tests you may be receiving as a part of the study and know how to take care of you if you have other health problems or needs during the study.

[Delete if using a separate consent for specimens or if this does not apply to your study and you know data will never be submitted to a data sharing repository (e.g. dbGaP for genome-wide association study (GWAS))]

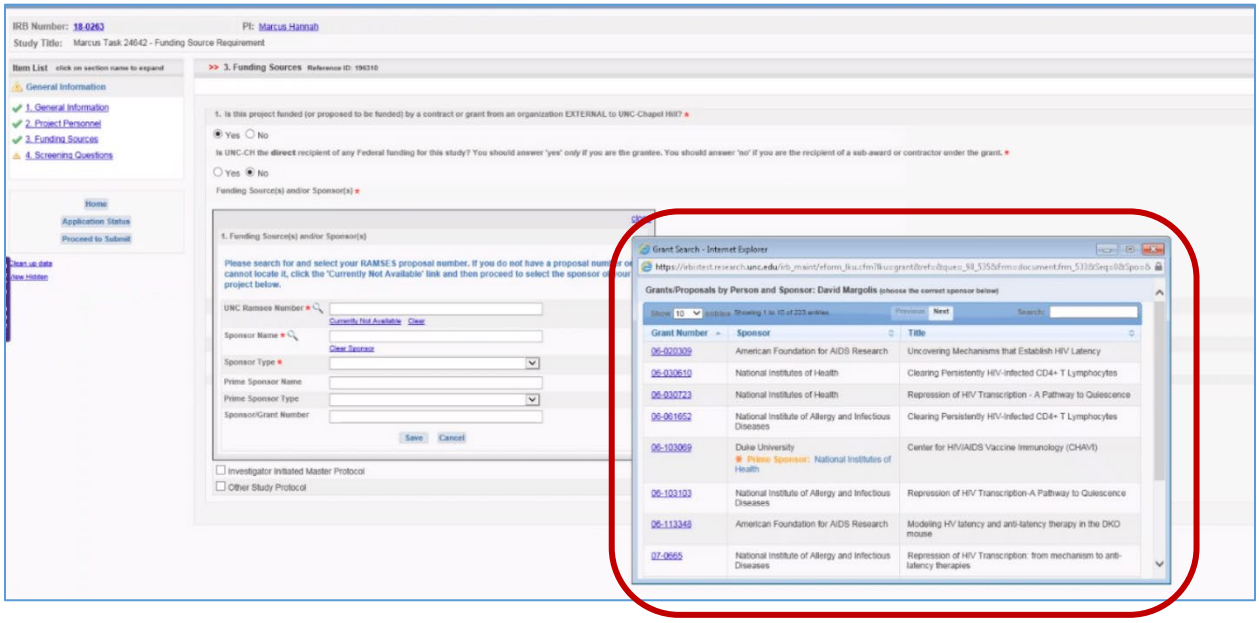
Consent Form Version Date:

A version number and date has been applied to the consent form templates to indicate which version of the OHRE consent form template is being used. Example: Version 2.0 – 12/5/2018
This information is planned to be moved to the footer of the document in a future update.



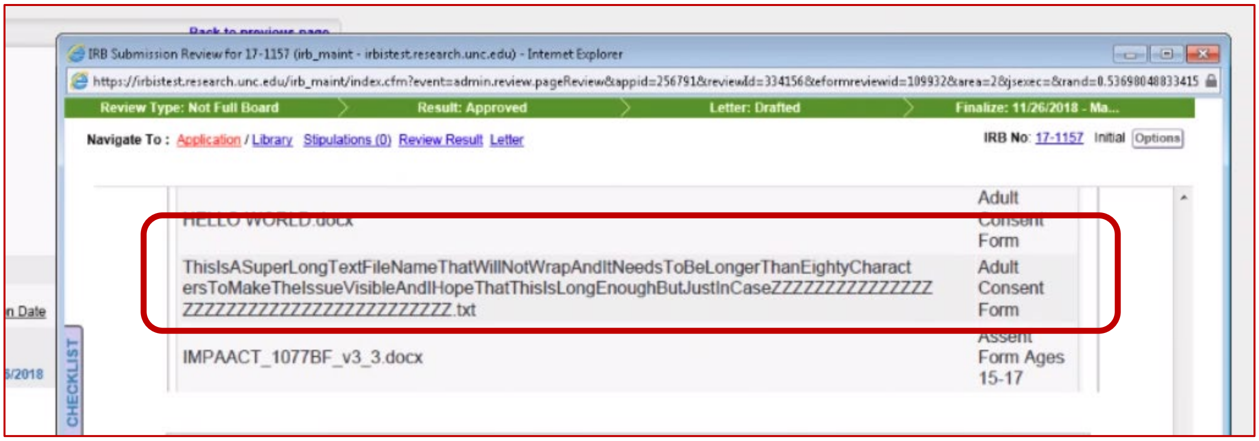
Funding Sources Update:

When using the Ramses Number search in the funding sources section, researchers search for the Lead Investigator of the EIPF Ramses Proposal. The results displayed now include the Grant Number (from Ramses), the Sponsor, and the Title. These new options to confirm and the ability to search should make it easier for Investigators to locate the proposal they are looking for and confirm it is the correct grant to link to the IRB:

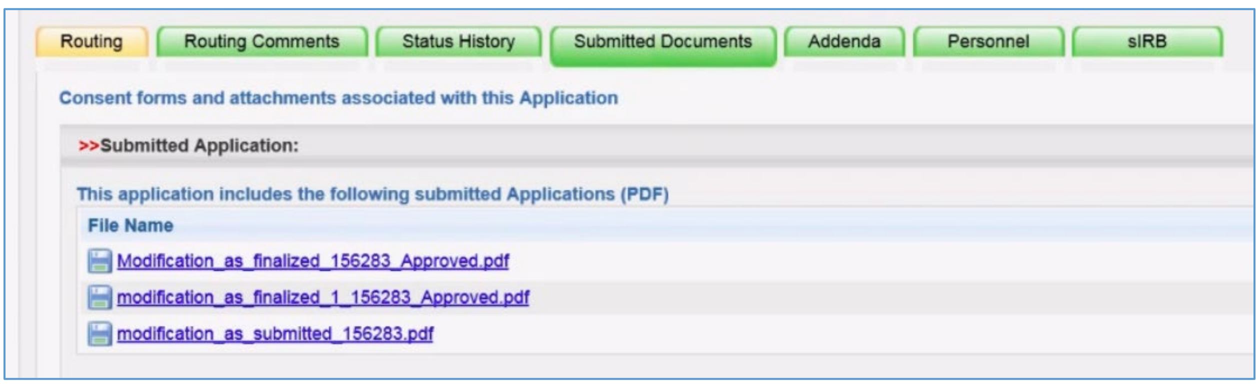


Fixes to PDF Files:

- When a submission is finalized and PDF is created, sometimes the text does not display properly due to lengthy attachment file names. These names will now be wrapped.



- Management tool: Manage eForm Final PDF, This new feature provides the ability to recreate a finalized PDF of a submission. If a PDF that is skewed and does not render properly, such as those that were created before the lengthy file name wrapping, this tool will allow OHRE Helpdesk to generate a new PDF.



Updates to Reporting:

- Repair an error in the Custom Submissions report that was causing issues when completing tasks such as the productivity report.
- Creating of a new reporting structure for future development of metrics and improved Admin home page bucket loading speeds.

NSI Follow-Up Update:

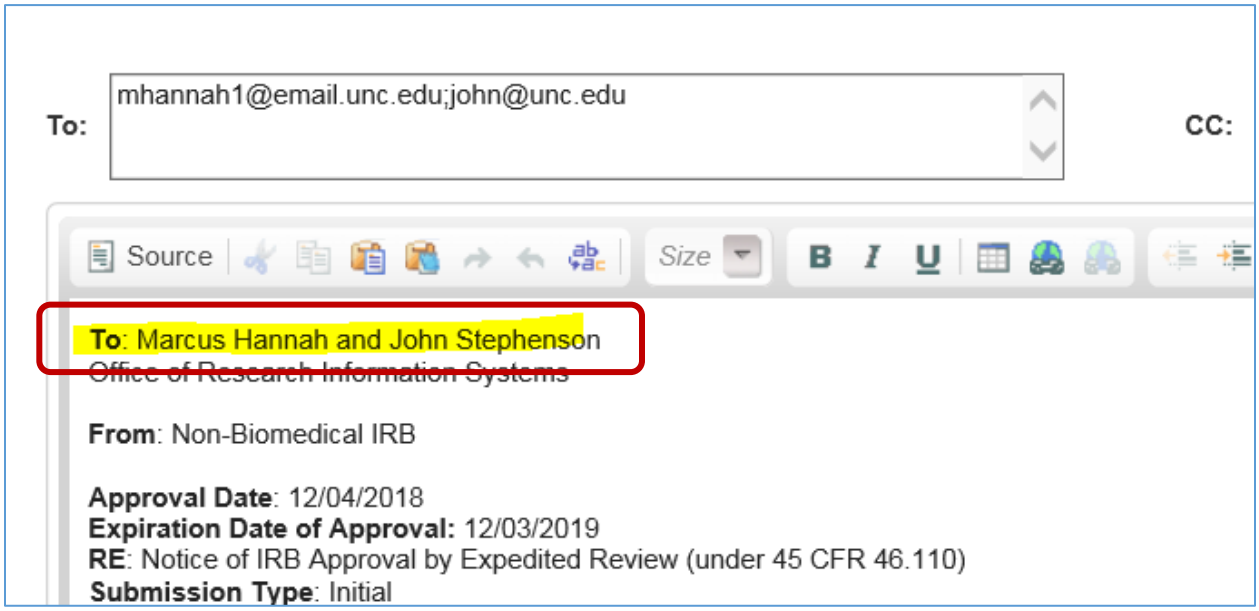
The option to Create new follow up NSI is removed if an NSI follow-up has already been created.

Example: The create new follow-up NSI will only be available for NSI 11620, but not the original report, NSI 3166.

Reference ID	Date Routing Complete	Submission Type	Submission Status	Full Board Agenda	Action Date	Letters
11641 as follow up to 8467	n/a	New Safety Information	In Draft	n/a	n/a	n/a
11628 as follow up to 8446	n/a	New Safety Information	In Draft	n/a	n/a	n/a
11627 as follow up to 3166	n/a	New Safety Information	In Draft	n/a	n/a	n/a
11626 as follow up to 3166	n/a	New Safety Information	In Draft	n/a	n/a	n/a
11621 as follow up to 6903	n/a	New Safety Information	In Draft	n/a	n/a	n/a
11620 as follow up to 3166 Create new follow up NSI	11/15/2018	New Safety Information	Submitted To IRB	n/a	n/a	
11619 as follow up to 6907	n/a	New Safety Information	In Draft	n/a	n/a	n/a
188218	5/16/2018	Renewal	Approved	n/a	7/27/2018	

Update to Letter Templates:

When a Faculty Advisor is indicated, letters will be sent and addressed to both the PI and the FA.



Updates to Data Security IRBIS page:

- When an administering department does not have a Data Security contact assigned, a default contact will be assigned using a hierarchical structure of the parent department's assigned contact. The parent department will also be displayed on the routing screen as the department that will oversee the data security for that submission.
    - Example: If the administering department is UNC Eshelman School of Pharmacy-Division of Pharmacotherapy and Experimental Therapeutics (452200) and no Data Security

Contact assigned, it will default to the parent department, UNC Eshelman School of Pharmacy-Office of the Dean (School of Pharmacy) (450100).