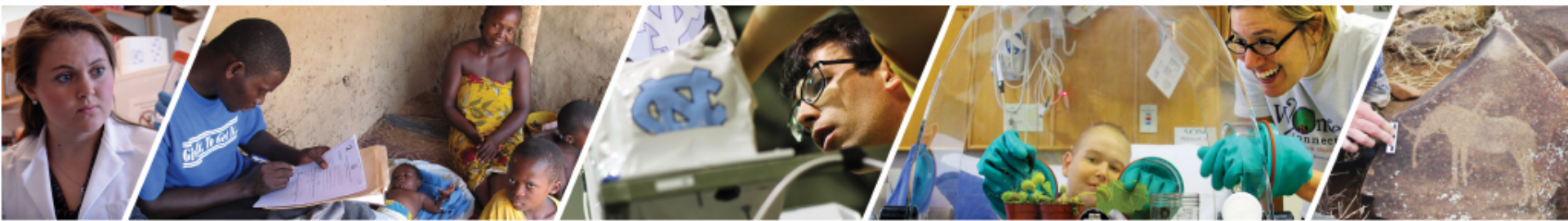


IRBIS Updates and Commercial IRB Utilization

Cassandra Myers, CIP

Director, Office of Human Research Ethics



UNC SYMPOSIUM
for
RESEARCH ADMINISTRATORS

Thursday, August 15, 2019
UNC Friday Conference Center

Objectives

IRBIS Updates

- Review the revisions implemented since the revised Common Rule update
- Review the results of the listening session and survey feedback
- Discuss upcoming IRBIS upgrades and timelines

Commercial IRB

- Review the drivers for increased commercial IRB utilization
- Review the IFB, survey and results from Q3 and Q4 of 2018
- Review Current and Future State Processes
- Discuss Implementation and System Upgrades



OHRE Mission and Metrics

The **Office of Human Research Ethics (OHRE)** is responsible for ethical and regulatory oversight of research at UNC-Chapel Hill that involves human subjects. The OHRE administers, supports, and guides the work of the Institutional Review Boards (IRBs) and all related activities.

- 6800+ Active Studies
- 15,000+ Submissions a Year
- 400+ Executed Reliance Agreements
- Quality, Reliance, Compliance and Education Areas
- 22 Staff
- IRB for UNC and UNC Health System



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IRBIS Updates

Common Rule and Beyond

Final Rule– Finally Here

On January 21, 2019:

- Final revision went into effect.
- 20 agencies have "signed on"
- FDA has not harmonized at this time

Largest Change Areas:

- Exempt Categories
- Consent Elements
- Annual Renewal/Continuing Review



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Exempt Change- Completed 1/21/2019

Exempt Categories

- Category updates in the system under “exemption requested”
- Re-reviewing previously approved to see if it meets new “exempt criteria”
- New table available for reference on OHRE website in September 2019



Exempt Change- Completed 1/21/2019

Consent Elements

- ❑ Any study with a consent form given initial approval on or after 1/21/2019 is required to have new elements.
- ❑ Do not utilize old approved consent forms for new studies unless pulling language into “revised template” available in IRBIS or on OHRE website.

Home / IRB and the Office of Human Research Ethics

IRB and the Office of Human Research Ethics

- About OHRE and the IRBs
- Getting Started
- Dates and Deadlines
- Just-in-Time / 118 Process
- IRBIS Online Submission
- Sample Consent Forms
- Additional Forms
- Reliance Agreements

IRB and the Office of Human Research Ethics

Announcements

Please click here to learn more about UNC's implementation of the Revised Common Rule which went into effect on January 21, 2019.

★ The UNC Office of Human Research Ethics/Institutional Review Board (OHRE/IRB) needs you! Please click here to learn more about the UNC IRB Membership Drive.

- April 9, 2018: IRBIS System Update related to Automatic Creation of COI Disclosures & New Safety Information. Click here for more

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[Help/Question](#)

UPCOMING

IRB



Annual Renewal- Completed 1/21/2019 & 7/16/2019

- Studies given final initial approval on or after 1/21/2019 under expedited review, and not regulated by the FDA, will **no longer require continuing review.**
- UNC-Chapel Hill is accredited by AAHRPP and their standards still require that a review be conducted, an administrative review will be required.
- In order to split administrative vs. continuing review we needed to revise the “Annual COI” process.
- Initial and renewal letters will state what “type” of annual review is required.



Annual Renewal- Completed 1/21/2019 & 7/16/2019

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Minimum levels of annual review required:

Types of Submission	Administrative Review	Continuing Review Req.
Exempt	N/A	N/A
Expedited- Not FDA Reg.	Yes	*
Expedited- FDA Reg.	No	Yes
Full Board Initial- Cat 9	No	*
Full Board- Not FDA Reg.	No	Yes
Full Board- FDA Reg.	No	Yes.

*May require continuing review if determined by reviewer or full board (e.g. vulnerable populations, experience, history of noncompliance).

How do I know what type of Annual Review is needed?

- Review the most recent “annual review letter”

Approval Date: January 29, 2019
UNC Administrative Review Due Date : January 29, 2020
RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)
Submission Type: [Initial, Renewal]
Expedited Category: 2.Minimal blood draw, 4.Noninvasive clinical data
Study #: [IRB_ID]

Study Title:

This submission, [REFERENCE_ID], has been approved by the IRB. It has been determined that the risk involved in this research is no more than minimal. **This research requires annual UNC administrative review.** Under the revised 'Common Rule' of 2018, this study does not require continuing review and IRB approval will not expire.

Administrative Review



Continuing Review



Approval Date: January 29, 2019
Expiration Date of Approval: January 28, 2020
RE: Notice of IRB Approval by Full Board Review
Submission Type: [Initial, Renewal]
Study #: [IRB_ID]

Study Title: [TITLE]

This submission, [REFERENCE_ID], has been approved by the IRB for the period indicated. It has been determined that the risk involved in this research is no more than minimal. **This research requires IRB continuing review. IRB approval will expire on January 28, 2020.**

- 2299 previously approved studies have been re-reviewed:
 - 1282 studies given administrative review
 - 217 studies transitioned to exempt



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Continuing Review Type- Completed 7/16/2019

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1st step for several upcoming features:

- “Study Type Specific Submissions” September 10, 2019
- Administrative Review Q4 2019
- Personnel Only Submissions Q4 2019

Create a Renewal

Use the choices below to begin the process of creating your Renewal.

No Changes

I will not be making any changes to my study.

Choose



Personnel Modification Only

I will be making changes to the project personnel.

Choose



Study Modification

I will be making changes to my study.

Choose



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Wrench- Completed 7/16/2019

- The “Wrench” feature will be very important for submissions going forward as additional updates are done.
- Allows for a submission change “type” (e.g., Renewal with no changes to personnel modification, or exempt to full submission)

The screenshot displays the IRB submission interface. At the top, the submission details are shown: IRB Number: [11-1050](#), PI: [Laura Cowan](#), and Submission Type: Renewal (No Changes). A blue wrench icon is located to the right of the Submission Type, with a blue arrow pointing to it from the right. Below this, the Study Title is "Demonstration Submission for Renewal Submission Types".

The main content area is divided into two sections. On the left is an "Item List" with the instruction "click on section name to expand". It contains several items: "Post Approval Submissions" (with a yellow warning triangle), "Renewal Action Requested" (with a yellow warning triangle), "Progress Report" (with a yellow warning triangle), "Continuing with Renewals" (with a green checkmark), and "Consent Forms" (with a green checkmark). The "Progress Report" item is selected, showing a "Reference ID: 248405".

The right section shows the "Progress Report" content, starting with "1. Number of Subjects involved through direct contact or use of...". Below this, there are two sub-sections: "A. Total projected number as approved by IRB: *" and "B. Total number of subjects included/enrolled to date (do NOT include...". Each sub-section has two input fields, both containing the number "6", followed by the text "(Prior Response)".

Overlaid on the bottom right of the screenshot is a dialog box titled "Change Renewal Type". The dialog box contains the text "Use the choices below to revise your study." and two main options: "Personnel Modification Only" and "Study Modification". Each option has a description: "I will be making changes to the project personnel." for Personnel and "I will be making changes to my study." for Study. Each option has a "Choose" button with a circular arrow icon. At the bottom of the dialog box is a "Cancel" button.



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RAMSES Personnel Import- Completed 7/16/2019

- List ONLY those personnel for whom this IRB will be responsible; do NOT include collaborators who will remain under the oversight of another IRB.
- If this is Community Based Participatory Research (CBPR) or you are otherwise working with community partners (who are not listed here as project personnel; consult with your IRB.
- If your extended research team includes multiple individuals with limited roles, you may not be required to list them here as project personnel.

The table below will access campus directory information; if you do not find your name, your directory listing may need to be updated. If a change to the Principal Investigator is requested during the course of the study, a [PI Change Form](#) must be submitted. *

[Click here to add personnel](#) [Click here to import personnel from your RAMSeS Proposal](#)

NOTE: The IRB database will link automatically to [UNC Human Research Ethics Training database](#) and the UNC Conflict of Interest personnel listed (for whom we have email addresses) will receive separate instructions about COI disclosures. The IRB will coordinate documentation is required.

3. If this research is based in a center, institute, or department, the home department will be AUTOMATICALLY inserted.

Department

Project Personnel Wizard

>> Import Personnel from Grant Proposal

Select Sponsor from the proposal for RAMSeS Number **10-3240** you want to import into your IRB Study.

Sponsor Name	Sponsor Type	Prime Sponsor	Prime Sponsor Type
<input checked="" type="checkbox"/> University of Toledo - Toledo, Ohio	Educational and Research Institutions		

Select personnel from the proposal for RAMSeS Number **10-3240** you want to import into your IRB Study.

Personnel Name	PID	Role
<input checked="" type="checkbox"/> Cheese, Chuck E.		Lead Principal Investigator
<input checked="" type="checkbox"/> Jowls, Jasper T.		Clinical Research Coordinator

[Import Project Personnel](#) [Cancel](#)

[Cancel / Search Again](#)



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Specific Submission Type- Est. Completion 9/10/2019

The screenshot shows the IRBIS Office of Human Research Ethics dashboard. The main content area is titled 'Create a New Study' and contains a table of submission options. The table has six columns: JIT/118, NHSR, Exempt, Full Form, Multi-Site, and Rely On. Each column has a description and a 'Choose' button with a help icon. Below the table is an 'Exempt' section with a detailed description. The left sidebar contains navigation links for 'Create New Submission', 'Submissions In Progress', 'All My Studies', and 'Routing Inbox'.

IRBIS Office of Human Research Ethics

HOME COMMITTEE REVIEWS ADMIN REPORTING GENERAL MANAGEMENT HELP DEVELOPER LOGOUT

Dashboard

Create New Submission

- New Study
- Modification
- Renewal
- New Safety Information
- Closure

Submissions In Progress

- In Draft (24)
- Being Routed (1)
- Dept Waiting PI Response (1)
- Submitted to IRB (1)
- IRB Waiting PI Response (1)

All My Studies

- My Studies
- Studies in My Dept

Routing Inbox

- PI/Advisor Certification (1)
- Dept Approval
- Dept Reviewer

Create a New Study

Use the choices below to begin the process of creating your New Study. Several time saving options have been provided to help streamline the creation of your New Study.

JIT/118	NHSR	Exempt	Full Form	Multi-Site	Rely On
Just In Time / 118	My study does not constitute research involving human subjects.	My study should be evaluated for a possible exemption.	My study is not NHSR, Exempt, Multi-Site, or RelyOn.	With Full Form: My study has personnel, organizations, or locations in addition to UNC-Chapel Hill.	My study will have reliance on an external IRB.
Choose ?	Choose ?	Choose ?	Choose ?	Choose ?	Choose ?

Exempt

Some research involving human subjects may be eligible for an exemption which would result in fewer application and review requirements. This would not apply in a study that involves drugs or devices, involves greater than minimal risk, or involves medical procedures or deception or minors, except in limited circumstances.

* Note- hovering over "Choose" will display help text.



Specific Submission Type- Est. Completion 9/10/2019

- Answers will be pre-populated to assist with Logic, and improving efficiency.
- The “Wrench” will be available to change submission type.



IRB Number: PI: Submission Type: Initial (JIT/118)
Study Title:

Item List [click on section name to expand](#) >> 4. Screening Questions Reference ID: 249985 [Online Submission FAQ](#) [Online Submission Guide](#)
Current Application: [Quick View \(HTML\)](#) [PDF](#) [Delete Submission](#)

[Post Approval Submissions](#)

[General Information](#)

[1. General Information](#)

[2. Project Personnel](#)

[3. Funding Sources](#)

[4. Screening Questions](#)

[Home](#)

[Application Status](#)

[Proceed to Submit](#)

The following questions will help you determine if your project will require IRB review and approval.

[The first question is whether this is RESEARCH \(click for details\)](#)

1. Does your project involve a systematic investigation, including research development, testing and evaluation, which is designed to develop or contribute to generalizable knowledge? PLEASE NOTE: You should only answer yes if your activity meets all the above. *No

1.A Are you using a Humanitarian Use Device (HUD), Expanded Access IND or IDE, or an Emergency use of an investigational drug or device? * No

[The next questions will determine if there are HUMAN SUBJECTS \(click for details\)](#)

2. Will you be obtaining information or biospecimens through intervention or interaction with the individual, and use, study, or analysis of the information or biospecimens? This would include any communication or interpersonal contact between investigator and subject such as using in-person or online questionnaires/surveys, interviews, focus groups, observations, treatment interventions, etc. PLEASE NOTE: Merely obtaining information FROM an individual does not mean you should answer 'Yes,' unless the information is also ABOUT them. * No

3. Will you be obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens collected through means other than direct interaction? This would include data, records or biological specimens that are currently existing or will be collected in the future for purposes other than this proposed research (e.g., medical records, ongoing collection of specimens for a tissue repository). * No

OR

Will you be using human specimens that are not individually identifiable for [FDA-regulated in vitro diagnostic \(IVD\) device investigations](#)? * No

The following questions will help build the remainder of your application.

4. Will subjects be studied in the Clinical and Translational Research Center (CTRC, previously known as the GCRC) or is the CTRC involved in any other way with the study? (If yes, this application will be reviewed by the CTRC and additional data will be collected.) * No

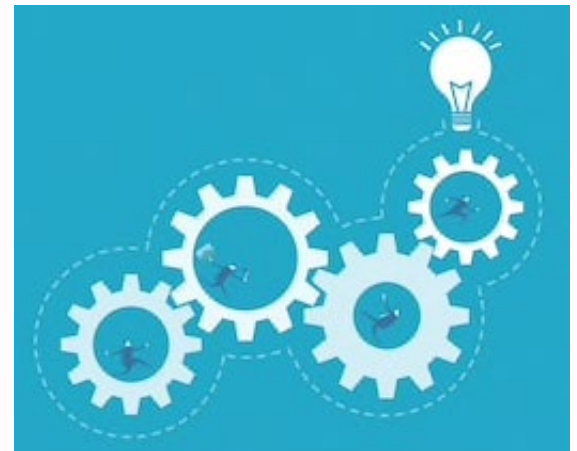
5. Does this study directly recruit participants through the UNC Health Care clinical settings for cancer patients or does this study have a focus on cancer or a focus on a risk factor for cancer (e.g. increased physical activity to reduce colon cancer incidence) or does this study receive funding from a cancer agency, foundation, or other cancer related group? (If yes, this application may require additional review by the Oncology Protocol Review Committee.) * No

6. Are any personnel, organizations, entities, facilities or locations in addition to UNC-Chapel Hill involved in this research (e.g., is this a multi-site study or does it otherwise involve locations outside UNC-CH, including foreign locations)? You should also click "Yes" if you are requesting reliance on an external IRB, or that UNC's IRB cover another site or individual. [See guidance](#). * No



Why Specific Submission Types?

- Allows for “submission specific” questions
- Remove or pre-answer un-needed questions
 - All applications reviewed over the next 18 months.
 - See Commercial IRB Rely-On Application Slides
- No loss of historical data
- Assists with future updates including personnel only modifications



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Commercial IRB Utilization

Change Drivers and Invitation for Bid (IFB)

Drivers:

- Focus on growing research at UNC
 - Industry Sponsored Clinical Trials
 - Federally Funded
- Resource limited departments
 - Focus on value-add
- Need to improve study start-up time

IFB:

- Provider(s) to perform Commercial Institutional Review Board Services (the "Services") **related to non-emergent, industry sponsored, multi-site clinical trials involving drugs, biologics or devices for more than minimal risk research.**



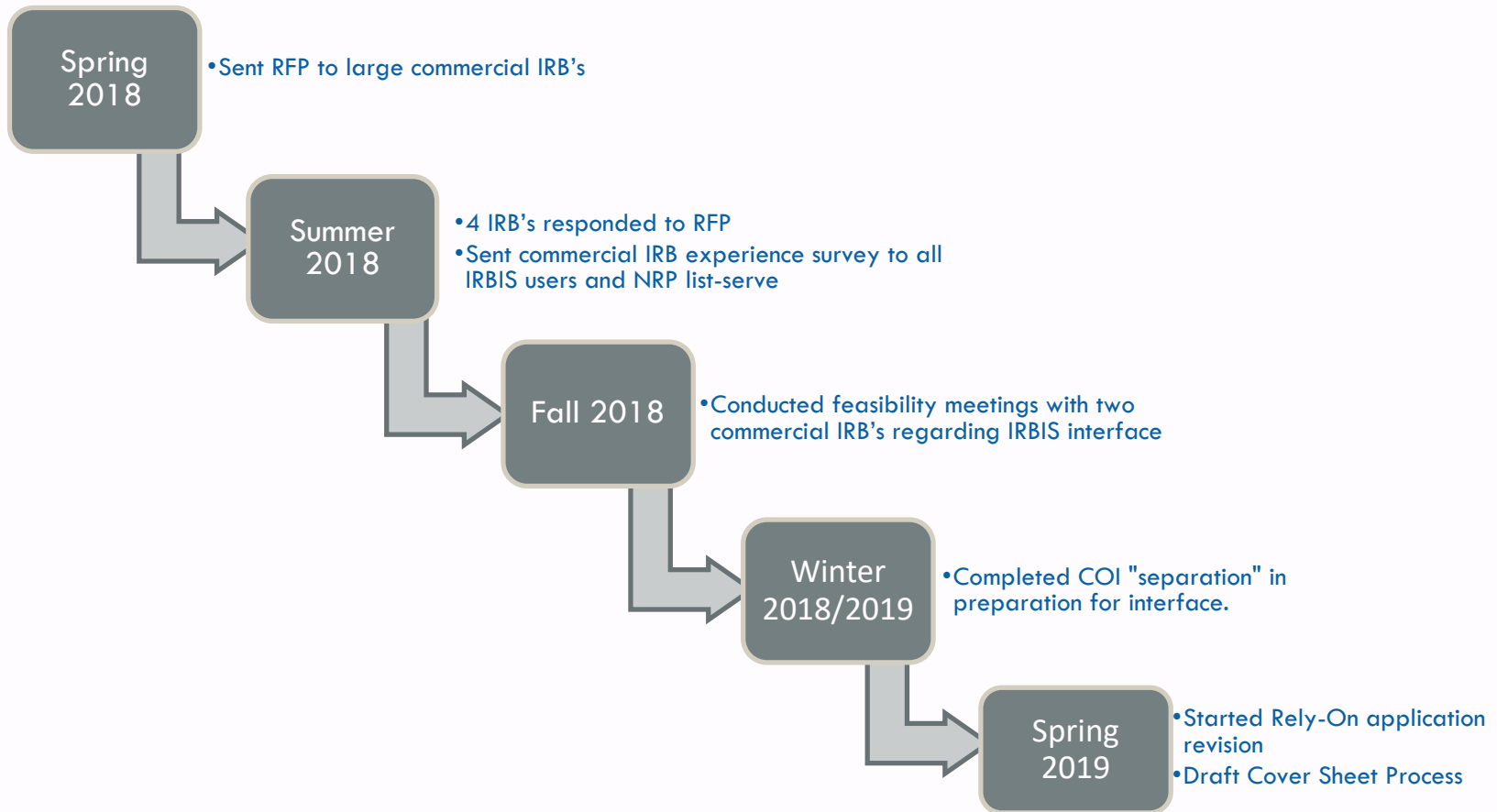
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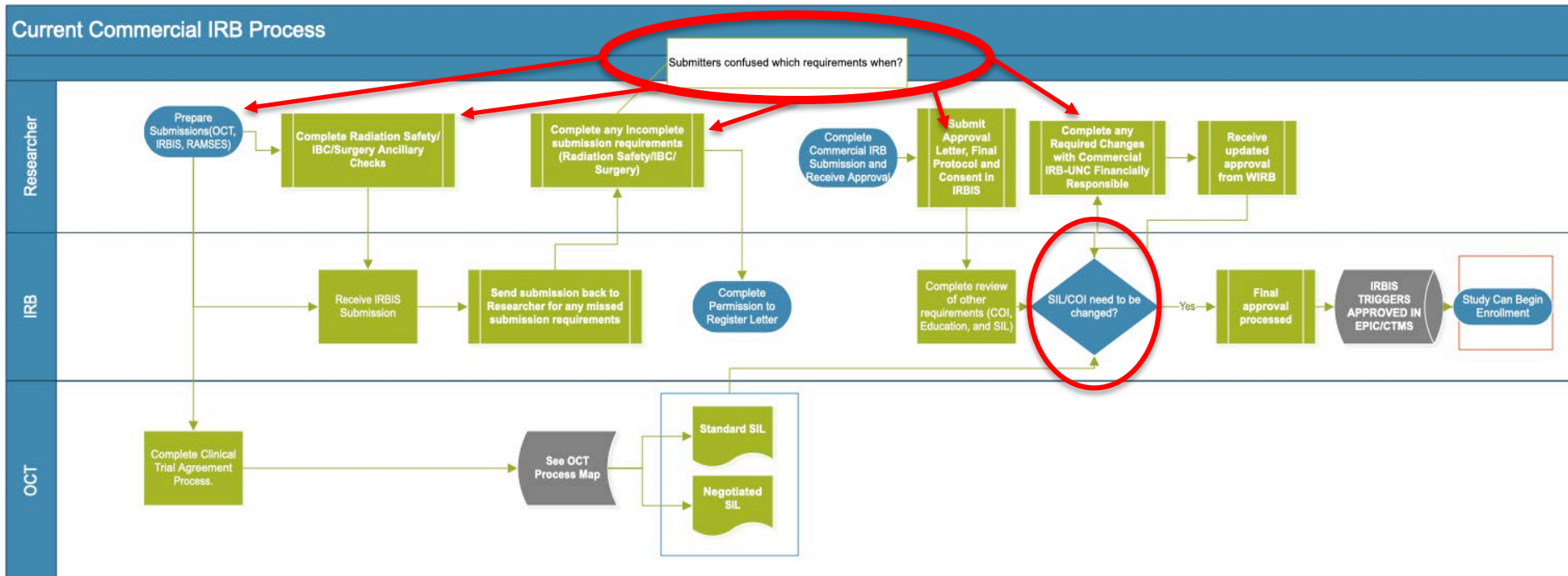
Timeline- Past



Current Process

Feedback:

- Difficult to understand what to submit and when in the process
- Multiple submissions for study start-up
- COI and SIL change requiring multiple modifications



Survey Results

- Multiple submission for initial approval (before and after IRB of record review).
- Confusion about when to submit when and where.
- UNC IRB's inconsistency in review for multi-site studies that are reviewed by commercial IRB
- WIRB was the most utilized
- Over 80% of our research community recommended utilizing commercial IRB's
- Over 90% of our research community stated that the commercial IRB was responsive to their concerns or questions



What does this mean ?

.....

New Industry Sponsored Multi-Site Clinical Trials:

- Commercial IRB Utilization*
- Application started by study team on or after 09/11/2019

Existing Industry Sponsored Multi-Site Clinical Trials:

- No change- Study can remain with current IRB of record
- May change reviewing IRB as appropriate, check with the OHRE Reliance Group

Federally Funded, Non-Funded, and Single-Site Trials/Studies:

- No change

*Studies may be reviewed by the UNC-IRB on a study by study permission basis

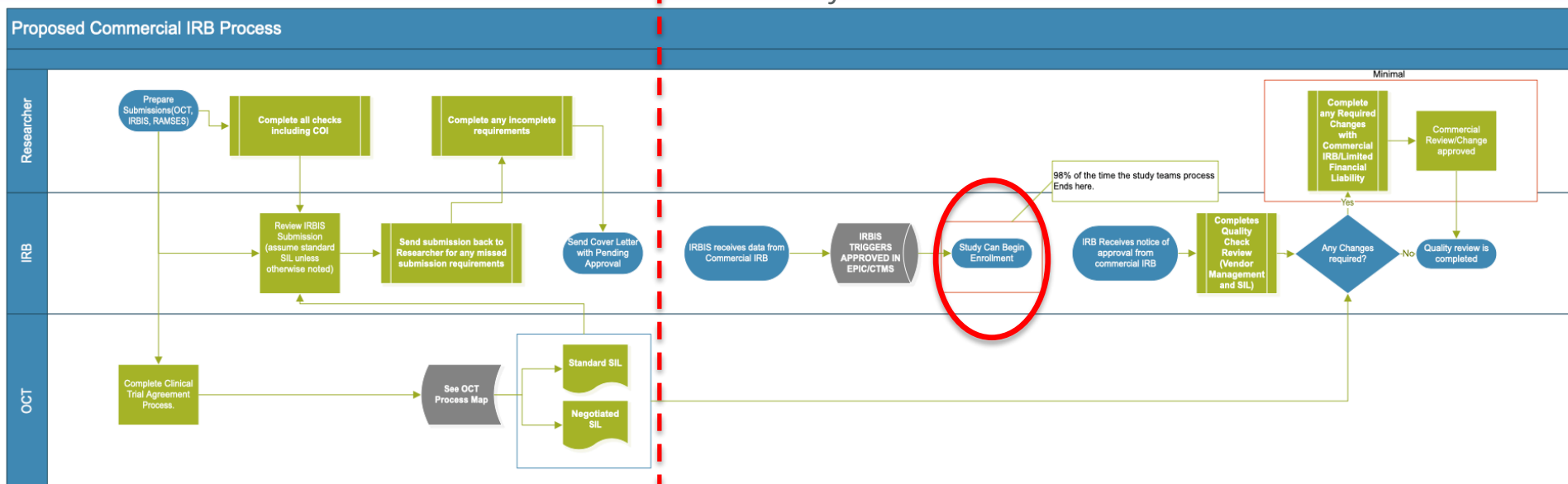


Future Process for WIRB

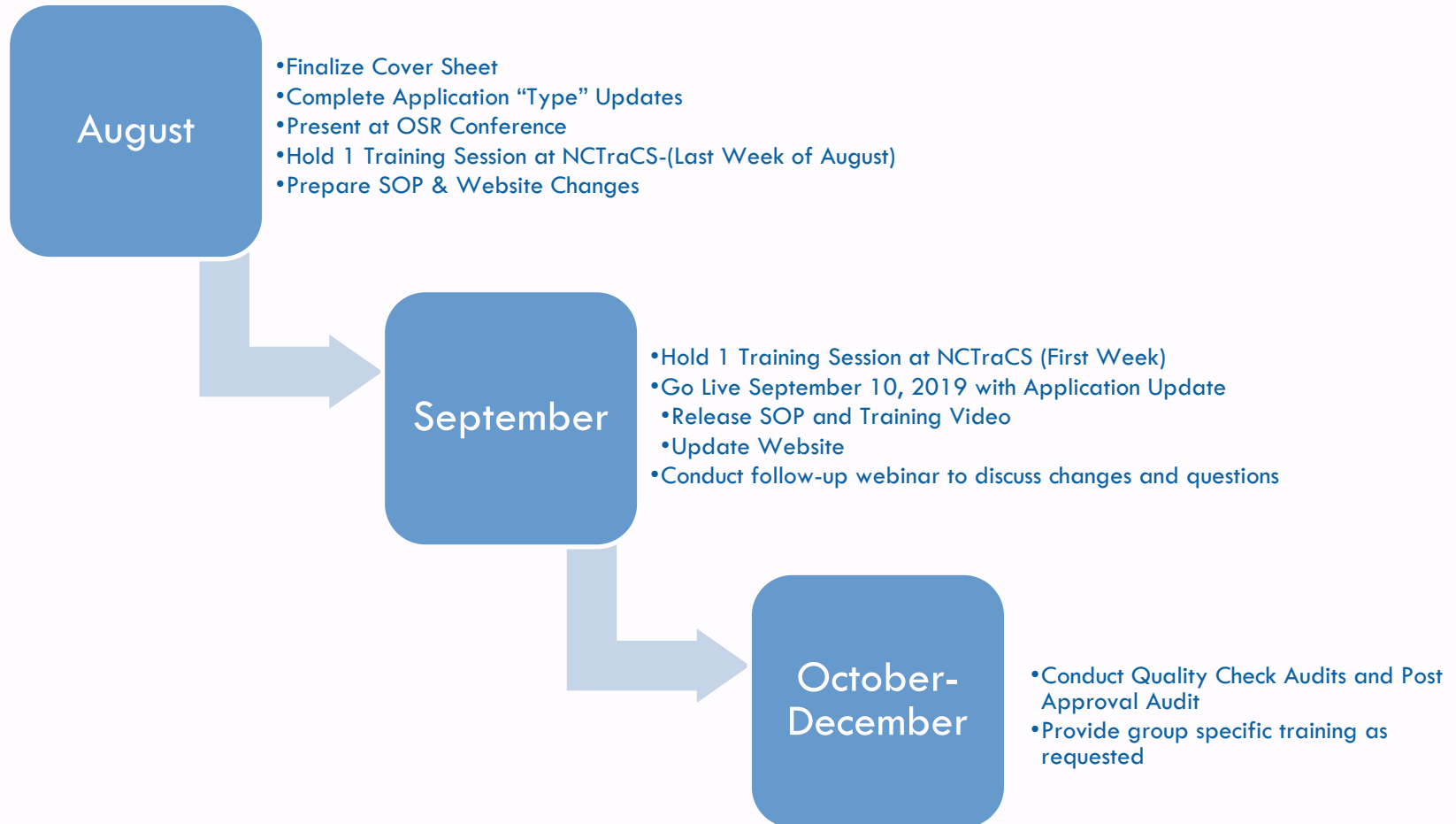
- Clarity in submission timeline and requirements
- All studies that utilize commercial IRB's can take advantage of revised forms and cover sheet up to the "dotted line"
- WIRB approval's and continuing review dates (future enhancement) will be provided via feed and will populate system, reducing submissions.

All commercial IRB's

WIRB only at this time



Timeline and Onboarding- Future



Rely-On Submission Type- Est. Completion 9/10/2019


The screenshot shows the IRBIS web application interface. At the top, there is a navigation bar with the IRBIS logo and the text "Office of Human Research Ethics". Below this, there are several menu items: HOME, COMMITTEE REVIEWS, ADMIN, REPORTING, GENERAL MANAGEMENT, HELP, DEVELOPER, and LOGOUT. The main content area is divided into several sections. On the left, there is an "Item List" with a "click on section name to expand" instruction. The list includes "General Information", "Relyon Information", "Multi-Site Information", "1. General Information", "2. Project Personnel", "3. Funding Sources", and "4. Screening Questions". Below the list are buttons for "Home", "Application Status", and "Proceed to Submit". The main content area is titled ">> 5.A. Information to rely on an External IRB Reference ID: 249987". It contains a section "1. Select External IRB: *" with four radio button options: "National Cancer Institute Central IRB (NCI CIRB)", "Independent/Central IRB already designated for this study by Sponsor/CRO", "Institutional IRB (e.g., another university)", and "Collaborative IRB". Below the options, there is a note: "* Required. To navigate the Application, press continue or any link in the Item List to your left." At the bottom right, there are three buttons: "Save and Stay", "Save and Continue", and "Clear Responses".

- The order of questions has been revised to be more relevant to the specific application type the researcher is interested in.
- For the Rely-On option, the first question will be which External IRB the researcher is requesting to rely on.
- Additional questions not relevant to this submission type have been removed or pre-populated to make the process more streamlined.



Cover Sheet

- Starting with WIRB there will be a “Cover Page” given with every external IRB sign-off



External IRB Submission Cover Page

All submissions to be reviewed by an external IRB must be accompanied by this UNC-Chapel Hill IRB signed cover page in order to be processed. UNC OHRE/IRB Staff will review the UNC-specific forms, sign this institution cover page, and return a copy to the submitting party via IRBIS.

Upon receiving this signed cover page from the UNC OHRE/IRB Office, submit the signed cover page and all required submission documents to the external IRB selected below.

Designated External IRB:

- Items covered in Cover Page will include:
 - Subject Injury Language
 - HIPAA Determinations (UNC-Full, WIRB Partial)
 - HIPAA Authorization
 - W-8/W-9 Requirements
 - COI Language

WIRB/Commercial IRB Utilization Training Sessions

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In-Person Training at NCTraCS

- August 27, 2019 1:00-2:00 PM
- September 5, 2019 11:00-12:00 PM
- Register online through NCTraCS website

Webex/Zoom

- Week of September 16th, 2019
- Invitation sent in NRP e-mail
 - Register for NRP List-Serve

Electronic Resources

- OHRE Website
 - IRBIS, SOP, Consent Form Updates
 - Summary of changes and training registration



Contacts

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