IRBIS Updates and Commercial IRB Utilization

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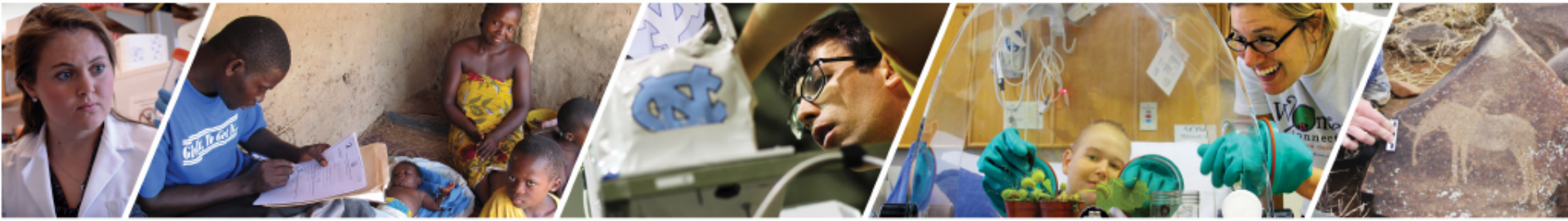
Director, Office of Human Research Ethics



UNC SYMPOSIUM for RESEARCH ADMINISTRATORS 2019

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

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

Exempt Change- Completed 1/21/2019

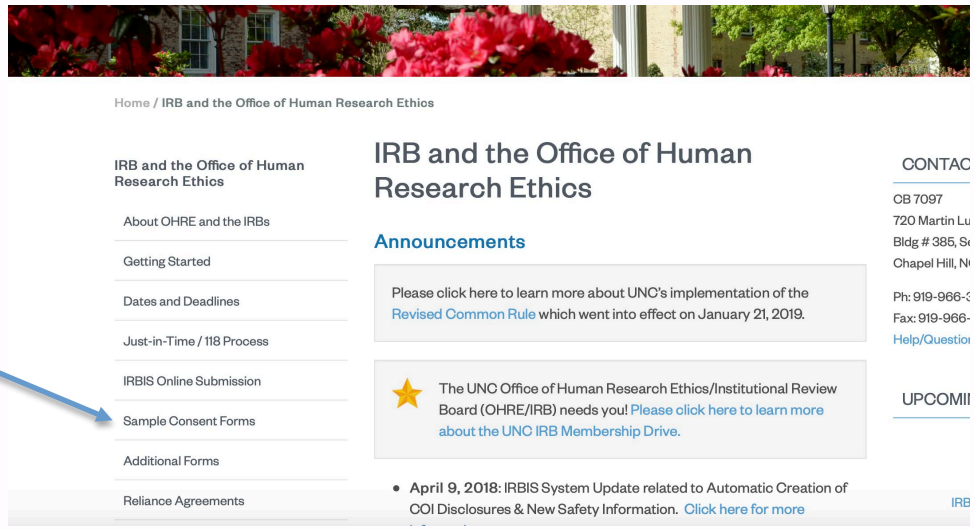
Exempt Categories

- 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.



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

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]

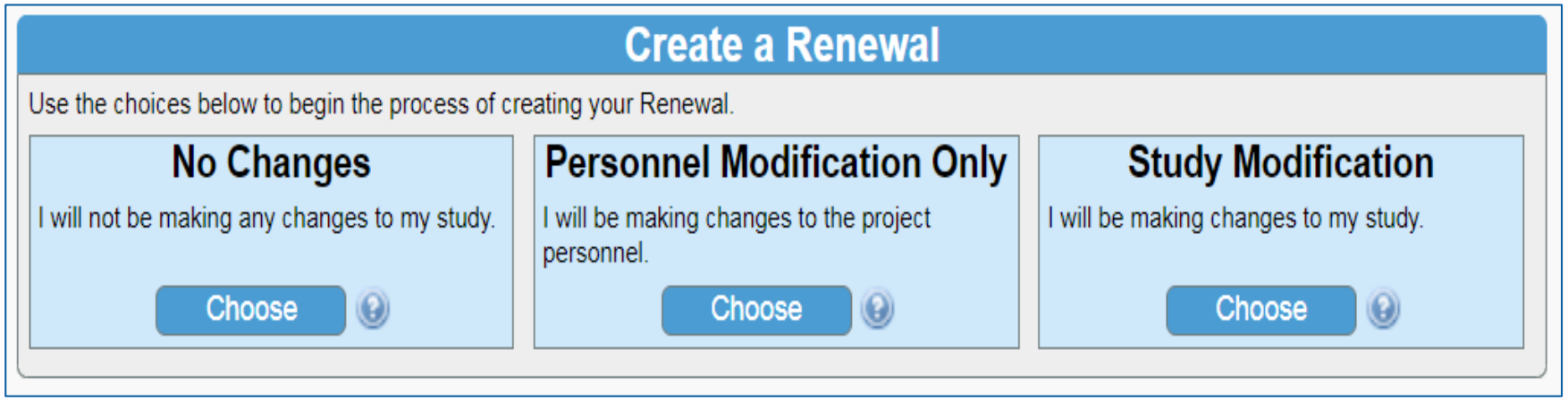
This submission, [REFERENCE_ID], has been approved by the IRB for the period indicated. It has been determined that the risk involved in this research is no more than minimal. **This research requires IRB continuing review. IRB approval will expire on January 28, 2020.**

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

Continuing Review Type- Completed 7/16/2019

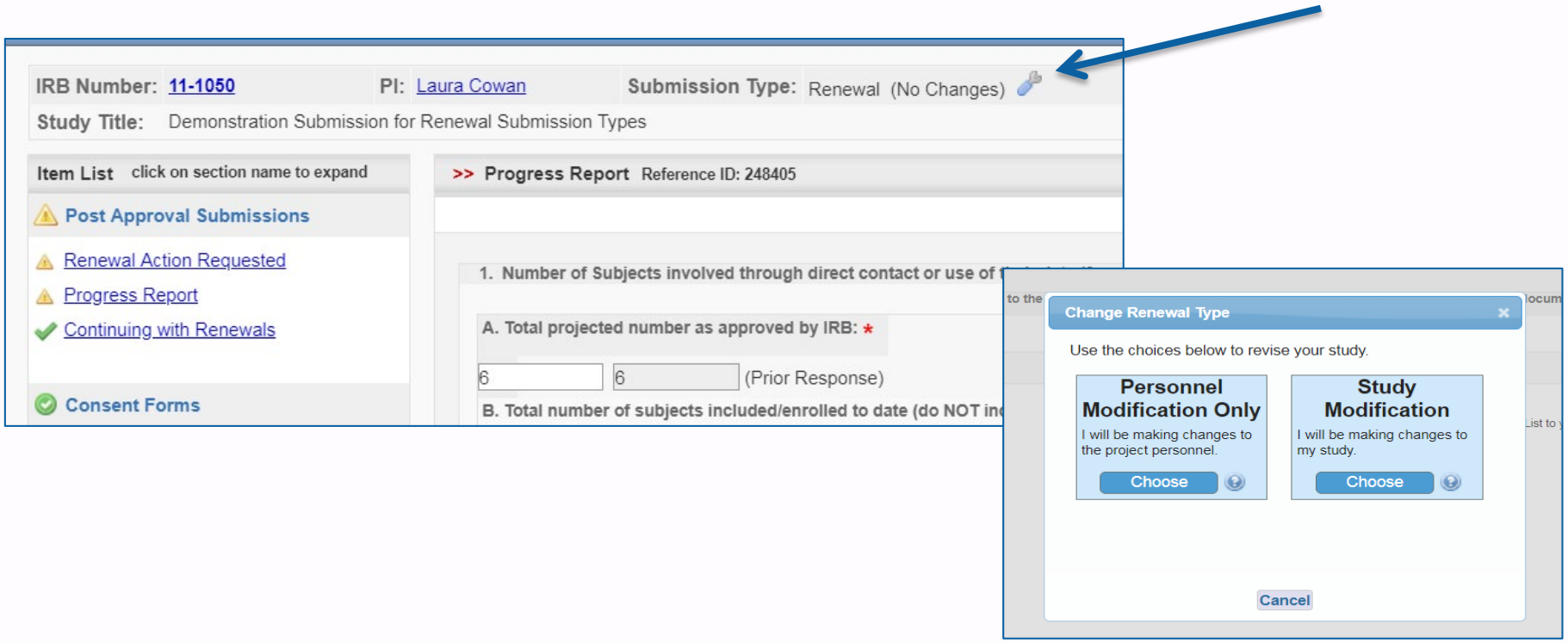
1st step for several upcoming features:

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

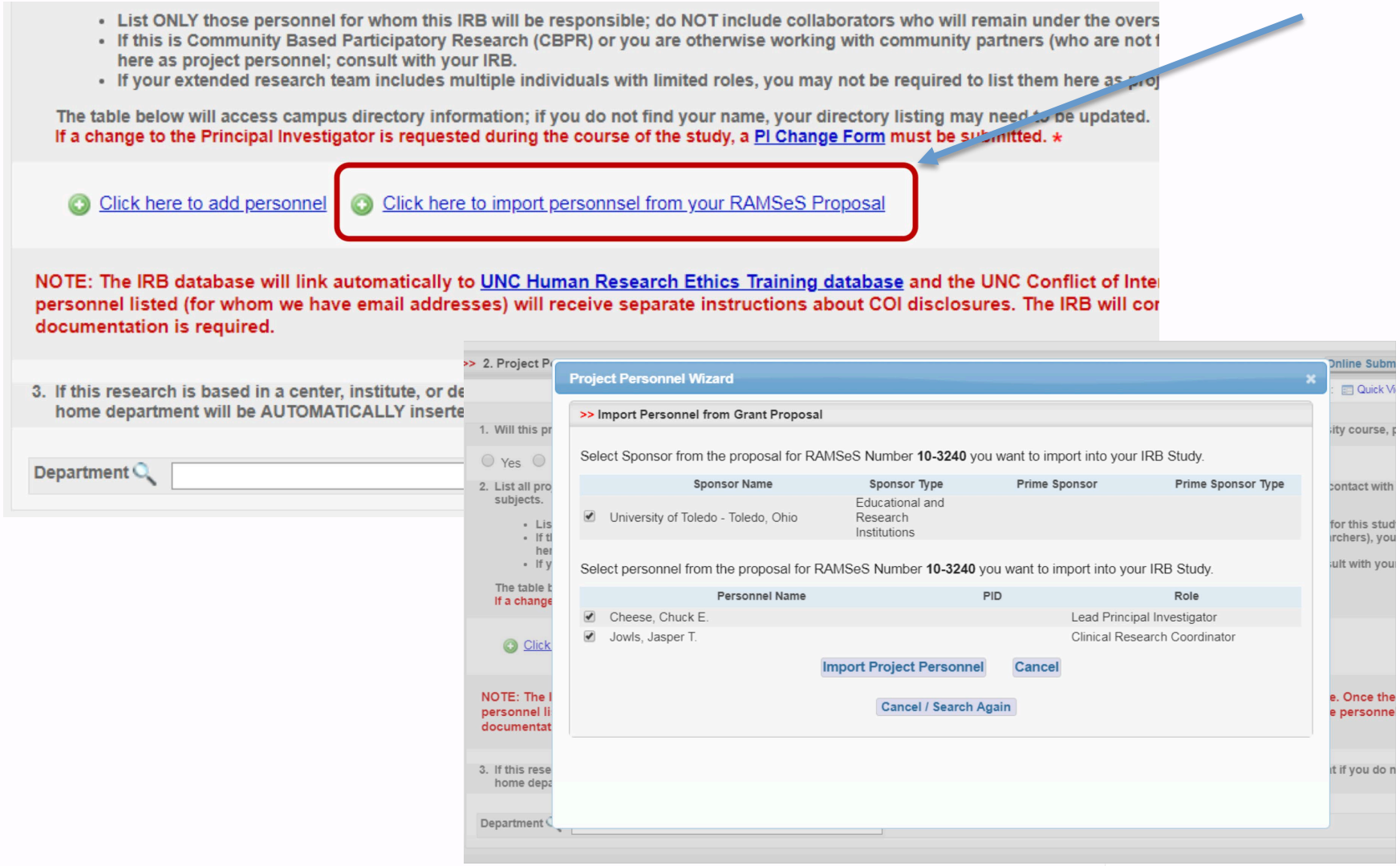


Wrench- Completed 7/16/2019

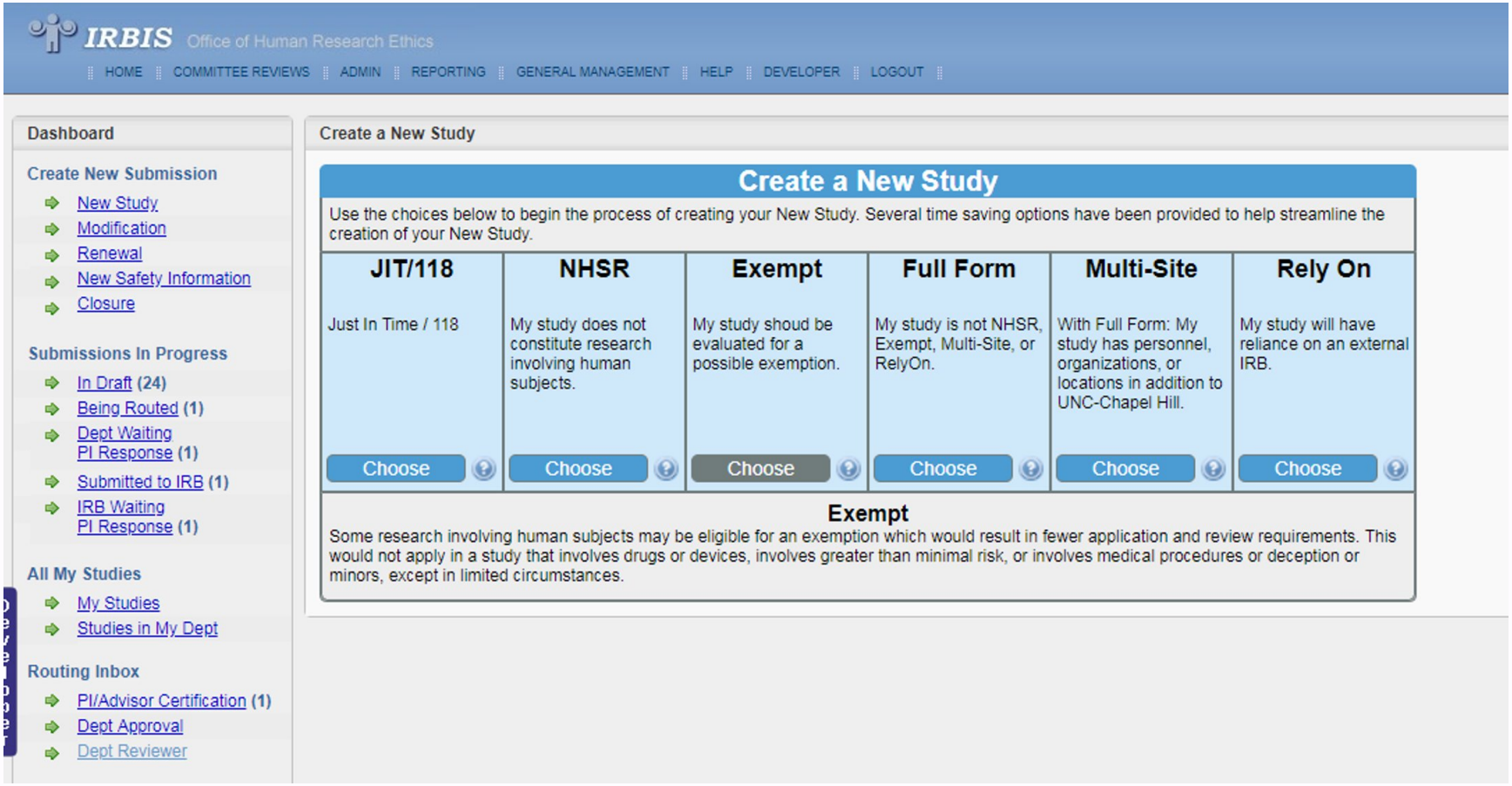
- The "Wrench" feature will be very important for submissions going forward as additional updates are done.
- Allows for a submission change "type" (e.g., Renewal with no changes to personnel modification, or exempt to full submission)



RAMSES Personnel Import- Completed 7/16/2019



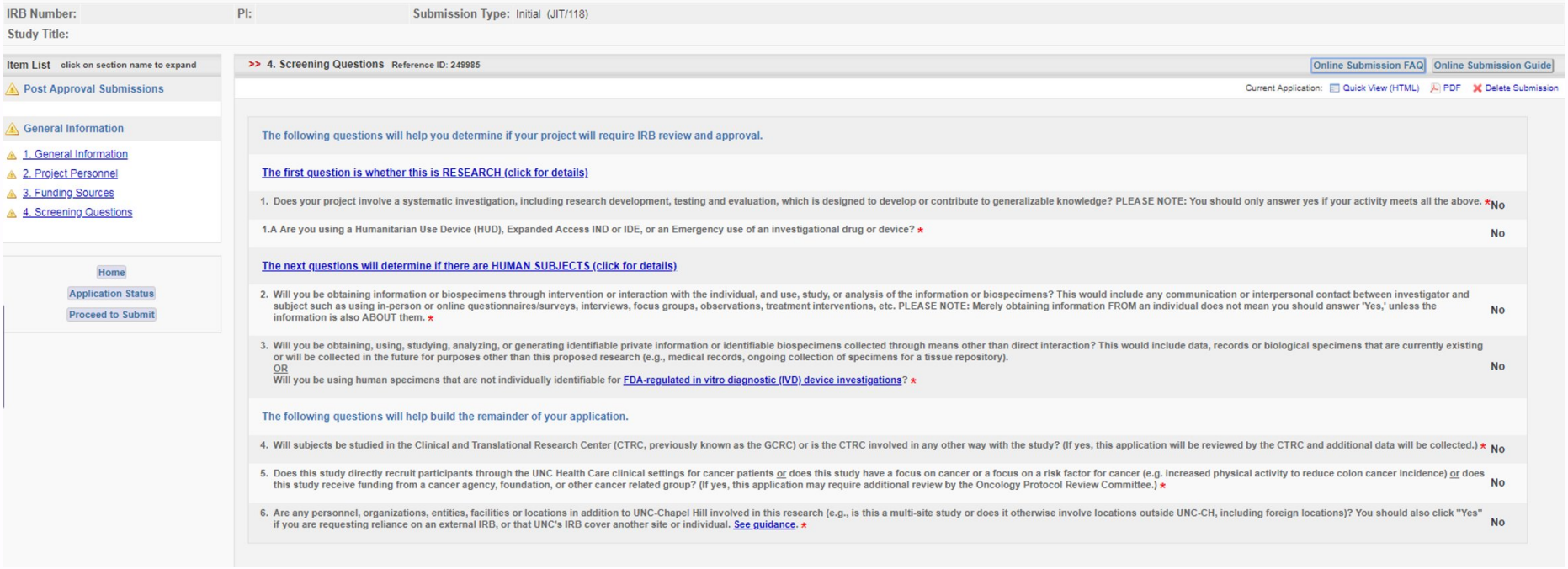
Specific Submission Type- Est. Completion 9/10/2019



* Note- hovering over “Choose” will display help text.

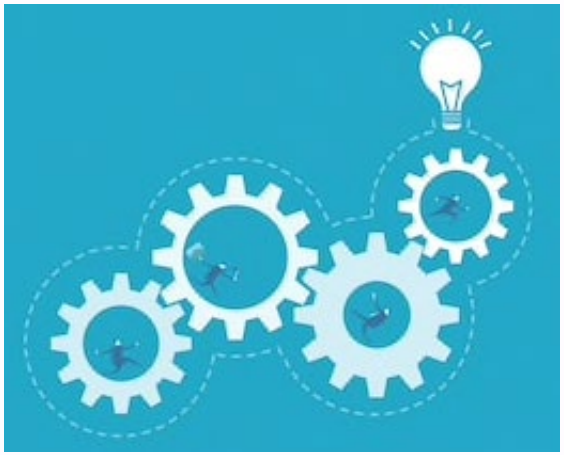
Specific Submission Type- Est. Completion 9/10/2019

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



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



Commercial IRB Utilization

Change Drivers and Invitation for Bid (IFB)

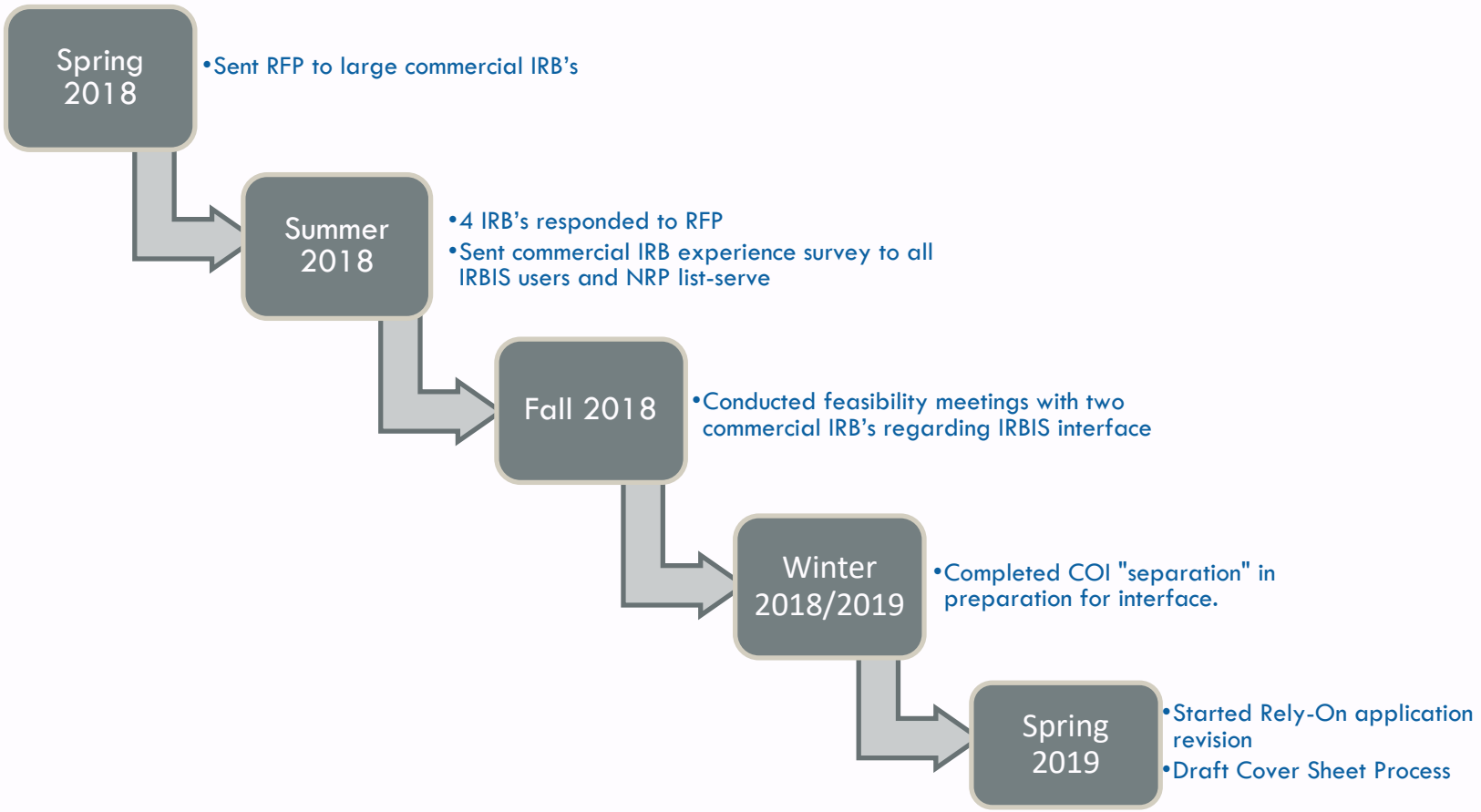
Drivers:

- 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.**

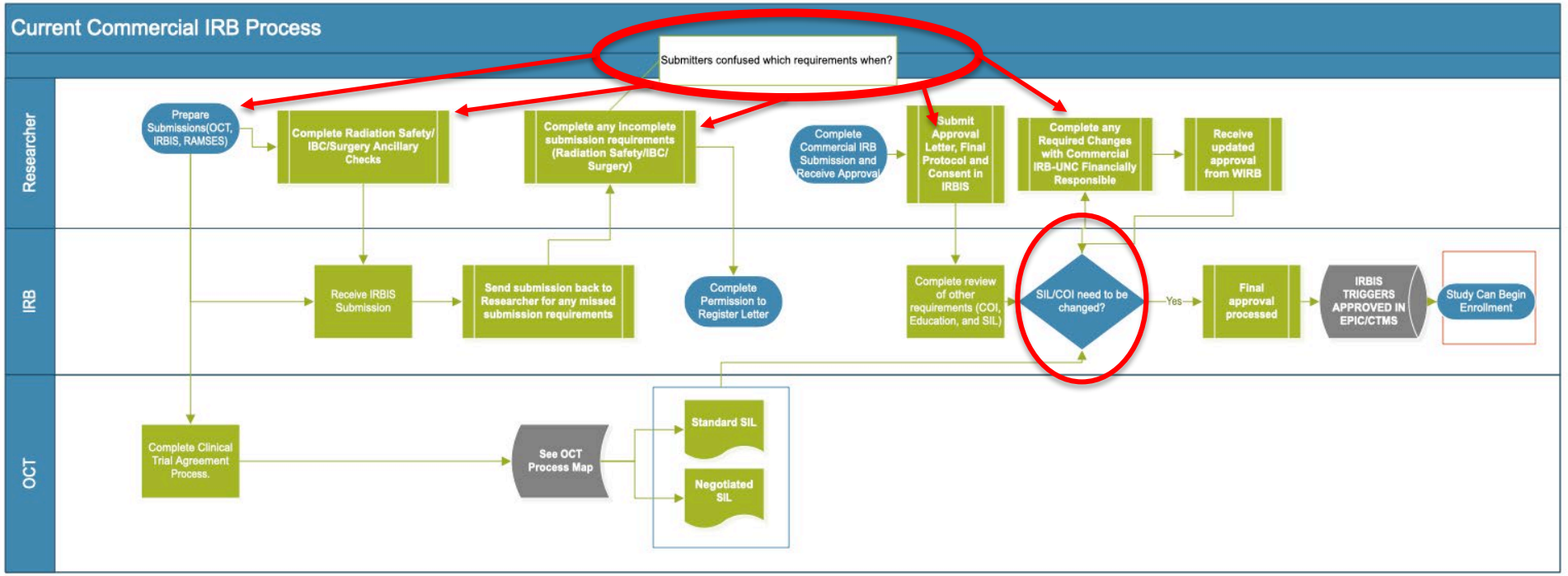
Timeline- Past



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

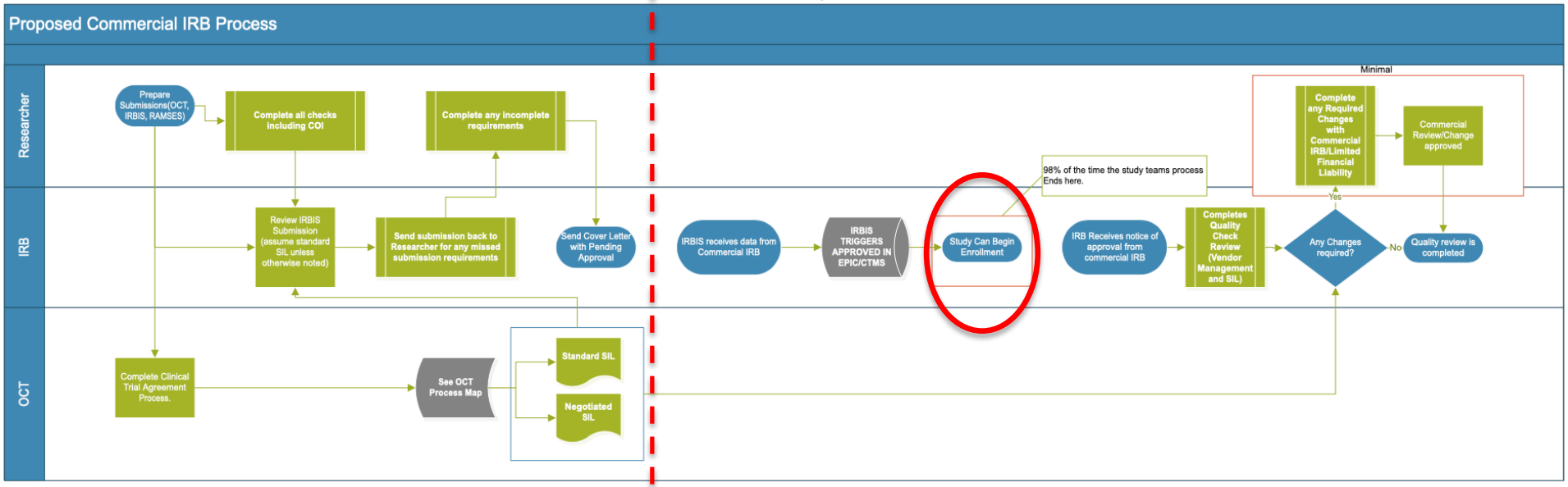
*Studies may be reviewed by the UNC-IRB on a study by study permission basis

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

August

- Finalize Cover Sheet
- Complete Application "Type" Updates
- Present at OSR Conference
- Hold 1 Training Session at NCTraCS-(Last Week of August)
- Prepare SOP & Website Changes

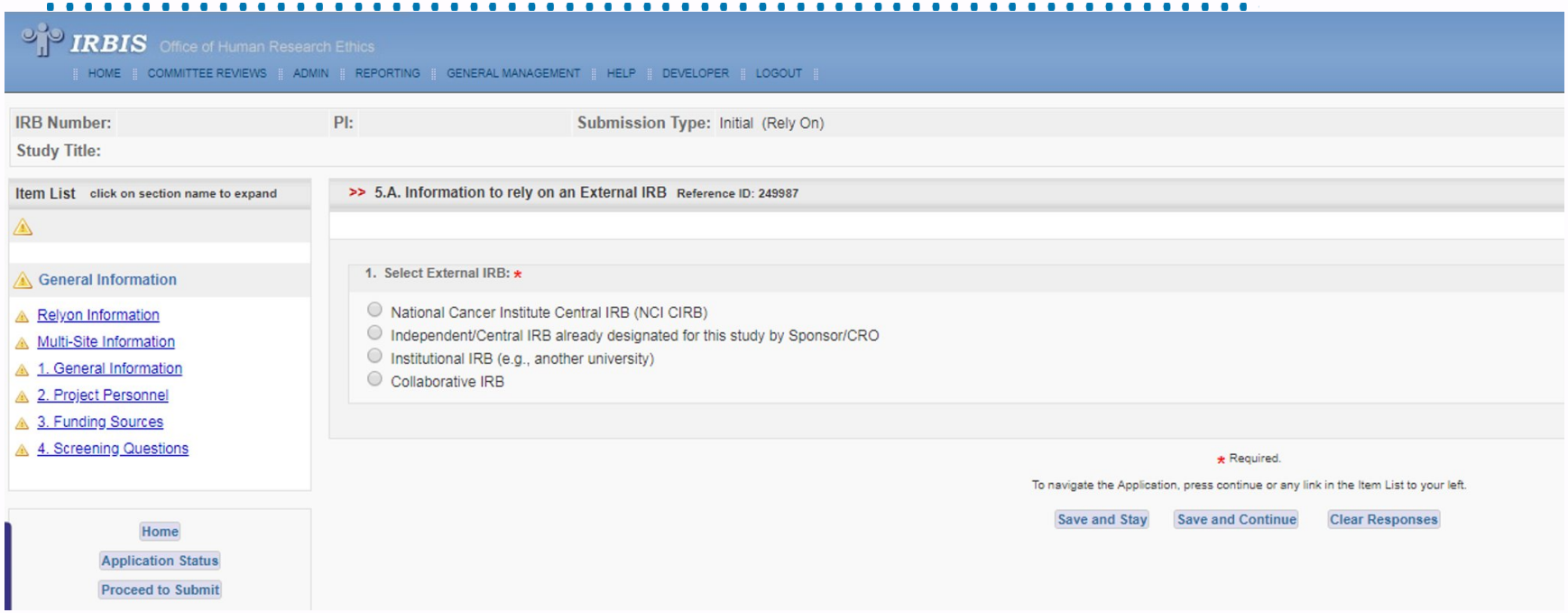
September

- Hold 1 Training Session at NCTraCS (First Week)
- Go Live September 10, 2019 with Application Update
  - Release SOP and Training Video
  - Update Website
- Conduct follow-up webinar to discuss changes and questions

October-December

- Conduct Quality Check Audits and Post Approval Audit
- Provide group specific training as requested

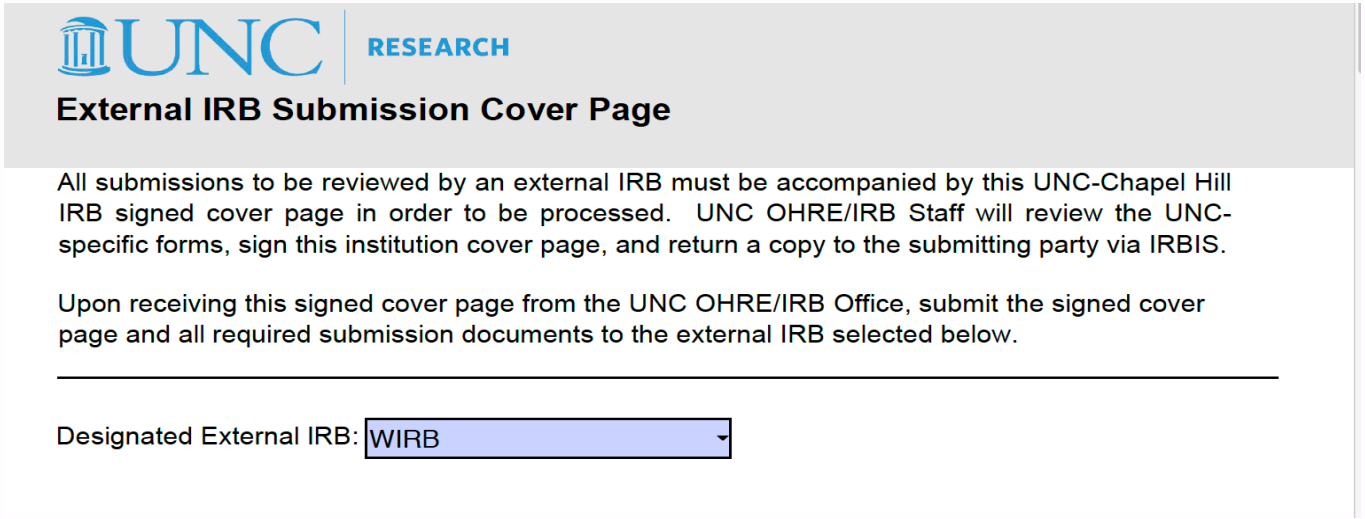
Rely-On Submission Type- Est. Completion 9/10/2019



- 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



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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: WIRB

- 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

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

UNC OHRE: Reliance Agreements/Commercial IRB Reliance

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UNC OHRE: General Questions

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