IRBIS Updates and Commercial IRB Utilization

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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
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.
Minimum levels of annual review required:

<table>
<thead>
<tr>
<th>Types of Submission</th>
<th>Administrative Review</th>
<th>Continuing Review Req.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exempt</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Expedited- Not FDA Reg.</td>
<td>Yes</td>
<td>*</td>
</tr>
<tr>
<td>Expedited- FDA Reg.</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Full Board Initial- Cat 9</td>
<td>No</td>
<td>*</td>
</tr>
<tr>
<td>Full Board- Not FDA Reg.</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Full Board- FDA Reg.</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*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”

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

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
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

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 send documentation is required.

Click here to import personnel from your RAMSeS Proposal
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

**Spring 2018**
- Sent RFP to large commercial IRB’s

**Summer 2018**
- 4 IRB’s responded to RFP
- Sent commercial IRB experience survey to all IRBIS users and NRP list-serve

**Fall 2018**
- Conducted feasibility meetings with two commercial IRB’s regarding IRBIS interface

**Winter 2018/2019**
- Completed COI "separation" in preparation for interface.

**Spring 2019**
- Started Rely-On application revision
- Draft Cover Sheet Process
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.
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
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

![UNC RESEARCH]

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

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