Objectives

- To inform Study Teams of the regulatory responsibilities they have when conducting research
Back in April, we had a lunch and learned diving into the weeds of regulatory binders. As a refresher, the binder is a framework for organizing study documents. While the IRB maintains our own records per the federal regulations, it is also the responsibility of the study team to maintain their own files. This task is usually delegated to one member of the team but everyone is ultimately responsible for ensuring compliance with this requirement.
Each study team member is responsible for keeping their own training up to date.

<table>
<thead>
<tr>
<th>Training</th>
<th>Frequency</th>
<th>Training Provider</th>
<th>Required for...</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biomedical Research</td>
<td>Every 3 Years</td>
<td>Citi</td>
<td>Personnel conducting biomedical or clinical research</td>
</tr>
<tr>
<td>Social &amp; Behavioral Research</td>
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<td>Citi</td>
<td>Personnel conducting social or behavioral research</td>
</tr>
<tr>
<td>Good Clinical Practice</td>
<td>Every 3 Years</td>
<td>Citi</td>
<td>Personnel conducting clinical trials</td>
</tr>
<tr>
<td>Conflicts of Interest in Research</td>
<td>Every 4 Years</td>
<td>Cats</td>
<td>All personnel</td>
</tr>
<tr>
<td>HIPAA Privacy in Research</td>
<td>Annual</td>
<td>Cats</td>
<td>All personnel</td>
</tr>
<tr>
<td>Bloodborne Pathogens – High Risk</td>
<td>Annual</td>
<td>Cats</td>
<td>All personnel</td>
</tr>
<tr>
<td>Shipping Biological Materials</td>
<td>Every 2 Years</td>
<td>Cats</td>
<td>Personnel shipping biospecimens</td>
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<tr>
<td>Annual COI Disclosure</td>
<td>Annual</td>
<td>Kuali</td>
<td>All personnel</td>
</tr>
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</table>
Submission of Renewals

Federal regulations require an IRB to conduct continuing review of research at intervals appropriate to the degree of risk. Continuing reviews are submitted using the Renewal form in the Kuali Research (KR) electronic submission platform.

**When to Submit**
To ensure adequate time for the IRB to review a Renewal application, the Study Team is required to submit the Renewal form:
- No later than 30 days before the Continuing Review Date for studies approved by the Full Board
- No later than 15 days before the Continuing Review Date for studies approved by the Expedited or Exempt procedure

In our March Lunch & Learn, we dove into the details of Renewals (aka Continuing reviews). Federal regulations require regular review of the research to ensure continued compliance with the study as it was approved and with the regulations.

As a courtesy, the Kuali system sends out email reminders of continuing review 60, 45, 30, 15, 7, and 1 day prior to IRB approval lapse; however, it is ultimately the study team’s responsibility to ensure that the renewal application is submitted timely.
Halting Research Activities

If IRB approval lapses, all research activities must stop immediately, except when the investigator judges it to be in the best interest of current participants to continue, in which case s/he must notify the IRB Office promptly.

How to Resume the Study
The Study Team may resume research activity once a Renewal application has been reviewed AND approved by the IRB.
Submission of Amendments

Federal regulations require an IRB to conduct review of all proposed modifications to a research study prior to those modifications being implemented. Modifications to research are submitted using the Amendment form in the Kuali Research (KR) electronic submission platform.

When to Submit
The study team should submit any proposed changes to the research prior to implementing those changes. They should be submitted as soon as possible to avoid any delays in planned implementation.
Any new information that may impact on the conduct of an IRB-approved research study or the safety and welfare of the participants in that study must be documented by the Study Team in the appropriate manner.

**PROMPT REPORTING**
Time Frame: **5 business days of becoming aware**
Method: Reportable Event Application

**RNIs that Require Prompt Reporting**
- Serious AEs
- Unanticipated Adverse Device Effect
- Serious or Continuing Non-Compliance
- Major or Continuing Consent/HIPAA Issues
- Major Protocol Deviations
- Emergency Deviations
- Incarceration of Study Participant
- Breach of Privacy/Confidentiality
- Hold/Suspension/Termination
- Results of Audit/Inspection by Government
- New FDA Black Box Warning
- Significant/Unresolved Subject Complaint
- State Medical Board Hospital Staff Action

**NON-PROMPT REPORTING**
Time Frame: Next Renewal or Closure
Method: Event Tracking Log

**RNIs that Do Not Require Prompt Reporting**
- Unexpected & related/possibly related AEs
- Minor Non-Compliance
- Minor Consent/HIPAA Issues
- Minor Protocol Deviations
- AEs and UPs that DO NOT occur locally

In our December Lunch & Learn, we discussed reportable new information and the reporting requirements set forth by Federal regulations and the institution. It is the study team’s responsibility to report RNIs accordingly in order to keep the study in good standing.
We are all familiar with the old adage its easier to beg for forgiveness than ask permission. That is not the case in the regulatory world.

<table>
<thead>
<tr>
<th>Staff Member</th>
<th>Title</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lynn Arnold</strong>, MBA</td>
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<td><a href="mailto:lar@lsuhsc.edu">lar@lsuhsc.edu</a> or (504) 568-3779</td>
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<td></td>
<td><a href="mailto:IRBOffice@lsuhsc.edu">IRBOffice@lsuhsc.edu</a> or (504) 568-4970</td>
</tr>
</tbody>
</table>

*In regulatory, it is not better to beg for forgiveness than ask for permission.*
# Save the Date!

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Topic</th>
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<tr>
<td>09/06/2023</td>
<td>12:00PM</td>
<td>FDA’s IRB Inspection: A Post-Mortem</td>
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