IRB Process for SURF
April 21, 2015
UNC-CH IRBs

• **Biomedical (A,B,C,D):** Expertise is focused on biomedical research (clinical trials, pharmacological research, etc)
  
  – Oncology = B and D
  
  – Dentistry = B and D

• **Non-Biomedical (E):** Expertise is focused on research in behavioral and social sciences; the humanities; and research in a public health or nursing (non-clinical) context

• **Special Issues (F):** Humanitarian Use; Single Treatment Use; Protocol Deviations, Non-Compliance, Continuing Serious Non-Compliance ....
Plan Ahead!

- Your application may be one of 100’s submitted that week
- **Must complete CITI Training & Conflict of Interest before submitting**
- Full Board only meets once per month
- Complete the application as directed
- Provide consents; recruitment materials; and supporting documents
- If you have **questions** while completing the application or consents, please

  » **call 919-966-3113 or email irb_questions@unc.edu**
Level of Risk Generally Determines Level of IRB Review

- **Minimal Risk?**
  - Is it on the list?
  - 9 Categories defined by Regs
  - Is it on the list?
  - 6 Categories defined by Regs
  - 2. Are there Human Subjects?
  - 1. Is it Research?

- **Not Human Subjects Research**
  - **“Exempt”**
  - Expedited
  - Full Board Review

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**RISK**
Types of Risk

- **Physical** (e.g. pain, drug side effects, or injury)

- **Psychological** (e.g. emotional distress)

- **Social** (e.g. stigmatization)

- **Economic** (e.g. loss of job—breach of confidentiality that relates to stigma, or workplace competency issues)

- **Legal** (requirements to report some illegal activities, whether the focus of the study, or which emerge without prompting)
Levels of IRB Review

- **EXEMPT** – Applies to specific categories of research, most often with extremely low risk or anonymous data.

- **EXPEDITED REVIEW** – Applies to specific categories of research with no more than minimal risk.

- **FULL COMMITTEE REVIEW** – All studies which do not qualify as exempt or expedited must be reviewed by a full IRB.

*Note:* The level of review is determined by IRB, not by the investigator or by the client. The requirements for each level are given in the regulations.
Minimal Risk

- **45 CFR 46.102(i)** defines minimal risk as: “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

- The IRB makes the determination of risk level.

- Minimal risk studies may qualify for exemption or expedited review.
Others may review protocols before the IRB, depending on area and focus of research

DEPT- OR SCHOOL-BASED REVIEWS
• Exercise & Sport Science
• Psychology
• Geography
• Urban & Regional Studies
• Anthropology
• Sociology
• Computer Science
• City & Regional Planning
• Ctr for Developmental Science
• Frank Porter Graham Child Development
• Kenan-Flagler Business School
• Sch of Information & Library Science
• Sch of Journalism & Mass Comm
• Sch of Social Work
• Sch of Government
• Sch of Education
• Office of the President

NIH-MANDATED CENTER REVIEWS
• Lineberger Comp Cancer Ctr (PRC)

UNIVERSITY OFFICES OR OFFICIALS
• Office of University Counsel
  — Research Compliance Officer
• Office of Sponsored Research
• Office of Clinical Trials

CONFLICT OF INTEREST COMMITTEES
• SOM
• Arts & Sciences
• Institutional COI

OTHER COMMITTEES OR GROUPS
• Institutional Biosafety
• Radiation Safety
• Investigational Drug Service
• Data and Safety Monitoring Board (SOM)
• HIPAA Privacy Officers, PHI Custodians

EXTERNAL TO UNC
• NC Dept. of Correction
• EPA
Criteria for IRB Approval

1. Risks minimized
2. Favorable risk : benefit ratio
3. Equitable selection of subjects
4. Informed consent sought
5. Informed consent documented
6. Monitoring plan for safety
7. Privacy and confidentiality protected
8. Additional safeguards for vulnerable populations

45 CFR 46.111 & 21 CFR 56.111
OHRE SOP 24.0
“Exempt” Research: 45 CFR 46.101(b)

- Six categories, defined by regulations
- PI may request an exemption
- IRB will make the determination
- Exempt from continuing review, once approved by the IRB
- Investigator obligated to conduct research as described in protocol
‘Exempt’ Research*: 45 CFR 46.101(b)

1. Normal educational practices in established educational settings

2. Educational tests, surveys, interviews, or observation of public behavior - unless identified & sensitive**

3. Research on elected or appointed public officials or candidates for public office

   * Exception for prisoners

   ** Exception for children

4. Research using existing data, if publicly available or recorded without identifiers

5. Evaluation of public benefit service programs

6. Taste and food quality evaluation and consumer acceptance studies
Expedited Review: 45 CFR 46.110

- Nine categories, defined by regulations
- Chair or designated member
- IRB Members informed
- Reviewer may not disapprove
Eligible for Expedited Review: (Initial Review)

1) Clinical Studies: IND/IDE NOT Required
2) Blood Sample Collection (Routine Methods – Small Amounts)
3) Prospective Collection of Biological Samples - Noninvasive Means
4) Data Collected Though Noninvasive Means (Routinely Practiced in Clinical Settings)
5) Materials (Data, Documents, Specimens etc.) Have Been Collected or Will Be Collected for Non-Research Purposes
6) Collection of Voice, Video or Digital Data for Research Purposes
7) Individual or Group Behavior, Surveys, Interviews, Oral Histories
Much SBER research is eligible for expedited review!

Applicability hinges on:

- determining whether it is ‘minimal risk’
- making sure all aspects of research fit into one or more of the categories
IRB Submission Process
Human Subjects Protection Training

• ohre.unc.edu → For Researchers → Ethics Training → CITI on-line course

• Previous CITI training? → Add an affiliation at UNC-CH and training records will link to UNC

• Enter UNC PID accurately (no hyphen, no space).

• Choose Human Subjects Protection ("IRB") modules → NOT GCP or RCR training

• Complete the Basic Course most appropriate to your area of research
Routing of IRB Submissions

*Note that student research will follow same routing process as any project*
Others may review protocols before the IRB, depending on area and focus of research

- **DEPT- OR SCHOOL-BASED REVIEWS**
  - Exercise & Sport Science
  - Psychology
  - Geography
  - Urban & Regional Studies
  - Anthropology
  - Sociology
  - Computer Science
  - City & Regional Planning
  - Ctr for Developmental Science
  - Frank Porter Graham Child Development
  - Kenan-Flagler Business School
  - Sch of Information & Library Science
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  - Sch of Social Work
  - Sch of Government
  - Sch of Education
  - Office of the President

- **NIH-MANDATED CENTER REVIEWS**
  - Lineberger Comp Cancer Ctr (PRC)

- **UNIVERSITY OFFICES OR OFFICIALS**
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    - Research Compliance Officer
  - Office of Sponsored Research
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- **CONFLICT OF INTEREST COMMITTEES**
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- **EXTERNAL TO UNC**
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Research Data Security Grading System

<table>
<thead>
<tr>
<th>Subject IDs</th>
<th>Sensitive Questions</th>
<th>Security Level</th>
<th>Requirements*</th>
</tr>
</thead>
<tbody>
<tr>
<td>---</td>
<td>---</td>
<td>I</td>
<td>Password protection</td>
</tr>
<tr>
<td>YES</td>
<td>---</td>
<td>II</td>
<td>Level I plus secure network</td>
</tr>
<tr>
<td>---</td>
<td>YES</td>
<td>II</td>
<td>Level I plus secure network</td>
</tr>
<tr>
<td>YES</td>
<td>YES</td>
<td>III</td>
<td>Level II plus encryption, vulnerability scans, security audits</td>
</tr>
</tbody>
</table>

* Note that schools and departments will be expected to play a more central role in ensuring security requirements are met. Investigators should consult with IT managers for their units.
IT Expert within the Approving Department
(Department Responsible for the Study)
IRB and Office of Human Research Ethics

Protecting Human Research Subjects at UNC: An Introduction

Last year, over one million people took part in research studies at UNC-Chapel Hill. Who are these participants, who is studying them and why? Read more...

March 2, 2015: The Online Submission Guide has been substantially updated and expanded.
Online Submission

Online Applications
All applications (i.e., Initial, Modification, Renewal, Closure/Unanticipated Problem/Adverse Event) are online. Please go to http://IRBIS.UNC.EDU to complete and submit your application to the IRB.

Additional Forms
There are a few ADDITIONAL FORMS that are not provided online and may be accessed here.

Help
IRBIS Help Desk: David Tegnell, 919-966-3685
Online Submission FAQ
Online Submission Guide
Online Submission Guide

Task- and screen-specific, printable guides on how to complete the IRB Application and navigate the IRBIS user interface:

**IRB login**
- The login screen

**Online application orientation**
- Initiating a new IRB application
- Application features: Data entry; adding UNC-affiliated personnel; attaching documents
- Configuring your application: NHSR/Full/Exempt
- General Information: Multi-site sections 5 and 5A
- Adding non-UNC affiliate at Project Personnel
- Copying an existing study

**Navigating IRBIS**
- The Home screen
- Two navigation bars
- Tracking submission progress: In draft/Being Routed/Under Review
- Checking your approval letter
- Accessing your approval letter
- Monitoring study submission status
- Routing (Investigator) (pdf)
  - Designating routing departments
1) From the Home screen Dashboard / Create New Submission, click New Study.

2) Complete the General Information 1 questions, then click the Save and Continue button to access and complete sections 2-4.

3) Upon completion of General Information 1, your application will be assigned a Reference ID and listed at the Home screen Dashboard / Submissions in Progress / In Draft.
   - Click Reference ID whenever you wish to retrieve and resume.
   (Note: IRB Number is assigned upon completion of Screening Questions.)
Where’s my application?
Where’s my application?

- Check to see who has certified
- Check to see who has been notified to certify
- Where IRB Marked Documents Will be located
- CONFIRM Training and COI
The IRB Meeting: Voting Options

- Approved
- Minor contingencies required for approval
- Deferred (major changes required)
- Disapproved
When You Get a Contingency Memo:

- Don’t despair and don’t take it personally

- It is rare for study not to raise at least one question from the IRB

- The PI should respond point by point in writing to the memo and make the corresponding changes to the application and consent forms
When You Get a Contingency Memo:

1. Please make any requested changes to the application, consent forms or attachments... or explain why changes were not made... AND...

2. Provide a response to each stipulation explaining how it was addressed, even if only stating "changes made," before resubmitting your revised submission. This will constitute your point-by-point response.

3. When all changes and responses are complete, please click the RESUBMIT button at the lower left.

Number of Stipulations: 2

General Information

1. General Information
   
   Brief Summary: Provide a brief non-technical description of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words. Please reply to each item below, retaining the subheading labels already in place, so that reviewers can readily identify the content. PLEASE NOTE: THIS SECTION MAY BE EDITED BY THE IRB FOR CLARITY OR LENGTH.

   Created by IRB Admin on 08/29/2012 03:38 PM

   Please revise this section to include more detail.

   Respond  Go to Question
Approved!

- Research may proceed upon receipt of written documentation of IRB approval

- Investigator has a responsibility to report to the IRB
  - Changes **BEFORE** they are implemented

- Unanticipated problems or serious adverse events that may occur during the research
What if you want to change the protocol?

Once your study is approved, you may submit modifications:

- All protocol changes must be approved by the IRB before implementation.
- All changes to documents used with subjects (consent forms, questionnaires, recruitment materials, etc.) must be approved by the IRB before using.
Modifications to Approved Studies

• The IRB assesses if the modification changes the level of risk:
  – Do subjects need to be made aware of the new information?
  – If a revised consent form is included, is it accurate?
  – Do subjects need to be re-consented?
When can I close my study?

- Renew the study as long as data analysis of identifiable data is on-going *(Remember the definition of human subject research)*

- When you are completely done with all interventions, follow-up and data analysis, the study should be closed
UNC IRB  Top 10 Tips

1.  Respect & Protect research subjects from harm. Remember Belmont Report principles: **Respect, Beneficence & Justice**.

2.  Federal Regulations Rule, they can shut your study &/or all research at UNC down.

3.  Submit to the IRB **BEFORE** doing research with human subjects,

4.  Submit to the IRB **BEFORE** implementing protocol changes,

5.  Do CITI Training & COI before submitting,

6.  Call the Office for Human Research Ethics for help before ....

7.  Visit an IRB meeting & Consider joining the IRB,

8.  Renew your studies on time,

9.  Prepare your IRB submission with the same care you did your grant.

10. Report UPs & Protocol Deviations **PROMPTLY!!**
FOR MORE INFORMATION

- Webpage: [www.ohre.unc.edu](http://www.ohre.unc.edu)
- E-mail: [irb_questions@unc.edu](mailto:irb_questions@unc.edu)
- Telephone: 919-966-3113
- Address: CB # 7097, Med School Trailer 52, Mason Farm Rd
- Guidances available at HHS’s Office of Human Research Protections:
  - [http://www.hhs.gov/ohrp/](http://www.hhs.gov/ohrp/)
  - [https://www.youtube.com/watch?v=hsUS0k3le_q&list=SP5965CB14C2506914&index=8](https://www.youtube.com/watch?v=hsUS0k3le_q&list=SP5965CB14C2506914&index=8)