HUMAN SUBJECTS RESEARCH IN THE DEPARTMENT OF EXERCISE AND SPORT SCIENCE

Approval of research to be conducted in the Department of Exercise and Sport Science involving human subjects involves two phases: 1) initial review and approval by the EXSS Human Subjects in Research Committee, and 2) final review and approval by the Biomedical Institutional Review Board (IRB). This process must be completed prior to initiation of data collection for all projects which involve contact with human subjects, including direct physical measurement, biological specimens, or surveys and questionnaires.

*All individuals who conduct research involving human subjects must first complete the University's required research ethics training (http://ohre.unc.edu/educ.php) prior to IRB submission. Furthermore, all individuals who will have contact with subjects or the associated data for a given project must complete the CITI training and be listed as a member of the research team in the IRB proposal.

IRB proposals must be submitted electronically via the IRB Information System (IRBIS). This document outlines the process for IRBIS submission and the EXSS Human Subjects in Research Committee review process.

Step 1: IRBIS

There are two options for building the IRB proposal based on preference. The entire document can be completed in IRBIS, as each section requiring typed text contains a word processor. However, some features (e.g. spell check, automated reference formatting) are not be available in this limited word processor, so investigators may choose to write the document in MS Word or another word processor and copy and paste it into IRBIS.

1. Login to irbis.unc.edu with your ONYEN and password.
2. In the Dashboard located at the top left of the screen, click New Study (or the appropriate option).
3. Follow the onscreen instructions for each section (similar to sections in the previous paper forms). Completed sections will be identified by a green check in the IRBIS Dashboard.
4. If additional documents are required (e.g. consent forms), IRBIS identifies these requirements and partially generates these files based on information previously entered. Some forms (e.g. surveys, recruitment fliers) are not generated by IRBIS, but can be attached as MS Word or pdf files.
5. When this process is complete, download the pdf file generated by IRBIS and email this document and any accessory documents (e.g. consent forms, recruitment flyers) to the chair of the EXSS Human Subjects in Research Committee (Dr. Troy Blackburn - troyb@email.unc.edu). *This email initiates the EXSS review process.*
6. **DO NOT CLICK THE SUBMIT BUTTON** at this time.

Step 2: EXSS Human Subjects in Research Committee Review

1. The committee chair will email the pdf file and any accessory files sent by the PI, and a fillable MS Word review form to two reviewers (one inside and one outside the PI's area of expertise).
2. The reviewers will complete the review within 7 working days and return the review materials to the committee chair via email.
3. Once the reviews are returned to the committee chair, he will forward the reviewer comments to the PI, who will then revise the documents as necessary in IRBIS.
4. The PI will send the revised documents to the committee chair via email.
5. The committee chair will then verify the revised document and approve the proposal.

Timeline for EXSS review process

1) The committee chair is notified of the submission via an email and sends the proposal to reviewers.
1-2 days

2) Reviews are returned to the committee chair within 7 working days. *If* no revisions are requested by the reviewers, the proposal is approved. If revisions are requested, the reviews are forwarded to the PI.
1-2 days *3-11 working days cumulative**

3) The committee chair sends the reviewer comments to the PI via email, and the PI sends a revised proposal to the committee chair via email for further review. The committee chair evaluates and approves the revised proposal.
1-2 days *4-13 working days cumulative**

**These times may vary considerably depending on the availability of reviewers and the timing of submission, and do not include the time required for the PI to revise the proposal. The cumulative review time is likely to be longer when proposals are submitted around University holidays, over the summer break, or during high-activity periods of the academic calendar (e.g. final exams). Additionally, the high volume of proposals received in the Fall Semester associated with master's thesis projects may also lengthen the review period.*

Step 3: After EXSS Approval

Once the proposal has been approved by the EXSS Human Subjects in Research Committee, the PI will receive an email from the committee chair confirming approval. The PI will then perform the following steps:

1. Login to IRBIS and select the appropriate study under the "In Draft" link in the Dashboard.
2. Click the "Submit" button below the Dashboard.
3. Once the proposal is submitted, the PI and faculty advisor for student lead projects will receive two emails from IRBIS: one requesting certification of the submission, and the other requesting completion of a conflict of interest form. Both individuals must follow the instructions outlined in the email to complete these steps.
4. IRBIS will send an email to the chair of the EXSS Human Subjects in Research Committee requesting approval of the proposal prior to IRB review after which the proposal will be routed to the Biomedical IRB.

The Biomedical IRB is composed of 4 subcommittees, each of which meets once each month such that reviews occur on a weekly basis. Important dates for submission and the review process can be found at (http://ohre.unc.edu/dates.php).

If the IRB identifies additional issues that must be addressed prior to final approval, the PI and faculty advisor will receive an email containing a link directing them to these contingencies/stipulations in IRBIS.

All actions associated with a proposal (renewal, amendment, closure, etc.) must be performed in IRBIS.

Common Issues that Require Revision of an IRB Submission

- Failure to follow instructions
  - e.g. Section 1.2 requests a summary 50-100 words in length. Extensive summaries should not be included in this section. More extensive rationale for the study can be included in section A.1 Background & Rationale
- Lack of proofreading
  - Grammatical errors
  - Documents written in technical rather than lay language
  - Agreement b/w proposal and consent form documents and sections in each document
    - e.g. # of subjects, number of groups, duration of testing
- Project Personnel
  - No advisor included
  - Incomplete CITI training
  - Failure to include ALL individuals who will interact with subject or data
- No consent form
- No rationale for exclusion of subjects (e.g. females)
- Vague descriptions of recruitment procedures

For questions regarding the IRB process, contact Dr. Troy Blackburn, chair of the EXSS Human Subjects in Research Committee. Additionally, Dr. Ed Shields serves as a member of the Biomedical IRB and can provide information specific to this review process. General information regarding the IRB can be obtained at http://ohre.unc.edu/guide_to_irb.php.