

## Human Subjects Research Ethics Review

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

### **Step 1: Review by the EXSS Human Subjects in Research Committee**

This committee is chaired by Dr. Troy Blackburn, and is composed of the members of the EXSS faculty. Proposals are submitted to Cindy Atkins in 209 Fetzer (EXSS Departmental Office). The chair then assigns each proposal to 2 members of the committee for review. These reviewers typically consist of one individual within the PI's area of specialization (i.e. Sport Administration, Exercise Physiology, or Athletic Training) and one outside that area. Reviews are requested within 7 working days, and are returned to the PI following overview by the chair. The PI is then required to revise the proposal as suggested in the reviews, or to provide justification for retaining the original format, and to return the revised proposal to Cindy Atkins. The chair then evaluates the revised proposal and either requests additional revision or approves the proposal, makes all necessary copies, and forwards it to the University-level IRB.

The description below provides a step-by-step timeline for Step 1 of the review process:

1) Proposal submitted to Cindy Atkins. Preliminary check for all required materials and selection of EXSS reviewers.

*1-2 days*

2) Proposal sent to reviewers with request to review and return within 7 working days.

*7-10 days                      8-12 days cumulative*

3) Reviews returned to committee chair for overview.

*If no revisions are requested by the reviewers*, the proposal is approved, copied, and forwarded to the University-level IRB.

*If revisions are requested by the reviewers*, the reviews are forwarded to the PI for revision.

*1-2 days                      9-14 days cumulative*

4) If revisions are necessary following the initial review, the revised proposal is returned to the chair for further review. Occasionally a reviewer requests to see the revision before approval, requiring additional time. Once the proposal is acceptable, it is approved, copied, and forwarded to the University-level IRB.

*1-5 days                      10-20 days cumulative\**

*\*These time frames are estimates and may vary considerably depending on the availability of reviewers, timing of proposal submission, and the extent of the suggested revisions. Please note that 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 and grant submission deadlines). Additionally, the high volume of proposals received in the Fall Semester associated with master's thesis projects may also lengthen the review period.*

## **Step 2: Review by the University-level IRB**

University-level review of each proposal is conducted by 1 of 3 IRBs: Social Behavioral, Biomedical, or Public Health-Nursing. The majority of proposals from EXSS are forwarded to either Social Behavioral or Biomedical. However, *the decision regarding which of these IRBs a proposal is forwarded to is made by The Office of Human Research Ethics (OHRE); not the PI, and not the EXSS Human Subjects in Research Committee.* A standard proposal form is required for all proposals (Application for IRB Approval of Human Subjects Research) and can be downloaded in various formats at (<http://ohre.unc.edu/forms.php>). Two different informed consent forms can also be found at this link, one for Biomedical and one for Social Behavioral proposals. These forms contain language specific to the types of research typically encountered by each IRB, but *submitting one of these consent forms does not guarantee that a proposal will be reviewed by that specific IRB.*

In the near future (date not yet known – TBD by The Office of Human Research Ethics), IRB submission will be performed electronically. These procedures will be altered slightly, but will still involve approval by the EXSS Human Subjects in Research Committee prior to University-level review. Specific information will be provided when the online submission system is made available to EXSS researchers.

Review periods for the University-level IRBs vary in length depending on the specific IRB to which a proposal is submitted. The Social Behavioral and Public Health-Nursing IRBs are each composed of a single committee which meets once each month, while 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>). Revisions received from the University-level IRB should be addressed via direct correspondence with the IRB itself, not the EXSS Human Subjects in Research Committee.

\*All individuals who submit IRB proposals are required to complete a Research Ethics Training course. Information on this required training can be found at (<http://ohre.unc.edu/educ.php>).

## **Approval, Renewal, Revision, and Termination of Active Proposals**

The EXSS Human Subjects in Research Committee requests that PIs forward all University-level decisions and changes in IRB status to Cindy Atkins ([atkins@email.unc.edu](mailto:atkins@email.unc.edu)). Once your proposal is accepted at the University-level, please forward the acceptance email and approved documents (proposal and consent form) for our records. Additionally, if a proposal is renewed or terminated, please forward the associated confirmation email. Lastly, if you make revisions to an approved proposal, please forward the revision approval email as well as the revised proposal and consent form.

For any questions regarding the IRB process, please contact Dr. Troy Blackburn, chair of the EXSS Human Subjects in Research Committee. Additionally, two EXSS faculty members currently sit on the Biomedical (Dr. Ed Shields) and Social Behavioral (Dr. Diane Groff) IRBs and can provide information specific to these review processes. Detailed information of the IRB process can also be obtained at ([http://ohre.unc.edu/guide\\_to\\_irb.php](http://ohre.unc.edu/guide_to_irb.php)).