

HUMAN SUBJECTS RESEARCH IN THE DEPARTMENT OF EXERCISE AND SPORT SCIENCE

All human subjects research to be conducted in the Department of Exercise and Sport Science must be submitted for evaluation by the Institutional Review Board (IRB) electronically via the IRB Information System (IRBIS). This process must be completed prior to initiation of any research-related activities for any project that involves contact with human subjects, including physical measurements, biological specimens, or surveys and questionnaires. All protocol modifications and renewals must also be submitted in IRBIS. This document outlines the process for IRBIS submission and the review process.

1. All individuals who will have any contact with subjects or their associated data must first complete the required research ethics training (<http://ohre.unc.edu/educ.php>) prior to IRB submission.
2. ***Proposals with a student as the Principal Investigator*** require documentation of approval by the Faculty Mentor. A letter template ([Faculty IRB Approval Letter](#)) is available [HERE](#). (If you receive a notification, allow the file to open.) This letter should be forwarded to the chair of the EXSS Human Subjects in Research Committee (Troy Blackburn, troyb@email.unc.edu) once the proposal is submitted in IRBIS.
3. Projects that involve greater than minimal risk to subjects must first receive approval from the Scientific Review Committee (SRC). A Master Protocol Document must be submitted to this body for approval, after which IRBIS submission can proceed. More information about federal guidelines defining “greater than minimal risk”, the SRC review process, and sample Master Protocol Documents can be found at (<http://research.unc.edu/clinical-trials/scientific-review-committee/>).
4. **IRBIS Submission Procedures**
There are two options for building the IRB proposal. The entire document can be completed in IRBIS, as each section requiring text contains a word processor. However, many features (e.g. grammar, syntax, and spell check; automated reference formatting; etc.) are not available in this limited word processor. ***It is highly recommended*** that the sections of the proposal be drafted in MS Word or another word processor and copied and pasted 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 (Figure 1), click New Study (or the appropriate option).
 3. Follow the onscreen instructions for each section. Completed sections will be identified by a green check in the IRBIS Dashboard (Figure 2).
 4. If additional documents are required (e.g. consent forms), IRBIS identifies these requirements based on information previously entered and partially generates these files. Some forms (e.g. surveys, recruitment fliers) are not generated by IRBIS, but can be attached as MS Word or pdf files (Figure 3).
 5. Once all items are completed, the proposal can be submitted.

Figure 1



Figure 2

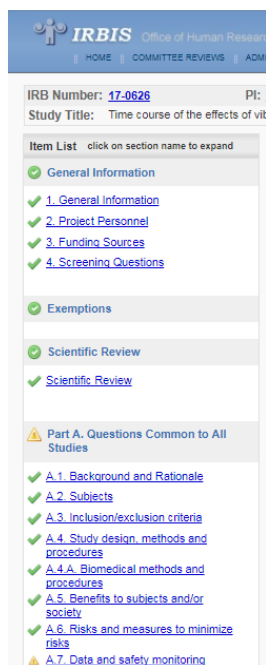
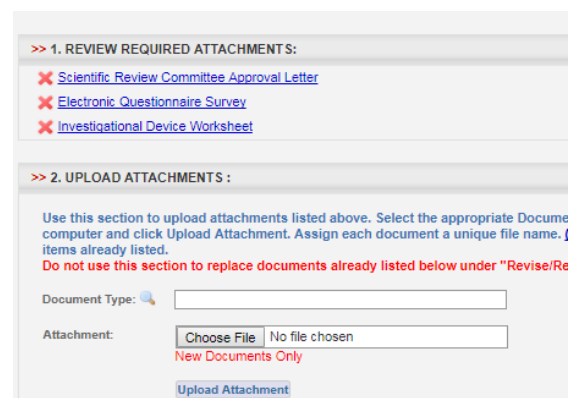


Figure 3



Timeline for IRB review process

All proposals from EXSS are forwarded to the Biomedical IRB. Once the proposal has been submitted in IRBIS, the following steps will occur:

1. The PI and Faculty Mentor will receive individual automated emails requiring certification of the proposal.
2. All members of the research team (excluding research assistants) will receive individual automated emails requiring completion of a Conflict of Interest Disclosure form.
3. The Faculty IRB Approval Letter should be submitted to the chair of the EXSS Human Subjects in Research Committee at this time.
4. Once the proposal is certified, the chair of the EXSS Human Subjects in Research Committee will receive an automated email requesting approval of the proposal in IRBIS.

IRB proposals are reviewed under the following categories. The decision regarding under which category the proposal is reviewed is determined by the IRB based on federal guidelines.

1. Exempt
 - a. Applies to specific categories of research, most often with extremely low risk or anonymous data.
 - b. The decision on exemption eligibility typically occurs within 3-5 business days.
2. Expedited
 - a. Applies to specific categories of research with no more than minimal risk.
 - b. The average initial review occurs in 5-7 days.
3. Full Board
 - a. Applies to all studies which do not qualify for exempt or expedited review.
 - b. The Biomedical IRB is composed of 4 subcommittees, each of which meets once per 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 approval, the PI (and faculty advisor) will receive an email containing a link directing them to these stipulations 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
- Excessive discipline-specific jargon
- Lack of proofreading
 - Grammatical errors
 - Consent 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
 - Incomplete COI disclosures
- No rationale for exclusion of subjects (e.g. females)
- Vague descriptions of recruitment procedures
- Inappropriate statistical or experimental design

For questions regarding the IRB process or examples of previous IRB protocols, contact Troy Blackburn, chair of the EXSS Human Subjects in Research Committee (troyb@email.unc.edu).