

## EXSS Process for Seeking Approval to Resume/Initiate Human Subjects Research

Updated 10/19/2020

All human subjects research must receive departmental approval as outlined below prior to resuming (studies with prior IRB approval) or initiating (new IRB submissions) study activities. This process must be completed for each study that involves direct interaction with human subjects.

1. Prior to submitting for department approval, the PI and the Lab Director\* for each lab in which study procedures will be conduct should discuss and agree upon the following:
  - a. Feasibility of conducting the research project
  - b. Project-Specific Safety Plan developed by the PI (see details below)
2. Once the PI and Lab Director have established feasibility and a Project-Specific Safety Plan, the PI must ensure the following for all personnel involved with the project:
  - a. Review and understand EXSS Policies and Procedures for Human Subjects Research
  - b. Complete UNC Environment, Health, & Safety Training on Protecting the Carolina Community from COVID-19
  - c. Review and understand the lab safety plans for all labs in which study activities will take place
  - d. Review and understand the Project-Specific Safety Plan
3. After the PI has verified personnel compliance with all of the above materials, the PI will complete an online form (Qualtrics) to request department approval to resume/initiate human subjects research
4. Initial review of the department approval form will be completed by Troy Blackburn
  - a. If the request for department approval involves a project with which Troy is affiliated, the review will be completed by an EXSS Lab Director who is not affiliated with the project
  - b. **Criteria for expedited approval** (review of Project-Specific Safety Plan not required)
    - i. PI attests that all associated research personnel have done the following
      1. Reviewed and understand EXSS Policies and Procedures for Human Subjects Research
      2. Reviewed and understand the associated lab safety plan(s)
      3. Reviewed and understand Project-Specific Safety Plan
      4. Completed EHS COVID-19 training
    - ii. The project does not involve high-risk participants
    - iii. The project does not involve moderate/vigorous physical exertion
    - iv. The project does not require violation of the 6-ft physical distance barrier,
    - v. The project is being conducted within the designated laboratory space for which the lab safety plan(s) was developed
  - c. **If the project involves high-risk participants, moderate/vigorous physical exertion, violation of the 6-ft physical distance barrier, or research is conducted outside of the laboratory space**, the PI must submit the Project-Specific Safety Plan for review
    - i. In these cases, the Project-Specific Safety Plan will be reviewed to determine if risks are adequately mitigated and the potential benefits outweigh the additional risk of COVID-19 exposure
    - ii. If there is a question about whether the potential benefits outweigh the risks, 2 additional reviewers (1 in the area of research and 1 outside the area of research) will be consulted to determine if the project is allowed to move forward
      1. In all cases, reviewers will not be affiliated with the proposed research

\*Some EXSS labs have co-directors. To simplify the approval process each lab will have only one point of contact as outlined here: Applied Physiology Lab (Abbie Smith-Ryan), Exercise Oncology Lab (Claudio Battaglini), Gfeller Center (Jason Mihalik), Human Performance Center (Abbie Smith-Ryan), MOTION Science Institute (Brian Pietrosimone)

### **Project-Specific Safety Plan Components:**

Project-Specific Safety Plans should be organized using labeled headings for each section noted below (Research Personnel, Cleaning Procedures, PPE Practices, and Space Considerations). For low-risk studies for which no additional information is required beyond that specified in the Lab Safety Plan, state in #2 that the project will adhere to the approved Lab Safety Plan. If the study will be wholly conducted in lab spaces with existing Lab Safety Plans, indicate “not applicable” for #4. Project-Specific Safety Plans should be maintained by both the PI and Lab Director.

1. List all research staff who will be working on the project
  - a. In the event that new personnel are added to the research team following initial Departmental approval and IRB modification, the PI should update the Project-Specific Safety Plan accordingly, but this action does not require further Departmental review
2. List the specific equipment that will be utilized and how it will be sanitized during the project
  - a. If the study is categorized as “low-risk” the specific cleaning equipment procedures (i.e. beyond those specified in the Lab Safety Plan) are not necessary
  - b. If study falls into one of the high-risk categories (high-risk participants, moderate/vigorous exertion level, data collection outside the laboratory) any additional sanitizing efforts should be outlined
3. List the PPE practices that will be utilized during data collection
  - a. If the study is categorized as “low risk” include the following:
    - i. PPE required of research personnel during data collection
    - ii. PPE required of participants during data collection
    - iii. Total number of people (research personnel + participant) that will be on-site for data collection
  - b. If the study falls into one of the high-risk categories provide information on additional PPE (e.g. gowns, face shields, etc.) for research staff and/or participants during data collection
4. For studies where data collection will take place outside of the lab space provide a description of the following:
  - a. Physical distancing practices for the proposed research space
    - i. This may include a physical space diagram similar to those in the Lab Safety Plans, but specific to the space the project will utilize outside of the lab
  - b. Sanitizing practices that will be implemented during off-site data collection