

**Minimal risk research involving procedures that are physically taxing  
to participants**  
*Guidance for researchers*

When researchers ask participants to engage in activity that may be physically taxing, those procedures typically fall under the Expedited category and, as such, additional cautionary language needs to be included in the informed consent statement. If the activity is no greater than what could be encountered in daily life (i.e., minimal risk research), the following items should be included in the informed consent form:

- A detailed description of the requested physical activity.
- A list of potential physical effects expected to be experienced by the participant while participating (e.g., increased heart rate, change in blood pressure, sweating, etc.).
- A statement regarding risk (e.g., “Participants will be at no greater risk during the study than during a similar unsupervised regime they are familiar with and participate in on a regular basis.”).
- A caution about any potential interfering medical conditions (e.g., “If you have any medical conditions that prevent you from engaging in the requested activity, you should not participate in this study.”).
- A statement of discontinuation (e.g., “If at any time during the physical activity you experience any undesired effects, you may stop participation without any penalty or loss of benefits otherwise entitled.”)

In addition, in the IRB form itself, researchers should indicate *how they would respond in the unexpected case of an emergency*. The recommended response would be to call 911 as well as Campus Police for assistance.

Furthermore, if the research involves providing interpretation of test results, diagnosis and/or recommendations, an appropriately credentialed individual needs to be listed on the IRB form as a co-investigator and actively involved or supervise the interpretation of the test results.

If the activity is more physically taxing than what could be encountered in daily life, then the research no longer falls under the minimal risk category and multiple additional protections need to be in place in both the research procedure and informed consent document. Because the necessary precautions would then be specific to the particular procedure employed, consultations with the IRB chair and/or the IRB representative from the Health Sciences Division are recommended prior to proposal submission.