IRB Updates

Forms, Templates, and Tools

The Institutional Review Board (IRB) recently launched revised research informed consent and assent templates.

Effective **July 1, 2022**, all new projects using an informed consent and/or assent document must use the revised document. Projects approved prior to this date do not need to be modified. When submitting materials to the FAU IRB, please select documents from the IRBNet.org library to ensure you are using the current version. The consent/assent documents include:

B Assent Ages 07-12 v3
B Assent for 13-17 or Persons with Impaired Decision Making Capacity v3
B Biomedical Research Consent v8
B Exempt and Minimal Risk Research OR Waiver of Documentation Consent v5
B_Non-Biomedical Research Consent_v1
B Parental Permission-Research Consent vl

A new IRB application document will go into effect on **July 1, 2022**. A supplemental personnel form is available to accompany this new document. The document will be an application and protocol in one for minimal risk research. Minimal risk projects will no longer require a separate protocol, when using the revised IRB application/protocol document. Projects that are greater than minimal risk-research with investigational drugs or devices, high risk research with special populations, or research where probability and magnitude of harm exceeds that which participants would experience in their routine, daily lives will still require a separate protocol in addition to the new application document. A revised protocol template is available to ensure researchers are providing sufficient information to the IRB. Researchers will be required to use the revised version of the new IRB application document after **October 1, 2022**.

Processes

When seeking a determination regarding whether a project requires IRB review, researchers are reminded to submit Form 6 Human Subjects Research Determination via IRBNet.
This submission should be signed by the Principal Investigator. The FAU IRB does not require additional signatory for review of a determination request.

Projects that received a determination of exemption only require IRB review for amendments if the project design changes, there is an addition of a vulnerable population, or there are other changes or information that may increase the risk to participants or others. Any other changes to the project do not require review by the FAU IRB prior to implementation.