** Institutional Review Board Composition and Procedures**

**Overview**

The Fisher College Institutional Review Board (IRB) is a group of five full time faculty and administrators who serve to oversee and support compliance with federal guidelines for conducting research that involves the use of human subjects.

The Office for Human Research Protections provides leadership for the protection for the rights, welfare, and well-being of human subjects involved in research. The Federal Guidelines for Protecting Human Subjects are available on the following website: <https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML>.

**IRB Application Process**

The application process for IRB approval involves the following general steps:

After reviewing federal guidelines for human subjects research and determining that your research project requires IRB approval, complete the Online Training in Human Subjects Research and submit your certificate of completion to the IRB chair. Complete Online Training in Human Subjects Research and submit certificate to the IRB chair to demonstrate successful completion of the Online Training in Human Subjects Research course. The certificate must have been completed within five years of the date in which the application is submitted.

Protecting Human Research Participants Online Training is available for $39.99 USD for all individual learners. Website: https://phrptraining.com/#!/register

Then, complete the Fisher College IRB Application Process. Submit your application form, the Informed Consent Form (available below) along with any relevant materials (surveys, questionnaires, etc.) to the IRB chair.
**IRB Applicant Review Process**

Applications that are received by the first of the month will be reviewed by the end of the month. The IRB committee will review applications that involve research using human subjects from September through May. Applications from June through August may be reviewed upon submitting a request for special permission through the Vice President of Academic Affairs.

An initial review of the application will be conducted by individual IRB committee members and any areas that need to be revised will be discussed with the applicant. This duty will be rotated across committee members, starting with the director of the committee and in alphabetical order thereafter.

The applicant will make a first round of revisions based on the feedback they receive during the initial review and they will resubmit a second version of the application to their initial reviewer, who will then send it to the committee for review.

The committee will meet on the 3rd week of each month to discuss each application and to vote to approve or to require additional revisions before approving. Applicants will be invited to attend this meeting to address questions and provide additional information, and then they will leave the meeting for the committee to vote.

* If committee members approve the project, the director will send a letter approving the project to the applicant.
* If committee members require additional revisions before approving the project, the director of the committee will discuss the revisions with the applicant and send a letter to the applicant outlining the additional revisions that are required before the project is approved.

The applicant will submit the application with the additional revisions and, if all revisions are made, the director will send a letter to the applicant approving the project.

If all revisions are not made, then the project will not be approved. The director will email a letter to the applicant informing them that the project is not approved and that they are not authorized to involve Fisher College students in the research project and do not have the support of Fisher College to conduct the research project.

 **IRB Committee Review Process**

1) An application is emailed to the director of the IRB committee. Applications that are received by the first of the month will be reviewed by the end of the month. The IRB committee will begin reviewing applications in September and applications will be accepted for review through May.

2) An initial review of the application will be conducted and any areas that need to be revised will be discussed with the applicant. This duty will be rotated across committee members, starting with the director of the committee and in alphabetical order thereafter.

3) The applicant will make a first round of revisions based on the feedback they receive during the initial review and they will resubmit a second version of the application to their initial reviewer, who will then send it to the committee for review.

4) The committee will meet on the 3rd Monday of each month to discuss each application and to vote to approve or to require additional revisions before approving. Applicants will be invited to attend this meeting to address questions and provide additional information, and then they will leave the meeting for the committee to vote.

* If committee members approve the project, the director will send a letter approving the project to the applicant.
* If committee members require additional revisions before approving the project, the director of the committee will discuss the revisions with the applicant and send a letter to the applicant outlining the additional revisions that are required before the project is approved.

5) The applicant will submit the application with the additional revisions and, if all revisions are made, the director will send a letter to the applicant approving the project.

6) If all revisions are not made, then the project will not be approved. The director will email a letter to the applicant informing them that the project is not approved and that they are not authorized to involve Fisher College students in the research project and do not have the support of Fisher College to conduct the research project.

**IRB Committee Composition and Procedures**

* There will be at least five members of the Fisher College IRB Committee. These members will fulfill one or more of the following roles:
	+ Scientist: should provide insight into validity of hypothesis and research; postgraduate training in conducting research needed.
	+ Non Scientist: review research from a nonscientific perspective; provide diverse perspectives on issues.
	+ The committee will seek an individual to fulfill the role of an unaffiliated member, who is not affiliated with institution, or is an immediate family member of an affiliated person.
		- Unaffiliated members can be: Past or current patients, former students, former or retired employees not receiving benefits from the institution. Paying them for IRB service does not make them affiliated.
* If IRBs review research involving prisoners, member must be a prisoner or prisoner representative (must not be connected to prison involved in research)
* Non-members of the committee, who are experts on particular research topics, may assist with review for relevant research project applications

**IRB Committee Membership Responsibilities**

* IRB Committee members will take the IRB Administrator Training Program every 3 years (<https://about.citiprogram.org/en/series/irb-administration/>).
* IRB Committee members should be committed to maintaining confidentiality in the review process to protect the integrity of the research and the outcomes of the review process.
* A quorum at IRB meetings is required to approve human subjects research: More than half of the primary members on the Committee must be present.

**IRB Committee Meetings**

Minutes of IRB meetings must be recorded and include:

* A list of attendees at the meeting (Quorum required to approve applications)
* Actions taken by the IRB
* The vote on these actions, including the number of members voting for, against, and abstaining
* The basis for requiring changes in or disapproving research
* A written summary of the discussion of controverted issues and their resolution

**IRB Record Keeping**

The Fisher College IRB Committee will prepare and maintain adequate documentation of IRB activities, including the following:

* Copies of all research proposals reviewed; scientific evaluations, if any, that accompany the proposals; approved sample consent documents; progress reports submitted by investigators; and reports of injuries to subjects;
* Records of continuing review activities
* Copies of all correspondence between the IRB and the investigators