** Institutional Review Board (IRB)**

**Proposal/Application Form**

The Fisher College IRB reviews all requests to conduct research involving human subjects. It is the investigator’s responsibility to give complete information regarding procedures and the informed consent process. Applicants are encouraged to review the Department of Health and Human Services’ federal guidelines on the Protection of Human Subjects available [here](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1115).

Before submitting the application, please read the following criteria to determine whether you are required to submit your research project for IRB review and approval.

* You are performing research using human subjects - IRB review and approval needed
* You are requesting a course reduction to do research with human subjects – IRB and Administrative review and approval needed \*\*

* You are requesting a course reduction for research that does not involve human subjects – IRB review (no approval needed) and Administrative approval needed \*\*

* You are requesting to use Fisher resources or information for a research or a project (e.g. dissertation or master’s research, graduate course project, etc.) with human subjects – IRB review and approval and Administrative review and approval \*\*

* You are requesting to use Fisher resources or information for research or a project (e.g. dissertation or master’s research, graduate course project, etc.) without human subjects – IRB review (no approval needed) and Administrative review and approval \*\*
* You are requesting to use Fisher resources or information for research or a project (with or without human subjects) and IRB approval has been granted by another institutions-IRB review is needed (no approval needed)\*

\*\*If your project requires Administrative Approval, it will be submitted to the appropriate Administration representative after IRB review.

\*IRB review means that the IRB committee members will review your application to ensure that the research is consistent with Fisher policies and procedures, but that IRB approval is not necessary. Review is often an expedited process, as opposed to a full review and approval.

The Principle Investigator must initially include the following (in addition to other required materials as requested in the form below)

* A completed application
* An informed consent form
* A copy of their NIH web-based training certificate (must have been completed within 5 years of the date in which the application is submitted)

**Institutional Review Board Proposal Form**

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| Principal Investigator: |  |
| Contact Information: |  |
| Project Title: |  |
| Proposal Submission Date: |  |
| Project’s Anticipated Start and End Date: (All projects extending beyond 1-year require a continuing review with annual application for renewal) |  |
| Does the proposed research fulfill a class assignment or requirement?  |  |
| Will a request for external funding be made in association with this proposed research? |  |

Fisher College’s Institutional Review Board requires all research investigators to complete the Online Training in Human Subjects Research. Office for Human Research Online Training is available for free for all individual learners and can be accessed on the following website: <https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/index.html>. Attach your certificate as an appendix at the end of this proposal 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 proposal for research is submitted.

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| **Protecting Human Research Participants Online Training** |
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| Date of Completion: |

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| 1. List the names, credentials/training, and specific roles of all the researchers that will be involved in this research. *Additional or new researchers may be added to your research project by submitting an addendum to your application to the IRB committee.* |
| **Name** | **Credentials/Training** | **Role** |
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| 2. Attach the informed consent form as an Appendix at the end of this proposal. Proposals will not be reviewed without this document. |
| 3. State the overall objectives and specific aims of the research. Describe how this work fits into the existing literature in the field.  |
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| 4. Participants |
| Do participants represent members of a population who have the ability to provide informed consent?  | (Yes or No) |
| Will participants be 18 years old or older? |  |
| Will the participants be Fisher College students? |  |
| List the specific criteria that will be used to include and exclude participants from the study. To ensure that the selection of subjects is equitable, review federal guidelines §46.111 Criteria for IRB approval of research. <https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1115> |
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| Describe how participants will be recruited for this study below (§46.111). If access to participants is sought from clinics, schools, agencies or other external sites, you are required to attach letters of approval as an appendix to this proposal form to be reviewed by the IRB. |
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| 5. Describe the study’s purpose. |
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| 6. Describe the study’s design and procedures. Describe in detail any experimental or interventional procedures or devices involved in the study. Attach the *final* *versions* of surveys, questionnaires, or other instruments as appendices at the end of this proposal. |
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| 7. Describe how specific data variables will be collected. Who will collect the data? Where? When? How will the data be recorded/coded? Describe how participants’ privacy will be maintained and how confidentiality will be guaranteed.  |
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| 8. How will this data be stored securely during and after the study? Per U.S. Department of Health and Human Services, data collected should be retained for at least 3 years. §46.115 IRB records. <https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1115> |
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| 9. If anonymity or privacy are requirements for this research and an electronic system will be used to administer a survey or questionnaire, please indicate what service will be used and provide proof that the service guarantees privacy and anonymity (from a terms of service or privacy statement). If anonymity and privacy are not required, please state this below.  |
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| 10. Describe the methodology that will be used to analyze the data collected.  |
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| 11. What risks are faced by participants in this research (e.g. injury, pain, emotional distress, embarrassment, or invasion of privacy – consider short and long term potential risks)? What measures will be taken to minimize these risks? |
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| 12. Will there be any costs to be borne by the participants by virtue of their involvement in this research? Will there be any compensation or reimbursement to participants in this research (i.e. monetary payments, course credit, services, etc)? Describe below. |
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| 13. What are the likely benefits of this research to the participants, as well as, to society?  |
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| 14. Describe the guidelines that will be used for adverse event reporting. In addition to the IRB, which other entities or persons will be notified if any of the participants experience difficulties as a consequence of participating in the study? |
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Any additions or changes must be submitted to the IRB for written approval prior to these changes being implemented.

Any problems connected with the use of human subjects once the project has begun must be brought to the attention of the IRB.

Informed Consent documents must be kept for a period of 3 years following the completion of the project.

**10. Signatures**

I certify to the best of my knowledge the information presented is an accurate reflection of the proposed research project.

A.

Principal Investigator Date

B.

Faculty Sponsor (only for students) Date

Faculty sponsor confirms the accuracy of the application and accepts responsibility for the conduct of the research.

C.

Program Director (if appropriate) Date