

SECTION 8: IRB: INSTITUTIONAL REVIEW BOARD

8.1 INTRODUCTION

John Carroll University approved and adopted a policy statement for the Institutional Review Board for the protection of human participants in 1997, applicable to all JCU faculty, administrators, staff, and students. A statement of ethical principles, definitions, and general policy guidelines can be found in the policy statement at the end of this section.

The IRB reviews proposals for research projects involving the use of human participants. The decision to approve or deny a project is based on the information presented in an application. The research project will be evaluated to ensure the protection of the rights of the individual. In cases of greater than minimal risk, the IRB may comment on the research design when warranted as mandated by federal regulations. Projects may not be started until IRB approval has been given.

The Sponsored Research website has devoted a section to IRB concerns, which can be found at www.jcu.edu/research/irb. Guidelines and forms are available at the website and at the end of this section. Also included on the website are helpful hints on selecting and completing forms, a FAQ (Frequently Asked Questions) list, resources of interest to researchers and reviewers, and a guide to types of IRB projects entitled “Does your project need IRB Review?”

See the Glossary in **Section 10** for an explanation of IRB terminology.

8.2 HISTORY & DEVELOPMENT

Federal protection of human participants was put in place after international concerns developed over the unethical treatment of humans participating in research studies. The Nuremberg Code, written in response to Nazi human

experimentation, concluded that voluntary informed consent is essential for any human research and that research should minimize any unnecessary risk to the participant. As adopted by the World Medical Assembly in 1964, the Declaration of Helsinki made similar recommendations. In the United States, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued The Belmont Report in 1969 stating basic ethical principles for biomedical and behavioral research.

By 1981, the US Department of Health and Human Services (DHHS) codified their regulations on the use of human research participants as Title 45 Part 46 of the Code of Federal Regulations. Reporting to the National Institutes of Health, the Office for Protection from Research Risks (OPRR) was created as the federal office originally responsible for implementing DHHS regulations governing research involving human participants and overseeing institutional review boards. As of June 2000, OPRR was elevated to the Office of Human Research Protections (OHRP), reporting directly to the DHHS.

8.3 COMPOSITION OF THE IRB

In compliance with federal regulations, the JCU IRB must be composed of at least five voting members reflecting diversity in race, gender, and cultural backgrounds. In addition, representatives are selected from each college and school of the University. At least one member must be from outside the University, one must be a non-scientist and one a scientist. Board members serve a three-year term and may be re-appointed by the Academic Vice President.

A faculty member serves as the Chair and is selected by the board and appointed by the Academic Vice President for a three-year term. The board selects an Acting Chairperson who is appointed each semester. The Director of Sponsored Research serves ex-officio as the Assistant Chair. Lastly, the IRB Administrator position provides support to all chairpersons and helps to maintain the daily functions of the IRB. The IRB Administrator is an ex-officio non-voting member of the board.

8.4 MEETINGS, QUORUMS, & DEADLINES

The IRB has scheduled monthly meetings during the fall and spring semester. For Full Board Review, a decision will be rendered by quorum of a majority of the total membership, including at least one member from a non-scientific field. Proposals should be submitted to the IRB chair at least four weeks prior to the start of the research project. An incomplete or unclear application will result in a considerable delay in processing the proposal. Applications are accepted during the summer but may experience a slight delay in processing.

8.5 SUBMISSION GUIDELINES

Research proposals involving the use of human participants are filed with the IRB using the *IRB Application for Human Participant Research* for exempt, expedited, and full-board review. Information Sheets 1 and 2 can be used to determine if a project falls under an exempt or expedited review category.

However, the type of review appropriate for the proposed project is ultimately decided by the IRB.

8.5.1 Research That Needs to be Filed with the IRB and Who Needs to File:

“Research” is defined as a systematic investigation designed to develop or contribute to generalizable knowledge. The following research proposals should be filed with the IRB if the results will be disclosed in any public manner, including poster displays, presentations, brochures, master’s theses, and other publications:

1. All research involving human participants conducted on campus by anyone, i.e., University-affiliated researchers and outside personnel.
2. All research involving human participants conducted by anyone affiliated with the University whether the research is conducted on campus or off campus.

Such research projects include but are not limited to: collection of oral histories, evaluation of teaching techniques resulting in publishable results, survey research, psychological experiments, and personal interviews.

8.5.2 Types of IRB Review for Research Projects: Exempt, Expedited, and Full Board

Depending on the complexity of the research project, the degree of risk, and other issues, your application may qualify for a relatively quick and easy review (Exempt from Full Board Review), a review by a few board members (Expedited Review), or an in-depth review by the entire board to be discussed and evaluated at the next board meeting; or your research may fall outside the jurisdiction of the IRB. The type of review for which your application is eligible is based on guidelines formulated by the federal government.

One original and one copy of the application and attachments should be submitted to the IRB Administrator in AD 250. Please allow sufficient time for possible revision. An incomplete or unclear application will result in a considerable delay in processing.

8.5.3 Making the Review Process Easier

A well-written, complete application will most likely have a quicker than average review time. Make sure to include a copy of any survey instrument and other pertinent material (e.g., cover letter, consent form, announcements, advertisements). Attachments should be labeled and

referenced in the IRB application (see also **Section 8.11 Checklist for Submittal**).

IRB reviewers are required to pay particular attention to certain parts of the application as required by federal regulations. A reviewer will typically look for answers to the following questions:

- ❖ *The participant pool:* Are participants representative of the general population? Can you justify narrowing the pool to a select segment of the population? Are you using vulnerable participants with justification, such as the mentally disabled?
- ❖ *The protocol:* Is your protocol fully described? Can it be validated? Can any risk to the participants be justified by the outcome of the research? Who will analyze the research and by what method?
- ❖ *The consent form:* Does the consent form provide all the information listed below in **Section 8.10**? If not, have you provided the reasons for the omission?
- ❖ *Advertisements:* Are any promotional materials that will be used to recruit participants (including e-mail announcements, flyers, brochures, and ads) attached to the application, and do they accurately describe the project?
- ❖ *Survey tools, instruments, tests:* Does the material avoid collecting unnecessary private data? The IRB strongly discourages the collection of social security numbers.
- ❖ *The data:* Will the data be carefully collected to protect the privacy of the participants? Are the data collected in an anonymous or in a confidential manner? Who will have access to the data? Where will the data be stored? When and how will the data be destroyed?
- ❖ *The results:* What will you do with the results of the data? Who will have access to the results and for what purpose?

8.6 CONTINUING RESEARCH

Please indicate on the IRB application if the research will be conducted on an annual basis. If the project will last longer than one year, you must file for a continuance by submitting a *Continuation Request Form* to the IRB; IRB approval is given only for a one year period or less depending on the degree of risk to human participants. The *Continuation Request Form* should be submitted to the IRB no earlier than six weeks before the expiration date (to avoid a change in the approval date) and no later than four weeks before the expiration date to allow enough time to review and approve the continuation request.

8.7 REVISIONS TO A PROJECT

All substantive revisions (i.e., modifications, addenda, amendments) to a project must be reviewed and approved by the IRB prior to initiation. An *Addenda Request Form* should be submitted to the IRB at least one month in advance to ensure enough time for it to be reviewed.

8.8 CLASSROOM RESEARCH

In most cases, class research projects involving human participants are not intended to contribute to generalizable knowledge and therefore do not require IRB review; however, if a class research project will be generalized (e.g, by being published, including as a master's thesis; presented outside the class; cited in another paper; or included in a poster presentation) the *IRB Application for Human Participant Research* must be filed and approved before the project begins.

8.9 INFORMED CONSENT AND THE CONSENT FORM

In compliance with federal regulations, the IRB carefully reviews consent forms to ensure that human participants are fully informed of their rights and that they understand the research. Biomedical research requires a more complex form. Note that federal regulations require that consent forms should be kept for three years after the end of the project. Use the following checklist to evaluate your behavioral research consent form:

- ❖ Is the consent form written in language easily understandable by the participants?
- ❖ Have you avoided the use of jargon?
- ❖ Does the participant know what type of research is taking place, who is conducting the research, how it will take place, why the research is being conducted, and who to contact for more information?
- ❖ Have you indicated the time required for the participant to complete the experiment or survey and provided a general description of what may be required of the participant?
- ❖ Have you listed any risks (physical, mental, or emotional) that the participant may experience during the research?
- ❖ Have you stated that participation is voluntary and that participants may withdraw from the project at any time without penalty?
- ❖ Are questions of privacy addressed? Have you indicated if the data will be collected confidentially or anonymously? Information is confidential if it can be linked to a particular individual through the use of codes or identifiers or by visual identification. Anonymous information cannot be traced back to any individual participant by the researcher.
- ❖ When working with students, is an age requirement listed on the form, if applicable? Participants under the age of 18 are considered minors and

therefore members of a vulnerable participant pool. Parental consent is required in most cases.

- ❖ Note that participants should receive a copy of the consent form to take home.
- ❖ Under certain circumstances, the use of a consent form may be waived.

8.10 IRB RESOURCES

Many resources are available to researchers interested in learning more about the protection of human participants in research and the role of the IRB. See the website www.jcu.edu/research/irb for resources available at the Grasselli Library and through OhioLINK, and for links to primary sources available on the Internet.

If you have any questions or concerns, contact the IRB Administrator or any member of the IRB. A list of current IRB members is posted on the IRB website.

8.11 CHECKLIST FOR SUBMITTAL

The amount of time that your application is under review depends in part on the completeness of the IRB forms and the consent form. Allow enough time for possible revision and second review before the start of your project. Use the following checklist to evaluate your application:

- ❖ Is the IRB application neatly filled out and easy to read?
- ❖ Is the IRB application completely filled out?
- ❖ Is the Methodology statement for the research (Item 10 on the IRB Application) complete, detailed, and clearly written?
- ❖ Does the consent form provide all the information required? (See separate checklist for consent forms in **Section 8.9** above.)
- ❖ Have you avoided the use of jargon?
- ❖ If applicable, have you attached a copy of the survey instrument along with any other pertinent materials including advertisements for participants?
- ❖ Do you have the required signatures on the IRB application?
- ❖ Are you submitting the application at least four weeks before the expected start of your project?

For further guidance and information on the completion of the forms, contact the IRB Administrator or any member of the IRB.

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APPENDICES TO SECTION 8:

- ❖ **IRB APPLICATION FOR HUMAN PARTICIPANT RESEARCH**
- ❖ **IRB APPLICATION GUIDELINES**
- ❖ **INFORMATION SHEET 1 – EXEMPT REVIEW**
- ❖ **INFORMATION SHEET 2 – EXPEDITED REVIEW**
- ❖ **CONTINUATION REQUEST FORM**
- ❖ **ADDENDUM REQUEST FORM**
- ❖ **IRB POLICY**