Institutional Review Board (IRB)

Policies and Procedures

Updated September 2014
## Table of Contents

Ohio Valley University Institutional Review Board 3  
Role of the IRB 4  
IRB Review Categories 4  
Criteria for IRB Approval of Research 6  
Protecting Human Research Participants Training Program 7  
IRB Records & Documentation 7  
Application Materials 8  

### Appendices

<table>
<thead>
<tr>
<th>I.</th>
<th>IRB Checklist</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>II.</td>
<td>Application for Research Study Approval</td>
<td>10</td>
</tr>
<tr>
<td>III.</td>
<td>Approval for Research Study by Instructor/Advisor</td>
<td>13</td>
</tr>
<tr>
<td>IV.</td>
<td>Consent Form Components</td>
<td>14</td>
</tr>
<tr>
<td>V.</td>
<td>Example of a consent form</td>
<td>15</td>
</tr>
<tr>
<td>VI.</td>
<td>Debriefing Form Components</td>
<td>16</td>
</tr>
<tr>
<td>VII.</td>
<td>Protecting Human Research Participants Training</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>(offered by the National Institutes of Health)</td>
<td></td>
</tr>
<tr>
<td>VIII.</td>
<td>Tips for Preparing a Successful Proposal</td>
<td>18</td>
</tr>
</tbody>
</table>
Ohio Valley University Institutional Review Board

The primary responsibility of the Ohio Valley University Institutional Review Board (IRB) is to ensure the ethical treatment and protection of the rights and welfare of human subjects participating in research activities. The IRB ensures that physical, psychological, and social risks to research subjects are minimized, and that the risks associated with the research are commensurate with the importance of the research and/or the knowledge to be gained.

This is accomplished by reviewing all proposed research that uses human subjects to ensure that the University, affiliate institutions, and investigators are compliant with the ethical standards and regulations governing human subject research. These regulations are summarized in the Code of Federal Regulations (45 CFR 46) from the U.S. Department of Health and Human Services.

The IRB is composed of two faculty members from disciplines in which research involving human subjects is integral to that discipline’s work, two faculty members whose primary interests are non-scientific, and one member from the community.

All faculty and staff (both full-time and part-time) using human subjects or identifiable information about human subjects to conduct research are required to have approval from the IRB before research is initiated. This policy also applies to students whose research is conducted under the advisement of a faculty/staff member (whether the research is a part of a course or an independent study); unless the faculty/staff member as already received IRB approval for the research being conducted.

Research that is conducted without IRB approval is not in compliance with Ohio Valley University policy and federal regulations. In these circumstances a non-compliance report will be sent to the Vice President for Academic Affairs for further action.

Questions should be or to the IRB (irb@ovu.edu), or directly to the committee members. A list of current IRB members may be obtained through the Office of Academic Affairs.
Role of the IRB

Ohio Valley University’s Institutional Review Board (IRB) follow the oversight role defined in the U.S. Department of Health & Human Services Policy for Protection of Human Research Subjects (§46.109 IRB review of research). This policy states that an IRB shall:

1. Review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

2. Require that information given to subjects as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

3. Require documentation of informed consent or may waive documentation in accordance with §46.117.

4. Notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

5. Conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

IRB Review Categories

Introduction

There are three categories of initial review that are defined by federal regulations: Full, Exempt, and Expedited Review. These reviews are explained below.

- **Full**: Research studies involving more than minimal risk to human subjects are required by federal regulations to be reviewed by the IRB full board.
- **Exempt**: Studies determined by the IRB to meet the exempt criteria as defined by the Federal Regulations. Exempt studies do not require periodic review by the IRB unless a change in the project is planned.
- **Expedited**: Review of proposed research by the IRB chair or a designated voting
member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research [45 CFR §46.110].

Research under review must be submitted to the IRB committee including a completed request form that justifies the request for an exempt or expedited review. [45 CFR 46].

Exempt Review

Guidance: Research activities involving human subjects that are exempt from IRB review are identified in 45 CFR 46.101(b)(1)-(6) (Institutions and IRBs may not create new categories of exempt research under 45 CFR 46). Institutions should have a clear policy in place on who shall determine what research is exempt under 45 CFR 46.101(b). Those persons who have authority to make a determination of what research is exempt are expected to be well-acquainted with interpretation of the regulations and the exemptions. In addition, the institution should be prepared to reinforce and review, as necessary, the method of determining what is exempt. OPRR advises that investigators should not have the authority to make an independent determination that research involving human subjects is exempt and should be cautioned to check with the IRB or other designated authorities concerning the status of proposed research or changes in ongoing research.

Institutions may elect to review all research under the auspices of the institution even if the research qualifies for exemption under .46.101(b). An institution with a Multiple Project Assurance (MPA) or Cooperative Project Assurance (CPA) should indicate in its Assurance if and how exempt research is reviewed. It is incumbent on the institution to advise investigators and others involved in the conduct and administration of research involving human subjects of the institutional policies for reviewing exempt research (http://www.hhs.gov/ohrp/policy/hsdc95-02.html).

Expedited Review

Guidance: The list of categories of research that may be reviewed by the IRB through an expedited review procedure was updated in 1998 and can be found at http://www.hhs.gov/ohrp/policy/expedited98.html. Additions to, and extrapolation from, this list by the institution or the IRB are not appropriate. For example, it is inappropriate to use an expedited review procedure for the initial review of either research that involves minimal risk but does not appear in the categories of research published in the Federal Register or research that involves greater than minimal risk.

Expedited review procedures are described in HHS regulations at 45 CFR 46.110. Under an expedited review procedure, the IRB Chairperson, or one or more experienced reviewers designated by the Chairperson from among the members of the IRB, reviews the research protocol. The IRB shall adopt a method for keeping all IRB members advised of research proposals that have been approved under the expedited review procedure. In conducting
expedited review, the IRB reviewers may exercise all of the authorities of the IRB except that they may not disapprove the research. A research activity may be disapproved only after review by the convened IRB in accordance with the non-expedited procedure set forth in 45 CFR 46.108(b). Under 45 CFR 46.110(d), HHS may restrict an institution's or IRB's authority to use the expedited review procedure (http://www.hhs.gov/ohrp/policy/exprev.html).

Criteria for IRB Approval of Research

In order to approve research, the IRB will determine that all of the following requirements are satisfied (§46.111):

1. Risks to subjects are minimized:
   - Through procedures consistent with sound research design and which do not unnecessarily expose subjects to risk.
   - Through procedures, whenever appropriate, already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
   - The IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).
   - The IRB will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable.
   - The IRB will take into account the purposes of the research and the setting in which the research will be conducted.
   - The IRB will be particularly aware of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Informed consent will be obtained from each prospective subject or the subject's legally authorized representative.

5. Informed consent will be appropriately documented.

6. There are adequate provisions, when appropriate, for monitoring data collection to ensure the safety of subjects.

7. There are adequate provisions, when appropriate, to protect the privacy of subjects and to maintain confidentiality.

8. Safeguards have been included in the study to protect the rights and welfare of subjects that are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
Protecting Human Research Participants Training Program

Anyone wishing to conduct research at Ohio Valley University will need to complete the Protecting Human Research Participants Training Program offered by the National Institutes of Health. A certificate of completion will be provided upon successful completion of the training program. This certificate will be included in the application materials submitted to the IRB for review.

IRB Records & Documentation

Ohio Valley University’s Institutional Review Board follow the records policy defined in the U.S. Department of Health & Human Services Policy for Protection of Human Research Subjects (§46.115 IRB records). This policy states that:

An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

1. 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.
   o Minutes of IRB meetings which shall be in sufficient detail to show:
     o Attendance at the meetings
     o Actions taken by the IRB
     o The vote on these actions including the number of members voting for, against, and abstaining
     o The basis for requiring changes in or disapproving research
     o A written summary of the discussion of controverted issues and their resolution

2. Records of continuing review activities.

3. Copies of all correspondence between the IRB and the investigators.

4. A list of IRB members in the same detail as described in §46.103(b)(3).

5. Written procedures for the IRB in the same detail as described in §46.103(b)(4) and §46.103(b)(5).

6. Statements of significant new findings provided to subjects, as required by §46.116(b)(5).

The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.
Application Materials (Appendices I through VI)

If you are interested in conducting research using human subjects, the following items will help you prepare the application packet that must be completed and submitted to the IRB for review:

- IRB Checklist
- Application for Research Study Approval
- Approval for Research Study by Instructor/Advisor
- Consent Form Components
- Debriefing Form Components
- Protecting Human Research Participants Training Program (offered by the National Institutes of Health)
APPENDIX I

IRB APPLICATION CHECKLIST

Please confirm that all of the following items are completed prior to submitting the application for study approval to the Institutional Review Board.

- Students: Document of Approval for Research Study by Instructor/Advisor
- Completed application
- Copy of all consent forms
- Copy of all debriefing forms
- Copy of all surveys or questionnaires
- Certificate of satisfactory completion of the Protecting Human Research Participants Training Program offered by the National Institutes of Health
APPENDIX II

IRB APPLICATION FOR RESEARCH STUDY APPROVAL

Answer the following questions completely. Email this document, and a copy of the informed consent and any instruments that will be used in the study, to irb@ovu.edu.

Date of Submission: _____________________

Primary Investigator: _________________________________________

Email: _________________________________________

Phone:_______________________________________

Office: ________________________________________

Campus Mail Box Number (If applicable)______________

Other Investigator(s): ________________________________

__________________________________

__________________________________

__________________________________

__________________________________

Students only:

The study must be approved by the course instructor or the research advisor before submitting to IRB. Approval granted: □ Yes □ No

Instructor/Research Advisor: ________________________________

Course: ________________________________________________

1. Provide a short description of the proposed research study. For example: “This quantitative study will compare the effectiveness of two analgesics in the treatment of headache.”

2. Explain the purpose of the research study.
3. Briefly summarize the important background information related to this study.
4. State the hypothesis (es) or research question(s) for the study.
5. Explain the research design that will be used for the proposed study.
6. Describe the population of interest.
7. Describe the sample/participants for this study.
   a. Provide a very detailed description of the sample/participants: number, demographics, inclusion criteria, exclusion criteria, etc.
   b. Provide a very detailed description of how participants will be recruited.
      i. Approaching potential participants in person to ask them to participate is not acceptable due to concerns of coercion.
      ii. Announcements may be made in group settings, and interested participants may contact the researcher or faculty supervisor.
      iii. Flyers, posters, large group emails to ask for participation are acceptable.
8. List and describe all materials and supplies that will be used in the study.
9. Describe all research tools, surveys, and questionnaires that will be used in the study. Attach copies of the research tools to be used to this submission.
10. Will any off-campus agencies or facilities be used for this study? If yes, explain.
11. If off-campus agencies or facilities are going to be used, has approval been granted by the agency/facility? (Must provide documentation of approval from the agency.)
12. Provide a very detailed description of the research procedure.
   a. Include specific measurements of any data that will be collected or variables that will be investigated.
13. If deception is used, justification for the deception must be provided. Include, the reason deception is needed, when the deception will be explained to participants, and how the debriefing will take place.
14. Explain the benefits, if any, for individuals who participate in the study.
15. Explain the risks, if any, for individuals who participate in the study.
16. Explain safety procedures that will be utilized to decrease hazards to participants and researchers.
17. If incentives are used, discuss all incentives that will be used to encourage individuals to participate.
18. Describe how you will obtain informed consent, addressing each of the following elements:
   a. Description of any foreseeable risks or discomforts for the participant
   b. Description of any benefits to the participant or others
   c. Alternative procedures or courses of treatment that might be advantageous to the participant
   d. Describe how confidentiality of records will be maintained
   e. Description of any medical treatments or compensation that will be provided if injury occurs
   f. Explanation of whom to contact for answers to questions
g. Statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the individual may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

h. A copy of the consent form/letter that will be used for the study must accompany this application.

i. Consent must be signed by potential participants before asking any questions (even questions that are posed to assess if the potential participant meets the criteria to participate in the study).

19. Provide a description of how data will be protected, how it will be destroyed, and when it will be destroyed. (Note: data must be kept for a minimum of 3 years after the study has been completed. The primary researcher must provide contact information that will be active for at least 3 years after the conclusion of the study.)

20. Time Frame for Completion
   
   Note: In accordance with §46.109 IRB review of research the IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

21. Approval Before Participants Selected: Approval from the IRB must be granted before participants are recruited and before data can be collected.

22. The completed proposal must be emailed to the IRB by the supervising faculty member. (This is how the IRB is assured that the proposal has been approved by the supervising faculty member.) Follow-up submissions may be emailed by the student or supervising faculty member. The faculty member must be copied on all correspondence between the student and the IRB.
APPENDIX III

APPROVAL FOR RESEARCH STUDY BY PROFESSOR/ADVISOR

Students: Approval for research study must be approved by the course instructor or research advisor prior to submitting the application to the IRB. Please complete the following:

Student Name: __________________________________________________________

Course: __________________________________________________________________

Title of Research Study ___________________________________________________

Approval granted by:

________________________________________________________________________

Signature of Instructor/Advisor      Date

I agree to conduct research study as approved.

________________________________________________________________________

Signature of Student          Date
Researchers must provide a potential participant with complete and accurate information about the research study prior to participation in the study. This disclosure is known as informed consent. The U.S. Department of Health & Human Services regulates informed consent in its Policy for Protection of Human Research Subjects (§46.116 & §46.117). The policy explains informed consent as follows:

No investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.

Ten basic elements that must be included in an informed consent form (Appendix A provides an example informed consent form with annotations illustrating the ten elements). These nine elements are:

1. **Overview** – An explanation of the goals of the research
2. **Description of Procedures** – An explanation of the treatment conditions, assessment procedures, and requirements of participation
3. **Risks and Inconveniences** – The physical and psychological risks and inconveniences/demands associated with participation
4. **Benefits** – Physical, psychological, and/or monetary benefits of participation
5. **Costs & Economic Considerations** – Charges and/or payment to the participants
6. **Confidentiality** – Assurance of how the information is confidential
7. **Alternative Treatments** – Alternatives available to the participant, if applicable
8. **Voluntary Participation** – A statement indicating that participation is voluntary and that participation may be declined at any time without penalty
9. **Questions and Further Information** – Contact information to receive answer to any further questions
10. **Signature Line** – A place to sign to acknowledge informed consent for participation in the research

Regulations (§46.117) require that informed consent is documented by using a written consent form that has been approved by the IRB and signed by the subject or the subject's legally authorized representative, and that a copy is given to the person signing the form.
Adaptability of Motor Performance
Researcher: Bethany Kordella

CONSENT TO ACT AS A RESEARCH PARTICIPANT

Name___________________________________________
Date____________________________________________

Primary e-mail address______________________________________________________________

We are conducting a research study to learn more about the correlation between adaptability to a specific motor skill and adaptability in general. To participate, you must be over 18 years of age.

If you agree to participate, then the following may happen. You may be asked to participate in one session, lasting between approximately one-half to one hour. The duration of the session will vary, based on the speed at which you complete a series of surveys and the motor task. During this session, you may be asked to complete up to four surveys and attempt a series of golf putts. The outcomes of your attempted putts may be recorded via the experimenter marking them on a chart; your responses on the surveys may also be used for research purposes.

There are no known risks associated with any of the procedures used in this study. There will also be no direct benefit to you from these procedures. However, we hope to learn more about motor adaptability and success in life. This may in turn help to direct future research on various issues relating to predictors of overall life success.

If you are in one of Dr. Miller’s classes you will receive 5 bonus points for your participation.

I have explained this study to you and answered your questions. If you have any other questions, or wish to report a research-related problem, you may call me at (xxx) xxx-xxxx or Dr. Miller, my advisor, at (304) 865-6168. This study has been approved by the Ohio Valley University Institutional Review Board (IRB; approval #xx-xxx). If you have any concerns about the ethics of this study or the treatment of research participants, please contact the IRB via e-mail at irb@ovu.edu.

Participation in this research is completely voluntary, and you may refuse to participate or stop at any time without penalty. However, to receive the extra credit for your course, you will need to finish all aspects of the study. Research records will be held in the strictest confidence, and will be used solely for research purposes.

By signing below you are indicating that you have read the above consent form, agree to participate in this study, and are 18 years of age or more.

Participant’s signature___________________________________________Date

Address:
___________________________________________________________
___________________________________________________________
___________________________________________________________

Phone Number:___________________________________________________________
APPENDIX V

COMPONENTS OF DEBRIEFING FORMS

At the conclusion of a research study good practice requires a researcher to fully explain the purpose of the research study to each participant and to give the participant another opportunity to ask questions about the research. This process is known as debriefing. Debriefing is especially critical if the research study employed any deception (active or passive). Debriefing serves five purposes. Debriefing attempts to:

1. Convey the true purpose of the study.
2. Counteract any negative effects of participation in the study.
3. Explain expected contributions of the research finds.
4. Reveal the use of any deception and explain any justification of its use.
5. Answer any remaining questions the participant may have.

The expectation is that any debriefing will occur immediately following the participant’s completion in the research study. The research should give an oral debriefing and provide a written debriefing form. An example debriefing form is provided in Appendix A.
APPENDIX VI

Protecting Human Research Participants Training Program

Anyone wishing to conduct research at Ohio Valley University will need to complete the Protecting Human Research Participants Training Program offered by the National Institutes of Health. A certificate of completion will be provided upon successful completion of the training program. This certificate will be included in the application materials submitted to the IRB for review.
APPENDIX VII

Tips for Preparing a Successful Proposal

1. The key is in the details. Provide as much detail as possible for all sections of the IRB application. Provide specific details as if you were building a house or writing a recipe. The proposal should contain enough detail that another person should be able to pick up the proposal and conduct the research.

2. When recruiting participants, researchers must provide potential participants with an “easy out”. Any recruiting technique that may have any degree of coercion will not be approved.

3. Start developing your proposal as soon as possible. It takes time to get the proposal read and approved by the IRB. It usually takes approximately 2 weeks for the original proposal to be reviewed and for feedback to be provided to the investigator. Revisions may take up to a week to be reviewed and feedback sent to the investigator.

4. Do not begin collecting data before the IRB has approved the proposal.

5. The supervising faculty member must email the first submission to the IRB. If the proposal is not emailed by the supervising faculty member the first time, it will be returned without an IRB review.