

**APPLICATION FOR USE OF HUMAN SUBJECTS IN RESEARCH**

**Instructions:**

- Prepare your research project according to the following outline. **(Hand written forms will not be accepted.)**
- Submit the signed form to the Office of Academic Affairs. All forms must be completed in full with appropriate signatures to be reviewed by the committee.

**Principal Investigator** \_\_\_\_\_ Phone Number \_\_\_\_\_  
Department \_\_\_\_\_ Campus \_\_\_\_\_ Email \_\_\_\_\_  
Correspondence Address \_\_\_\_\_

**Faculty Sponsor (If Applicable)** \_\_\_\_\_ Phone Number \_\_\_\_\_  
Department \_\_\_\_\_ Campus \_\_\_\_\_ Email \_\_\_\_\_

**Project Title:** \_\_\_\_\_

**Type of Project:** Faculty Research   
Student Directed Research  
 Thesis  Dissertation  Other ( \_\_\_\_\_ )  
 Course Requirement:  16 week  8/9 week (course #: \_\_\_\_\_)

**Duration of Project:** Starting Date \_\_\_\_\_, **but not before written approval is obtained.**

Expected End Date \_\_\_\_\_

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I certify that to the best of my knowledge the information presented herein is an accurate reflection of the proposed research project. I accept the responsibility for the conduct of this research, the supervision of human subjects and maintenance of informed consent documentation as required by IRB. I certify that the research procedures for this project and the method of obtaining consent (if any), as approved by the IRB, will be followed during the period covered by this research. Any future changes will be submitted for Board review and approval prior to implementation. An End-of-Project Form must be submitted upon completion.

\_\_\_\_\_  
Principal Investigator Date

\_\_\_\_\_  
Faculty Sponsor (If PI is a student) Date

\_\_\_\_\_  
Chair of Department Date  
(If PI is a Faculty Member & Project is Level II or III)

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**REVIEWER(S)**

\_\_\_\_\_  
Primary Reviewer (Level I) Date

\_\_\_\_\_  
Primary Reviewer (Level II) Date

\_\_\_\_\_  
Chairperson, IRB (Level III) Date

**ACTION TAKEN:**

Approved  Contingent  Disapproved

Approved  Contingent  Disapproved

Approved  Contingent  Disapproved

Comments or Contingencies, see attached

Periodic Review Due: \_\_\_\_\_

End-of-Project Due: \_\_\_\_\_

**GENERAL INSTRUCTIONS**

1. This form (1040) is to be completed if you are conducting a research project that does not follow guidelines of the Form 1040EZ-A, Form 1040EZ-I, Form 1040EZ-O or Form 1040EZ-S. Webster records containing confidential information require Academic Affairs approval for release, prior beginning of research.
2. You should make every effort to protect the confidentiality of subject data.
3. All researchers, instructors and students are expected to examine the information available on the IRB web site <http://www.webster.edu/irb> before beginning this form.

**PART I:** Please answer the following by checking the correct response:

- Yes  No  1. Will subjects be identifiable to anyone other than the researchers through records, responses or identifiers linked to the subjects?
- Yes  No  2. Could subjects be at risk of criminal or civil liability, damage to employability or to financial standing or undue embarrassment, if responses became known outside this research project?
- Yes  No  3. Does research deal with sensitive aspects of subjects' behavior, such as illegal conduct, drug use, sexual behavior or use of alcohol?
- Yes  No  4. Does research involve the collection or study of existing data from sources not publicly available (existing data can be documents or records)?
- Yes  No  5. Are subjects free to withdraw at any time without penalty?
- Yes  No  6. Is there deception of subjects? **(If yes, you must ALSO complete the Deception Appendix)**
- Yes  No  7. Does research deal with subjects who are children under eighteen years?
- Yes  No  8. Will the project be conducted in conjunction with another institution (business or education)?
9. Does research deal directly with subjects who are:
- |   |   |
|---|---|
| Yes <input type="checkbox"/> No <input type="checkbox"/> not-legally competent adults | Yes <input type="checkbox"/> No <input type="checkbox"/> prisoners                  |
| Yes <input type="checkbox"/> No <input type="checkbox"/> mentally disabled            | Yes <input type="checkbox"/> No <input type="checkbox"/> pregnant women             |
| Yes <input type="checkbox"/> No <input type="checkbox"/> physically challenged        | Yes <input type="checkbox"/> No <input type="checkbox"/> other "special population" |

If you answer yes to any of the above, please provide details in Part III, A.

10. Does the research project involve:

- |  |  |
|--|--|
| Yes <input type="checkbox"/> No <input type="checkbox"/> administering drugs   | Yes <input type="checkbox"/> No <input type="checkbox"/> drawing blood                         |
| Yes <input type="checkbox"/> No <input type="checkbox"/> taking tissue samples | Yes <input type="checkbox"/> No <input type="checkbox"/> administering nutritional supplements |
| Yes <input type="checkbox"/> No <input type="checkbox"/> giving injections     | Yes <input type="checkbox"/> No <input type="checkbox"/> other invasive medical procedure      |

**If you answer yes to any aspect of question 10, you must ALSO complete the Medical Appendix**

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**PART II: Attach** a summary of your project. This addendum should include the following components:

- Introduction – Discuss the goals and purpose of the present study. Include citations to relevant studies if you feel this would help the Board make their decision.
- Methods – Describe the procedures you will be using to conduct the study. This should be **very** detailed. The Board should be able to “conduct” your research using this description.
- Stimulus materials – Provide all scripts, consent forms, and questionnaires cited in the Methods section.

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**PART III:** Please answer **all** of the following items providing additional information where appropriate. Use NA when questions are not applicable.

**A. Participants**

1. Describe your subject selection procedures. Include the criteria to be used for inclusion or exclusion of subjects (append any questionnaires used for participant exclusion).
  
2. Describe the characteristics of your population(s). Include the size of your sample, the ethnic background, sex, age, and their state of health. Include rationale for use of special classes of subjects such as pregnant women, children, institutionalized mentally disabled, prisoners or those whose ability to give voluntary informed consent may be in question. If your population is all one gender or ethnic group, please explain.
  
3. Who makes the initial contact with the participants? (If you want to use patients/clients of another professional, the other professional must make the initial contact, to protect patient/client confidentiality)

**B. Confidentiality** (helpful tips to protect confidentiality are available at the IRB web site <http://www.webster.edu/irb/confid.html>).

1. Will subjects be identifiable to anyone other than the researchers through records, responses or identifiers linked to the subjects? Yes  No
  
2. **How** do you intend to record information so participants can not be identified directly or through identifiers? Address how you will protect their rights, welfare and privacy.
  
3. Will subjects' responses be:      Video Taped?      Yes  No       Audio Taped?      Yes  No 
  - If yes, how do you intend to protect the subjects' identity (e.g., erase tapes following transcription)?
  
  - If yes, will subjects be given the opportunity to review the tapes immediately following the interview? Will subjects be given the opportunity to withdraw the use of their taped responses from the research project immediately following the interview? Explain why or why not.

**C. Risks** (information on the risk/benefit analysis is available at the IRB web site - <http://www.webster.edu/irb/riskben.html>)

1. Identify any risks – physical, psychological, and/or social – to which your participants may be exposed as a result of taking part in your project (beyond the risks normally encountered in everyday life). Risks should be presented in lay language in the Consent Letter.
  
2. What safeguards will you use to protect the subjects from risks? (Never answer "NA")

3. Identify any monetary expenses that participants will incur as a result of participation in your project. Any monetary expenses should also be presented in the Consent Letter.

4. Participants will be informed of the risks through (select as many as apply):

- consent form (include a copy in your Appendices)
- verbal (include a script in your Appendices)
- other (explain)

**D. Benefits**

1. Describe any form of compensation to participants (e.g., money, grade, extra credit). If money, extra credit or grade is given to individuals who participate in the project, what opportunity for extra credit or grade is provided to those who choose not to participate? The nature of the compensation should be stated in the consent form (information on compensation is available at the IRB web site - <http://www.webster.edu/irb/incent.html>)
2. Describe the benefits you expect to be gained from this project. (This should include any direct benefits to the participants as well as any general gain in knowledge.)

**E. Vulnerable Populations**

1. If you will be using children under age 18, explain in detail how you will obtain parental consent and assent (for children ages 5-11) or consent (for children 12 to 17). If assent/consent will be obtained orally, supply a script of what you will say and how you will give the children the opportunity to say "yes" or "no" (information on the use of children in research is available at the IRB web site - <http://www.webster.edu/irb/child.html>).
2. If you will be using adults whose ability to give voluntary informed consent may be in question (e.g. institutionalized, mentally disabled, or legally incompetent), explain in detail how you will obtain guardian consent and assent/consent from the subject. If assent/consent will be obtained orally, supply a script of what you will say and how you will give the individual the opportunity to say "yes" or "no." (information on the use of vulnerable populations in research is available at the IRB web site - <http://www.webster.edu/irb/vulner.html>)

**F. Records**

1. In which Webster University faculty or departmental office will the signed consent forms be kept? (Consent forms must be kept on campus, not in a private home or office). Consent forms should be separated from the data to protect anonymity.
2. What do you intend to do with the data collected? (e.g., publish data, present paper, erase tapes)
3. Will subjects' personal files (school, medical, etc.) be read? Yes  No   
If yes, explain where the files will be kept and who will gather the information?

- If yes, has permission been obtained to gather this information? (Attach documentation)

- If yes, do the subjects (and/or their parents or guardians) know that these files will be read? Explain.

4. Will any standardized test results (e.g., IQ tests, personality tests, medical tests) be disseminated to the subjects (and/or their parents or guardians)? Yes  No

- If yes, explain the qualifications of the person(s) interpreting the results.

**G. Other**

1. Is the proposed study part of an on-going research program? Yes  No

If yes, please append a letter of support from the principal investigator of that program.

2. Does the proposed study take place at an off-campus site? Yes  No

If yes, please indicate the Site(s) \_\_\_\_\_

3. Does this project involve approval/permission from other institutions? Yes  No

Guidelines for determining whether off-site approval is needed can be found at <http://www.webster.edu/irb/offsite.html>

- If yes, please attach documentation stating you have permission to conduct research at that specific site. This includes IRB approval from that site (if applicable). If documentation is not yet available, it must be submitted to the committee prior to the beginning of data collection. In addition, the principal investigator (and the faculty sponsor if the PI is a student) must sign below to certify the following statement: "I/we will not begin research at other institutions before having obtained their permission to do so."

\_\_\_\_\_  
Principal Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Faculty Sponsor (If PI is a student)

\_\_\_\_\_  
Date