

**Human Subjects Protection
 Self-Assessment Decision Tree**

Step #1 - Human Subjects

YES

a.	<p>Human Subjects are not part of my research or evaluation If data or information is not collected from human subjects you are exempt from the provisions of the UW-Extension Human Subjects Protection Policy</p>		<p>ACTION: None Required (STOP)</p>
b.	<p>Human Subjects are part of my research or evaluation If data or information is collected from human subjects you are required to comply with the provisions of the UW-Extension Human Subjects Protection Policy</p>		<p>ACTION: Go to Step #2</p>

Step #2 - Purpose of information/data collection:

YES

a.	<p>Research The collection of information/data which is intended to prove or disprove a stated hypothesis that will in turn contribute to a theoretical framework or an established body of knowledge. The research design is intended to be replicated in other settings and the results are expected to be generalized to a larger population beyond the site of the data collection. The primary beneficiaries of the research are other researchers, scholars, and practitioners in the field of study. Publication of the results of the research is intended to inform the field of study.</p>		<p>ACTION: Submit “Request for Approval” to Human Subjects Protection Administrator (first, continue through Step #7)</p>
b.	<p>Non-Research Assessment The collection of information/data which is intended to inform the participants in the study, to improve the quality of a program, to assess the value of programs or services received by the participants, or to inform the design and development of an educational program. The design of such studies is not intended to be replicated in other settings and the results are not expected to be generalized to a population beyond the site of the data collection. The primary beneficiaries are the program participants. They benefit from a broader knowledge of public/community opinions, greater program accountability, and improved program quality.</p>		<p>ACTION: Go to Step #3</p>

Step #3 - The intended use of collected information/data will be:

YES

a.	<p>To publish information in written and/or oral forms The collected information/data (including summaries, abstracts, and selected segments thereof) is intended to published by presentation on a public interest WWW site, in a news release, a journal article, a bulletin, or a public forum. Investigators are encouraged to contact the Human Subjects protection Administrator, even if the intent to publish is a secondary consideration at the time the data is collected.</p>		<p>ACTION: Contact the Human Subjects Protection Administrator (first, continue through Step #7)</p>
b.	<p>To provide program accountability and/or improve program quality The collected information/data (including summaries, abstracts, and selected segments thereof) will only be distributed to those individuals and organizations who are directly involved in the planning, management, and implementation of UW-Extension educational programs.</p>		<p>ACTION: Go to Step #4</p>

Did you answer “yes” to Step #2, question b. and “yes” to Step #3, question a.? (If “no”, move on to Step #4.)

If you answered “yes” to Step #2, question b., and “yes” to Step #3, question a., you are in a rare category of projects. It is unusual (but not unheard of) for a project to be published and not be defined as research since generalizability and dissemination are key features of a project defined as research. Please take this opportunity to reconsider your responses and change them, if necessary, to accurately reflect this effort. If they accurately reflect your effort, simply note your reasoning for not considering a project that will be published to be a research project:

Step #4 - Participants in information/data collection includes:

YES

a.	<p>Vulnerable Populations Youth under the age of eighteen, pregnant women, prisoners, institutionalized individuals, or others where participation may be considered as involuntary.</p>		<p>ACTION: Make any necessary adjustments to your protocol and go to Step #5</p>
b.	<p>Non-Vulnerable Adults Adults over the age of eighteen who are not a member of a vulnerable population, noted above.</p>		<p>ACTION: Go to Step #5</p>

Step #5 - Sample size and methodology:

YES

a.	<p>Does not protect the privacy and confidentiality of the participants Information obtained is recorded (written, audio, video, etc.) in such a manner that the subjects can be identified by the investigator or any other individual.</p>		<p>ACTION: Make any necessary adjustments to your protocol and go to Step #6</p>
b.	<p>Protects the privacy and confidentiality of the participants The sample size and the data collection methods are appropriate to protect the privacy and the confidentiality of the participants to the extent allowed by law. Subject's identities are impenetrably disguised in any report.</p>		<p>ACTION: Go to Step #6</p>

Step #6 Questions include requests for:

YES

a.	<p>At Risk Information Information obtained could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.</p>		<p>ACTION: Make any necessary adjustments to your protocol and go to Step #7</p>
b.	<p>Minimal Risk Information No sensitive information/data is collected, adheres to the requirements of steps 1-7 in this document.</p>		<p>ACTION: Go to Step #7</p>

Step #7 - Consent Form:

The collection of any information/data must be accompanied by a consent form that includes:

- a. Title of the project/program (Required)
- b. Names, titles, and affiliations of investigators (Required)
- c. Purpose of the study (Required)
- d. Procedures (As appropriate)
 - Pre-study screening
 - What participants will do during the study
 - Foreseeable risks or discomforts
 - Benefits to be expected from the study
 - Alternative procedures
- e. Confidentiality with qualifications (Required)
- f. Compensation for injury (As appropriate)
- g. Voluntary participation (Required)
- h. Who to contact if one has questions. Location of the Local Administrative Unit where the Human Subjects Protection Self-Assessment/Approval file is located (Required)
- i. Signature or Implied Consent Statement (Required)

ACTION: Go to Step 8

Step #8 - Implementation:

If you answered "yes" to the (a) choice in Step 2:

1. Complete Human Subject Protection Approval Form
2. Attach copy of consent statement/form that includes a statement on the location of the human subjects protection approval document from the Office of the Human Subjects Protection Administrator
3. Attach copy of data collection instrument and protocol design description
4. Send to UWEX Human Subjects Protection Administrator

If you answered "yes" to ANY of the (a) choices in Steps 3-6:

1. You are probably not required to submit for approval. If you are uncertain, or if you simply wish to consult about this effort to assure yourself that you are implementing the "best practices" for protecting the participants of either research or non-research assessments, you are invited to contact the Human Subjects Protection Administrator:

Ray Schultz, Secretary of the Faculty and Academic Staff
501 Extension Building • 432 North Lake Street • Madison, WI 53706-1498
Tel: 608-262-4387 • Fax: 608-262-8404 • ray.schultz@uwex.edu

- ◆ Be prepared to provide a copy of this completed self-assessment decision tree, along with the data collection instrument and the consent statement/form being proposed.
- ◆ Upon determination that this effort does not require formal approval, follow the instructions below (pertaining to those answering "yes" to all of the (b) choices in Steps 2-6). If it is determined that it requires formal approval, you will follow the steps above.

If you answered "yes" to ALL of the (b) choices in Steps 2-6:

1. If required by your unit, sign and date a copy of this form:

Investigator Signature: _____ Date: _____

2. If required by your unit, share this form with your Department Head/Supervisor/Collaborators, along with your data collection instrument and consent statement/form.
3. If required by your unit, attach a copy of your data collection instrument and consent statement/form and related description of your protocol design and file all of the above in a "Human Subjects Protection Self-Assessment/Approval" file in the appropriate local administrative unit or your personal office files.
4. Non-research assessments that you determine do not require formal approval are not required to be documented and filed as outlined in steps 2 and 3 above, unless your unit has a more specific standard. It is expected that over time the features of this self-assessment decision tree will be assessed by you "intuitively" as opposed to "formally" unless an assessment rises to the level of research or is being published.