



**Human Subjects Protection
Frequently Asked Questions About
Conducting Research & Non-Research Assessments Involving Human Subjects¹**

What is the “Human Subjects Protection” effort all about?

Human Subjects Protection is about safeguarding the welfare and protecting the rights of individuals who participate as subjects in research and non-research assessments sponsored by UW-Extension. This gets accomplished by employing the highest standards of research ethics (core principles) and applying these in “best practice” approaches to research and non-research assessments involving human subjects. Of particular concern are issues of *vulnerability* of the subjects of one’s inquiry, protection of the subjects’ *privacy and confidentiality*, and the level of *risk* inherent in the questions being asked.

What is the goal of the UW-Extension Human Subjects Protection effort?

The goal of the UW-Extension Human Subjects Protection effort is to ensure that employees engage in high quality research and non-research assessments accompanied by high standards of research ethics.

What are the *core principles* that guide this effort?

Three core principles (known as “The Belmont Principles”) guide this effort: *respect* (acknowledging the dignity and freedom of every person); *beneficence* (maximizing the benefits of the research/non-research assessment and minimizing the harms associated with the effort); and *justice* (equitable selection and recruitment and fair treatment of subjects).

What is the Institutional Review Board (IRB) and what is its purpose?

The Institutional Review Board, or IRB, is the body of persons responsible for the review of research proposals involving human subjects to assure that the welfare and rights of those subjects are best safeguarded and protected. The IRB also acts as an advisory group to oversee the regular administration of the UW-Extension Human Subjects Protection program, administered by the Secretary of the Faculty and Academic Staff on behalf of the Provost. The broader program sets policies and issues guidelines that govern the ethical practices of educators conducting all types of assessments, whether defined as research or non-research.

Who are the members of the IRB?

The UW-Extension IRB consists of seven members (at least one represents primarily scientific concerns, at least one represents primarily non-scientific concerns, and at least one

member is a non-University lay person). Aside from the community member, others are UW-Extension faculty and staff that conduct research and assessments and are familiar with research ethics. Contact the Human Subjects Protection Administrator for information on the current members and their alternates.

When did UW-Extension start requiring Human Subjects Protection and implement its IRB?

Until July 2000, UW-Extension implemented its program through the UW-Madison HSP/IRB system. The increasing number of activities that require consideration and may result in formal review necessitated that UW-Extension establish its own policies and procedures.

What rules are behind this effort?

The formalization of a code of ethical conduct for research involving human subjects came as a result of the trials of Nazi doctors who used concentration camp inmates as research subjects. Included in the legal judgment and sentences handed down at the culmination of the trial were ten points describing required elements of conducting research with human subjects. These points came to be known as the Nuremberg Code. Subsequent enhancements to these principles, including the Declaration of Helsinki, set the stage for the implementation of the IRB process.

Is there a federal policy?

A number of federal regulations enacted in the 1970s and 1980s were designed to protect human research subjects. In 1979 The National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research published the "Belmont Report." This work identified the basic ethical principles that underlie all human subject research: respect for persons, beneficence, and justice (The Belmont Principles).

The basic federal regulations (45 CFR 46) for protecting research subjects is known as the Common Rule (Dept. of Health and Human Services Regulations), adopted by numerous federal agencies and departments. The federal regulations provide three basic protections for human subjects involved in research: review by an Institutional Review Board (IRB); commitment to use informed consent; and institutional assurances that the regulations will be applied to all research.

What are the criteria to decide whether or not research is ethical?

From the principle of respect for persons comes the need to conduct an initial (and continuing) informed consent, voluntary participation, including the opportunity to withdraw, and maintenance of the welfare of each subject. Does the consent process maximize autonomy? Does the protocol maximize autonomy? Have additional protections been put in place for vulnerable populations? Does this study maximally protect subject privacy?

From the principle of justice one needs to evaluate the social and scientific value of the research, the scientific validity of the research, and determine whether the research has a favorable risk-to-benefit ratio. Is the research design adequate? Have the risks been minimized? Have the benefits been maximized?

From the principle of justice one needs to evaluate whether there is fair subject selection, including the criteria for inclusion and exclusion and the methods of recruitment. Does recruitment for the research or assessment target the populations that will most benefit from the effort? Does it unfairly target a population? Are the inclusion/exclusion criteria fair?

What are UW-Extension’s guidelines and policies for human subject research and non-research assessments?

UW-Extension expects all faculty and staff to employ the best practices of research ethics to their research and non-research assessments. At a minimum, thorough consent language will be regularly used prior to initiating any efforts. It is every investigator’s responsibility to be familiar enough with the issues surrounding human subject protection to adequately diagnose whether their effort is a research or non-research assessment involving human subjects. We have developed a self-assessment decision tree to assist faculty and staff with making this determination (<http://www.uwex.edu/hsp/documents/tree.pdf>). Every investigator who seeks approval for a research project is required to have successfully completed the requisite training modules. Every investigator that concludes that their effort is research involving human subjects is required to make application for approval and to abide by the conditions established by the Human Subjects Protection Administrator or IRB—prior to initiating their research. Every investigator is obligated to conduct the research according to the approved protocol, to obtain continuing permission for projects that extend beyond 12 months, and to file project completion reports once an approved project is concluded.

Why do the “best practices” apply to non-research assessments if it isn’t required by federal law?

Every investigator has an obligation to conduct her/his research and non-research assessment with the highest of ethical standards, whether or not it is an explicit condition of approval. The UW-Extension policy to apply the best practices of research ethics detailed in the Common Rule to non-research assessments is based on the premise that ethical principles common to research should be applied to all human subjects, regardless of the formal requirement that the law may only apply to that work defined discretely as research. Frankly, the institution simply cannot justify not applying these basic respectful ethical practices to all of the work we do.

What steps do I take to determine if my effort falls under this policy?

If an investigator is familiar enough with the issues surrounding human subjects protection to adequately diagnose whether her/his effort is a research or non-research assessment involving human subjects, s/he are asked to complete the self-assessment decision tree. If an investigator lacks sufficient understanding of the issues, s/he is obligated to complete the web-based training, even though s/he may not ultimately be required to be certified since s/he may not conclude that the project rises to the threshold of requiring an approval. Once an investigator has made an initial attempt to diagnose her/his project and determine if it is indeed research involving human subjects, s/he may consult with the UW-Extension Human Subjects Protection Administrator. This informal review can often sort out challenging nuances that allow an investigator to take the most prudent course of action in establishing a protocol that protects subjects while allowing them to achieve their research objectives. It is

understood that once an investigator has developed a familiarity with this process s/he may diagnose their effort less formally. It is not critical that written responses be recorded to the prompts on the decision tree if the process of making those determinations has become second nature to the researcher. The formality of the diagnosis is dependent upon the experience of the investigator and the complexity of their project.

What steps do I take to get proper authorization to proceed with my effort if approval is required (what to submit, where and how)?

If an investigator believes that they have a research project involving human subjects, they are required to submit an application for approval to the Human Subjects Protection Administrator. The application requires that the investigator first successfully complete the web-based training. Along with the application for approval, the investigator must submit a copy of their written research protocol, including consent language, inquiry instrument (survey, questionnaire, etc.), and proposed correspondence to research subjects. This can be submitted via e-mail, fax, or surface mail to: Ray Schultz, UW-Extension Human Subjects Protection Administrator, 501 Extension Building, 432 N. Lake Street, Madison, WI 53706; Fax: 608-262-8404; or ray.schultz@uwex.edu. Submissions need to allow a minimum of 10 days for review and potential approval. Approval of exempt projects can be made within this timeframe. Expedited or full IRB Reviews will require substantially longer review periods. Investigators cannot proceed without prior authorization.

Who is required to comply with this policy (faculty, staff, students, partners/collaborators)?

University of Wisconsin-Extension employees (payrolled persons) that are conducting research and non-research assessments involving human subjects must comply. Employees of other University of Wisconsin System institutions must comply with the policies of the organization to which they are payrolled, regardless of whether the initiative involves an Extension program, with the following caveat. When a project is being undertaken by an integrated faculty or staff member and is substantially (more than 50%) undertaken for the benefit of the Extension outreach programming responsibilities of that person, the project may be submitted to the UW-Extension Human Subjects Protection Administrator for consideration. Some projects may be reviewed by both UW-Extension and a campus, or upon consultation, the campus and UW-Extension will determine the proper submission course.

How are the different levels of review determined?

The Common Rule requires that IRBs review and approve research involving human subjects. UW-Extension's policy relies on the professional judgment of investigators in determining if their efforts are research or non-research assessment involving human subjects (refer to the following questions and answers for more details on these definitions). Investigators are encouraged to seek the counsel of the Human Subjects Protection Administrator to aid in this assessment. If an effort is deemed to be research involving human subjects, an application for approval will be submitted by the investigator to the Human Subjects Protection Administrator. After review by the Human Subjects Protection Administrator, a determination about the level of review will be made and the appropriate process commenced—full IRB review, expedited review, or exempted research approval.

What is the difference between “informal’ review,” “exempted research,” “expedited review,” and “full board review?”

If an investigator makes application for approval but the Human Subjects Protection Administrator finds that the project does not meet the threshold of research involving human subjects, the review will be documented as an “informal review” and no further approvals will be recorded.

A project that otherwise meets the definition of research with human subjects may be eligible for exemption from IRB review. This determination is made by the Human Subjects Protection Administrator (not the investigator). The Common Rule provides six categories of research that may be eligible for exemption, with the following three most frequently applicable to UW-Extension efforts: 1) research conducted in established or commonly accepted educational settings, involving normal educational practices; 2) research involving survey procedures, interview procedures, or observation of public behavior, providing that any disclosure of identifiable information outside the research setting would not place the subjects at risk for criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation; and 3) research involving the collection or study of existing data if the data is publicly available or recorded by the investigator in such a manner that the subjects cannot be identified.

Research involving human subjects that is otherwise not exempt must be approved by the IRB, either in an expedited review by a subset of the IRB, or after review by a convened IRB (referred to as full review).

The expedited review is allowed when the research poses no more than minimal risk to subjects, and/or falls into one of the categories of activity eligible for expedited review as specified in the regulations. [See 45 CFR 46, Subpart A.]

Research involving human subjects that pose more than minimal risks to subjects, and/or that do not fall into one of the categories of activity eligible for expedited review as specified in the regulations require review by a convened IRB (referred to as full review).

How long does the review take?

The IRB meets on an as-needed basis. Contact the Human Subjects Protection Administrator for further details on the scheduling of IRB meetings. The time period required for an expedited review will be determined in consultation with the Human Subjects Protection Administrator and the Chair of the IRB. In each case, these determinations are made after an initial review by the Human Subjects Protection Administrator. Reviews of applications for approval require a minimum of 10 calendar days from the date received. Investigators should also factor in the time it takes to register for and then complete the required online training.

What training or certification is required?

If you are affiliated with UW-Extension, or you are collaborating on a project with UW-Extension faculty and staff, you must complete the required training units regardless of where

the research is being conducted. The UW-Extension Human Subjects Training is web-based and is sponsored by the Collaborative IRB Training Initiative (CITI) and the University of Miami. Although the main national training Web page states the training will take 4 to 6 hours, the portion required by UW-Extension will take 1 to 3 hours depending upon your personal speed in completing each module since you are only required to complete modules 1-6 and read the Belmont Report. Modules 8, 9 and 11 are optional, and need to be completed only if your research effort involves those subjects. Applications for approval will not be considered unless investigators are certified as having successfully completed this training. While it is not a requirement to take this training if an investigator is not conducting *research* involving human subjects, they will nonetheless be held to the standards of research ethics and expected to employ best practices in *non-research assessments*.

What is the definition of a “human subject?”

A human subject is a living individual about whom an investigator conducting research or doing a non-research assessment either: 1) obtains data through intervention or interaction with the individual; and/or 2) gains access to identifiable private information, even if obtained indirectly.

What if I’m working with existing data that someone else collected?

If you are using data collected by someone else that includes identifiable private information about a living individual, it is treated no differently than if you asked that individual for the information directly. Remember, the definition of a human subject is not limited to those living individuals about whom the investigator conducting research or doing a non-research assessment obtains data through intervention or interaction directly. It may also include those living individuals about whom one gains access to identifiable private information, even if obtained indirectly.

When is it “research” and when is it a “non-research assessment”?

The essential question concerns the intention of the researcher. Is it to contribute to generalizable knowledge or to accomplish something else, such as program improvement?

Non-research assessments are characterized as: 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.

Research is characterized as: 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.

What does it mean to “publish” my results and what difference would that make?

Publication of results can signal whether or not research is generalizable, but it is not a perfect measure. Collected information/data (including summaries, abstracts, and selected segments thereof) that will only be distributed to those individuals and organizations that are directly involved in the planning, management, and implementation of UW-Extension educational programs, particularly to provide program accountability and/or improve program quality, does not constitute publication. This is true even when it may incidentally be made “public” such as in the recorded minutes of an organization or by being posted on a web site that is generally not used beyond the institutional or organizational borders.

On the other hand, if it is the intention of the researcher to publish information in written and/or oral forms, including summaries, abstracts, and selected segments thereof, by presentation on a public interest web site, in a news release, a journal article, a bulletin, or presentation at a public forum, even if the intent to “publish” is a secondary consideration at the time the data is collected, it is likely that the generalizability would result in this being defined as research.

What is informed consent?

Informed consent is simply seeking permission. Subjects are to be “duly informed” of the potential risks and benefits of the research or non-research assessment, and offered the right to say “no.” Stating the purpose of the activity, identifying who is involved, clarifying issues of confidentiality, asserting the voluntary nature of one’s participation, providing contact information and seeking permission prior to conducting the research or non-research assessment provide the basic components of a legally effective agreement to proceed. The bottom line is that the private or personal information of participants does not belong to us. Investigators are asked to honor subjects by “asking before you take.” The requirement to obtain informed consent is derived from the principle of respect for persons.

What needs to be included in the informed consent?

Whether passive or active, appropriate consent notices must include: title of project, names and contact information of investigators, a statement of the purpose of the study, an outline of the procedures (as appropriate), a confidentiality statement, an assertion of the voluntary nature of participation, information about who to contact (if not the investigator), the location of the research approval (if applicable), and an informed consent statement or signature(s) (as appropriate).

When does active consent need to be used and when is it okay to use passive consent?

Active consent (documentation proving that the individual agrees to participate, such as a signed agreement) should be used in cases where participants, or their parents or guardians, may reasonably express some concerns over participation, if not beforehand, perhaps during or after the research. Vulnerable populations, often, but not always, signal that it may be

appropriate to seek active consent. The type of inquiry often hints strongly at whether active or passive consent (simply alerting the participant, in writing or orally, that participation is voluntary and that the act of participating provides evidence of agreement to do so) is appropriate. When highly personal, private, or other sensitive information is being sought, or generally when inquiries may provoke personal or community-level concerns about the research or assessment, it is wise to use active consent. Depending on the conditions of the approval of research projects, active consent may be required as a condition of approval.

Is it always a requirement that parents or guardians provide written permission for their children to participate?

The consent paradigm for research with children is that parents or legal guardians give permission for their children to become research subjects. Children between 11-17 also provide *assent* (they sign too, but as a secondary feature to their parent's or guardian's approval). Our "best practices" philosophy would suggest that this also be the rule when conducting non-research assessments involving youth. Taking our prompt from the waivers of parental permission that are found in the Common Rule (they also apply to other elements of informed consent, regardless of age), the following may justify deviation from a strict use of the requirement for parental permission (and child assent):

- 1) the research involves no more than minimal risk to the subjects;
- 2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- 3) the research could not practicably be carried out without the waiver or alteration; and
- 4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Consultation with the Human Subjects Protection Administrator is strongly recommended in order to determine applicability for each case.

Similar research is being conducted by another organization (university or public agency), and they don't have to seek active consent, why should I have to?

Admittedly, there are differences in the interpretation of these rules and their application. UW-Extension's policy is more onerous than some and more gracious than others. What is uncompromising, however, is the goal of protecting the health and welfare of the subjects of our research and non-research assessments. Opinions of the Human Subjects Protection Administrator can be appealed to the Institutional Review Board. In cases in which active consent (or another condition) is required, notwithstanding that it may not be required by a collaborating partner's organization, the researcher will have to abide by the conditions set forth by the Human Subjects Protection Administrator and/or the Institutional Review Board.

Can a research subject quit the study prior to its conclusion once they've agreed to begin?

An ethical researcher must permit subjects to withdraw for whatever reason (they do not have to provide one) at any time. Any real or perceived negative consequence for not participating, or a unique benefit for participating (other than reasonable remuneration), in a study is regarded as coercing participation. The freedom to volunteer for research without

coercion or undue influence from others is a central feature of autonomy that is derived from the principle of respect for persons.

What does it mean to tell a subject that their information will “remain ‘confidential’?”

A researcher can only tell a subject that their information will remain confidential, without any qualifications, when there are no identifiers that link her/his responses to them. If one gathers the information through an interview, then one cannot make this claim. If one gathers the information on a document that has unique identifiers that link that subject with the document that will be retained, then one cannot make this claim. If one has a small or unique sample and seeks demographic or other private data that could make it clear who a particular respondent is, then one cannot make this claim. The courts have found that other interests may be more compelling than a researcher’s desire to keep a respondent’s information confidential, and there have been times when litigation forced a researcher to produce files that linked a particular subject with their responses. In cases when one endeavors to keep the information private, but one’s protocol demands that identifiers be used to track subjects, the claim of confidentiality should be modified to state that “responses will remain confidential to the extent allowed by law.”

Won’t this weaker statement of confidentiality prevent some from responding?

It is possible that with a less definitive guarantee of confidentiality there will be a dampening of the response rate. However, that would never justify being anything but perfectly candid with one’s subject about the true degree of confidentiality. Many researchers follow up the statement “responses will remain confidential to the extent allowed by law,” with a clarifying note that describes their intention to guard that respondent’s confidentiality by noting how the individual responses will be treated, and making a strong affirmative statement about the intent to protect the respondent’s anonymity in the sharing or reporting of any data (assuming that is the case).

What are “vulnerable populations?”

Vulnerable populations include groups of people who may be more susceptible to coercion or undue influence, or may not be able to make an informed decision on their own, such as: youth under 18 years of age, institutionalized individuals, or others where participation may be considered involuntary.

What if my subject is part of a “vulnerable population”?

If your subject is part of a vulnerable population, you will be asked to reflect on the sample methodology and research protocol to determine if the recruitment of subjects is fair and proper. The protocol, including specific elements of the inquiry, should be scrutinized to assure that it does not expose this vulnerable population to undue risk or harm. The explicitness of the consent statement, often requiring active consent in situations such as these, will need to be carefully reviewed. If your subject is simply incidentally a part of a category of a vulnerable population, a pregnant women, perhaps, but is not being targeted because of that feature, condition, or characteristic, then they would not trigger a vulnerable population concern.

What is meant by “sensitive information?”

The level of risk that is inherent refers to that which could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject’s financial standing, employability, or reputation. Sensitive personal information or private behavior-related inquiries may also raise the level of “risk” inherent in the inquiry. The researcher would do well to consider this from the perspective of the subject, the subject’s family or personal acquaintances, the subject’s work, home, or community setting, etc.

What information might be considered “sensitive”?

The Protection of Pupil Rights Amendment (PPRA), amended by the “No Child Left Behind Act of 2001”, has a provision that requires parental consent before minor students (at schools receiving any funding from the U.S. Dept. of Education) are required to participate in any survey, analysis, or evaluation that reveals information concerning: political affiliations or beliefs of the student or the student’s parents; mental and psychological problems of the student or the student’s family; sex behavior or attitudes; illegal, anti-social, self-incriminating, or demeaning behavior; critical appraisals of others with whom respondents have close family relationships; legally recognized privileged relationships; religious practices, affiliations, or beliefs of the student or the student’s parent; or income. While we stop short of endorsing this list as always applying to our work, it offers a fair sense of the degree of sensitivity that would likely result in an investigator being expected (or required in the case of research) to carefully construct an ethically rigorous protocol, including the use of active consent.

Once my research protocol is approved, do I have to get it renewed?

The IRB is required by 45 CFR 46.109 (e) to conduct an annual review of each IRB-approved protocol that is continued beyond the 12-month approval period. If one’s research is not concluded in a year, then a Request for Continuing Review application must be submitted to the Human Subject Protection Administrator within 3 months of the expiration of the current approval period. Research cannot proceed, even under the previously approved terms and conditions, unless a valid extension has been approved. Research that has been interrupted or was suspended for any reason, or research in which there is ongoing data analysis or the writing of results (if not enrolling new subjects) is still subject to the requirement for renewal.

Do I have to report when it’s concluded?

The conclusion of previously approved research must be reported within 6 months of the end of the research.

What records are kept, and by whom?

Officially approved exempt, expedited, or full reviews are filed in the Office of the provost, UW-Extension. Informal reviews are tracked by the Human Subjects Protection Administrator. Individuals are encouraged to keep complete files that adequately document efforts to comply with these policies. Some divisions, units, programs and offices have specific requirements for filing documentation of compliance with the Human Subjects Protection policies that may need to be followed.

NOTES

¹Answers were derived from a number of sources, including The Belmont Principles; 45 CFR 46; CITI Modules 1-6, 8, 9 and 11.

CONTACT

Ray Schultz, Secretary of the Faculty and Academic Staff
Human Subjects Protection Administrator
501 Extension Building
432 N. Lake St.
Madison, WI 53706-1498
Tel: 608-262-4387
Fax: 608-262-8404
ray.schultz@uwex.edu
<http://www.uwex.edu/hsp/>

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