New Study Application

ALVERNO COLLEGE INSTITUTIONAL REVIEW BOARD

This form is used to apply to the Alverno IRB for approval to conduct research using human participants. *Many studies will qualify for an Exempt Determination. The Exempt Determination form can be used to apply for approval for those studies.* The New Study Application form is for investigators who are conducting *research* that requires either full or expedited Alverno IRB review. Research is formally defined as a systematic investigation (including research development, testing, and evaluation) designed to develop or contribute to generalizable knowledge. Full review means that the Institutional Review Board evaluates the study during an IRB meeting. Expedited review means that a member of the IRB (or an alternative designated reviewer) conducts a review outside the context of an IRB meeting. Some proposals may not qualify for expedited review.

This New Study Application must be accompanied by a completed Research Protocol form.

Study Identification

Principal Investigator: _____

Study Title: _____

IRB# (assigned by IRB): _____

Date: _____

Principal Investigator's Affiliation with Alverno (faculty/staff/student): _____

If not affiliated with Alverno College, indicate institution and contact information:

_____

Will the study be funded by any source other than yourself? Indicate sources of funding. In particular, indicate if the study receives federal funding (e.g. a grant from a federal agency).

_____

Analysis of Risks and Benefits

In this section, you will describe the risks to participants presented by your study, and the measures you will take to minimize those risks. The standard for Exemption is that a study present participants with no more than "minimal risk", which is defined in 45 CFR 46.102:

Minimal risk *means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

"Risk" implies potential. For example, if you are collecting employees' opinions about their employer you should recognize the risk that some of those opinions may be unpopular with the employer. Were the employer to become aware that a particular employee holds such an opinion the employer might retaliate against the employee. In your analysis of risks you would identify this possibility and talk about what you intend to do to prevent it from occurring.

You will also identify any benefits to the participants. The analysis of risks and benefits involves weighing the risks and benefits to the participants to determine if the risks are justified. However benefits are **not** to be used to entice participants into participation. If you used the promise of a gift certificate to entice employees to give their opinions about their employers you would have undermined the employees' right to make a free informed judgment about their participation in your study.

Directions:

Identify any risks to participants presented by participation in your study as well as any efforts to avoid or minimize those risks. Also identify any direct benefits to participants and explain why those benefits will not entice participants to participate despite the risks. Make a case that participation in your research involves no more than minimal risk.

Informed Consent and Vulnerability

In this section, you will describe your plans to gather and document informed consent from your participants. The principles of ethical treatment of research participants requires that the researcher obtain freely given informed consent for participation from each participant. "Freely given" means that the participants are not coerced, bribed, or threatened into participation. "Informed" means that they are provided with information about the research and about their participation in the research as well as the opportunity to ask additional questions that they might have about their participation. The information must be provided in a format that is understandable to each participant, so in an appropriate language and at an appropriate reading level. It is the researcher's responsibility to ensure that the participants understand what they are asked to consent to.

Some potential research participants cannot legally give consent for their own participation. In most cases the free informed consent of a parent or legal guardian of such a participant can substitute for the participant's own consent. In such cases the positive assent of the participant should be sought. In practical terms that means that even if you have consent from the parent or guardian of a child or of an adult who cannot legally give consent, you should make a reasonable effort to respect that child or adult's own wishes about whether or not to participate. Parental consent does not mean that a child must participate if that child does not want to.

For the purposes of IRB evaluation, the term "children" is defined by 45 CFR 46.402:

Children *are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.*

Generally this means that a person is a child until reaching the age of 18 years. However college students below the age of 18 are considered adults who can give consent for participation.

Participant consent is typically documented through signed and dated consent forms which the researcher retains for a reasonable time after the study is completed. It is the researcher's responsibility to gather and retain that documentation of consent.

Research participants have specific rights as participants, and informed consent documents must inform those participants of their rights.

- The right to refuse to participate.
- The right to withdraw from participation during the study. As long as it remains possible to remove a participant's responses from the data collected the participant has the right to have those responses removed. Obviously at some point in the analysis and reporting this is no longer possible, but the participant can withdraw up to that point.
- The right to ask questions about participation. When a study requires that some information be withheld from the participants the participants have the right to a debriefing after the study is completed.
- The right to direct complaints, questions, or issues concerning their participation to someone in authority other than the researchers themselves. Typically this means providing participants with contact information for the IRB Chair (irbchair@alverno.edu).

Directions:

Describe how you intend to collect informed consent from your participants. Include copies of your consent letters or of the materials you will present to potential participants to inform them about your study and their participation. If you intend to waive documentation of consent indicate that and explain why documentation of consent elevates the risk to the participants.

It is assumed that your materials including consent materials will be in English. If you anticipate that some of your participants are not native English speakers describe how you will ensure that all of your participants can understand your consent materials and meaningfully evaluate the risks and benefits of participation.

If your participants include children indicate how you will obtain and document free informed consent from their parents and/or legal guardians. For documentation purposes be mindful of the fact that the child's last name and the parent's or guardian's last name may not be the same. Explain how you will ensure that you can identify the appropriate consent form for each child if you are required to produce that form.

Does the research recruit other participants whose consent may be coerced or otherwise not valid? Examples include (but are not limited to) prisoners, poor or uninsured persons, cognitively or emotionally impaired persons, psychiatrically impaired persons, limited/non-readers, wards of state—such as foster children— nursing home residents, persons who have terminally illnesses.

If so, again, what protections are in place to ensure that consent is freely given and valid?

Does this study involve deception of participants, or concealment or intentional withholding of information about the study from participants?
Remember that deception can affect the validity of consent. If there is deception, concealment or withholding of information, explain why this is necessary to the study and why it does not put participants at risk in this particular situation.

Study Location

In this section, you will briefly describe the location where the study will take place.

Directions:

Briefly describe the location of the study. Will you meet in person with participants, or is participation entirely through internet or telephone interactions? Will you collect data from participants at Alverno College?

Will any of your data collection happen at a HIPPA covered entity? (typically a medical office, clinic, hospital or related facility). If so, do you plan to gather protected health information? Explain how you have gotten authorization from that facility.

Describe other external permissions that you need for your data collection (for example, another IRB or an organization's Director).

Timeframe of Study

Approval of a research study is not open-ended. We will need to establish a completion date and you will need to report to us when you have completed your data collection. In addition, studies that take longer than a year to complete will need annual renewal. Some studies may need reapproval over a shorter time period.

Directions:

What are the dates when you expect to begin and complete your data collection?

How long will you retain the records of your collected data? How do you propose to dispose of those records after your study is completed?

Request for Expedited IRB Review

In most cases ,studies at Alverno College that do not meet the conditions for Exempt status will qualify for an Expedited IRB Review. This simply means that the review can be conducted without the need to wait for a meeting of the full IRB. The study can be reviewed and approved by either an IRB member or someone specially delegated by the IRB to conduct such reviews. The main standard for Expedited Review is that the study incur no more than minimal risk to participants.

Conditions for expedited review include the following:

- Participation in the study must present no more than minimal risk to participants and involve only procedures found in the list below (in *Directions*).
- The categories apply regardless of the ages of the participants except where noted.
- If participation in the study would, if participants' identity or responses become public, raise their risk of criminal or civil liability, financial standing, employability, insurability, reputation or stigma then the privacy protections provided by the study must reduce the risk to no greater than minimal. Researchers should pay close attention to these factors and be prepared to defend their protection procedures.

Federal regulations list the categories of research that are eligible for expedited review. The first three categories will rarely if ever be used at Alverno and have been omitted from the list below. They include clinical studies of drugs and medical devices, collection of blood samples, and "prospective collection of biological specimens". If your study includes any of these activities, you will need to discuss your application with the IRB Chair. More generally in the unlikely case that your study does not qualify for Expedited Review we will need to convene the IRB for a Full Review.

The full list of categories and other details can be found here: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html

Directions:

Most non-exempt research at Alverno will fall into one or more of the following categories qualifying for the Expedited Review process. Identify the category or categories your research falls into:

1. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
2. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). **Note that this kind of research often qualifies as Exempt**.
3. Collection of data from voice, video, digital or image recordings made for research purposes.
4. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. **Note that this will be a common category at Alverno**.

Attestation to Research Responsibilities

I attest, as principal investigator, that I have to the best of my knowledge and ability completed this form, and that I understand my continuing responsibility for the safe and ethical conduct of this research, including provision of informed consent as appropriate. As part of my ethical commitment:

- I will not begin data collection before I receive written approval from the Alverno IRB Chair.

- I understand that if any organization requires its institutional permission for me to collect data in this study (as described in Section III), I cannot begin collection of any human research data until I have received from the organization any needed approval.
- I will immediately notify the Alverno Institutional Review Board of any case of an undesirable and unintended effect on a research participant that results from his or her participation in the research or in an accompanying intervention. Note: Examples of an adverse reaction include (a) intense mental distress regarding subject matter or procedures, (b) physical injury, and (c) unexpected allergic/physical reactions.
- I will immediately notify the Alverno IRB of any breach of confidentiality, such as access to data by unauthorized individuals.
- I will promptly report to the Alverno IRB any findings that emerge during the course of the study that meaningfully alter estimation of the risks and benefits associated with participation in the study.
- I will obtain from the Alverno IRB prior written approval for modifications to my submitted research protocol that might reasonably be expected to increase risks or decrease anticipated benefits to participants in the study.
- I will complete continuing review requirements as specified by the Alverno IRB in their written approval and as modified in the future.

Principal Investigator Signature: _____

Print Name: _____

Date: _____