Required Elements in a Research Protocol

In addition to the required forms (e.g., minimally Form 1, the protocol cover sheet), your IRB submission must include a detailed ‘research protocol’ as a Word document or PDF. All research protocols must include each of the following:

- Title of research project
- Name of principal investigator
- Dates of proposed research
- Subject profile
- Rationale for research
- Hypothesis or research question
- Research methods
- Risks
- Benefits
- Subject selection and recruitment
- Informed consent (or ‘assent’ for children)
- Privacy, confidentiality, and data security

Each element listed above is described in greater detail below.

Subject profile refers to a short description of the human subjects you plan to include in your research. Include approximate number and any inclusion or exclusion criteria. Indicate, for example, if you plan to include only women, or only individuals who identify themselves with a specific ethnic group. Inclusion and exclusion criteria may include variables such as sex, age, place of residence, health condition, etc. If your research involves children, indicate age ranges.

Rationale refers to the reasons for conducting research and is related to your research question. The rationale should indicate why the research should be conducted, e.g., its importance or significance.
**Research methods** refers to a relatively detailed discussion of how you plan to collect your data. Will you use observational methods? Interviews? Surveys? Questionnaires? How will you select and approach your research participants? Will you ask them to complete a written survey or will you ask them questions verbally? How long will the interview or survey take? Will participants be providing identifying information? Will they be participating in a public space or in private?

**Risks** refers to the probability and magnitude of harm or discomfort to human subjects. Risk involves two components: 1) Probability—how likely is the participant to be harmed or experience discomfort? If so, how will risk of harm be minimized? 2) Magnitude—how severe is the harm and of what nature? Is it permanent? Long-term? Temporary? Psychological? Physical? Legal? Financial?

All behavioral and education research involves some level of risk. Most such research involves ‘no more than minimal risk.’ ‘Minimal risk,’ is defined as that level of risk encountered ordinarily in daily life or in the routine performance of physical or psychological examinations or tests.

Research protocols must clearly state whether the proposed research represents 1) ‘no more than minimal risk’; or 2) ‘greater than minimal risk.’

If the research presents ‘greater than minimal risk,’ that risk must be clearly described both in the protocol narrative and in the informed consent document. The protocol narrative must describe how risk will be minimized and human subjects protected to the extent possible.

The IRB evaluates research protocols on the basis of its risk / benefit ratio; that is, are the anticipated risks reasonable relative to the anticipated benefits and importance of the knowledge that may be generated.

**Benefits** may accrue to either the individual research participant, to society, or both.

An individual research benefit is something that contributes in a positive way to the human subject’s health and well-being. Compensation for participation in research is not considered to be a benefit; it is remuneration for time and inconvenience.

A benefit to society is one in which the proposed research contributes to valuable and generalizable knowledge.
Research protocols must clearly state whether 1) there is an anticipated direct benefit to the individual subject; and 2) the research is likely to yield valuable, generalizable knowledge.

**Selection criteria** and **recruitment** refer to how the PI will determine who is eligible to participate in the research and how those subjects will be recruited. The research protocol must describe how the subjects will be selected and the methods by which they will be approached or contacted about participation, e.g., by a health care professional, by advertising, by flyers or posters, in a public park, on the street?

The PI must include any flyers, posters, or announcements to be used in the IRB submission. If recruitment is by phone or in person, the proposed text should be submitted to the IRB.

Selection and recruitment must be **equitable**; that is, participants may not be excluded on the basis of sex, gender, religion, ethnicity, level of education, etc., unless specified by the study parameters. Whenever possible, PIs should attempt to avoid burdening vulnerable populations, such as children.

**Informed consent** is the process of obtaining a subject’s agreement to participate in research. In all cases, consent must be **voluntary** and may not be coercive or use coercive language.

Informed consent is necessary in all research with human subjects. You must **always** obtain informed consent. However, if your research poses only minimal risk, you may not need to prepare an actual informed consent form. In such cases, please provide a proposed informed consent script that the researcher will use to obtain verbal consent.

In seeking informed consent from research participants, whether verbal or written, researchers must include the following:

- statement that the study involves research;
- explanation of the purpose of the research (e.g., “in order to better understand . . .”);
- statement of expected duration of participation (e.g., 15 minutes, 2 hours, etc.);
- description of procedures (e.g., “ask you some questions” or “talk to you about”);
- statement or description of risk; most social science research involves “no more than minimal risk”;
- description of benefits to research participant (there may be no direct benefits);
- clear and unequivocal statement that participation is voluntary;
- description of the extent of confidentiality that the research will maintain with regard to the data.
Researchers may obtain informed consent verbally, but in all cases should provide research subjects with information sheets, cards, or cover letters that identify the researcher and/or faculty member (if a student researcher) and provide contact information.

For research involving children: Instead of informed consent, researchers are required to obtain 1) parental permission; and 2) the child’s assent. Protocols should include text of letters requesting parental permission as well as the script of verbal requests for a child’s assent if written forms are not being used.

Text of informed consent documents, parental permission forms, and text requesting the assent of a child must be written in straightforward, understandable language that avoids acronyms and legalese to the extent possible.

**Privacy** refers to access to an individual physically, behaviorally, or intellectually, whereas 'confidentiality' refers to access to information *about* a person. All protocols must address how the privacy of a subject will be maintained during the data collection and analysis processes. Issues to consider in discussing the issue of privacy in a research protocol include whether an observed behavior is public or private, how sensitive the information solicited or behavior observed is, and cultural norms.

For example, consider the different privacy expectations of individuals in a study of how children interact on a playground versus research on the psychological state of a recently bereaved spouse.

**Confidentiality of personal data** Generally, research protocols should be structured in a way that minimizes the amount of personal information solicited during research. Whenever possible, data should be collected anonymously. If such an approach is impractical, then personal identifiers should be removed from data sheets, etc., as soon as possible following data collection.

If it is necessary to maintain identifiable data, the PI must explain how the **security** of the data will be ensured. Considerations include who will have access to the data, where the data will be stored, when and how the data or data sheets will be destroyed. For example, will the data be shared? If so, under what circumstances? Will the data be kept on multiple computers? Networked? How will the data sheets be secured? Stored in a locked office? Destroyed immediately upon data entry?

If you still have questions, contact Erica Hill, IRB Chair, at 907.796.6017 / erica.hill@uas.alaska.edu