

Key Elements of a Social Science Research Protocol

A research protocol describes planned research activities. The protocol includes a description of the research purpose and the research design/methodology, how prospective research participants are chosen, a detailed description of what will happen during the study, recruitment and informed consent procedures, what data will be collected, and procedures for protecting participant privacy and data confidentiality.

The protocol should describe the “Who, What, When, Where, How, and Why” of the project.

Below is a list of the types of information that should be included with your protocol. This information should be provided in the appropriate sections of the USA IRB protocol submission.

Research Objectives and Purpose

Explain the purpose of the research, including the research question, and how the study will contribute to existing knowledge. There is no need for an extensive literature review for a simple study.

Research Methods

Describe the study procedures (what research subjects will be asked to do) **IN DETAIL**. It is helpful to walk through the process step-by-step of what a research participant would be asked to do, including any screening questions/procedures, consent process, a detailed description of study procedures (including any surveys/questionnaires, observational/ethnographic methods, specimen collection, use of devices such as EEGs, MRIs, etc).

If your project will involve secondary data analysis or secondary analysis of previously collected biospecimens, explain who are the data/specimen providers, whether the datasets are public use or restricted use datasets, whether any data use agreements will be in place to access the data, and what identifiers will be included with the data/biospecimens.

Study duration and locations: What is the expected duration of subject participation? Where will the research be conducted? If the research involves multiple institutions, explain which research procedures will be carried out by which institution.

Standard tools: Will any standard tools/assessments be utilized?

Any surveys/questionnaires/interview guides that you plan to use must be included with your IRB protocol submission.

Study Participants

- Who will participate in the research? How will they be selected? Why are they the target subject population? What are the inclusion and exclusion criteria (eg, why only men and not women included as research participants)?
- Explain whether you are including any vulnerable populations in your research (such as, children, pregnant women, prisoners, individuals with mental illness, developmentally challenged individuals) and justify any risks to vulnerable populations.

- Estimated number of subjects to be enrolled (if there is more than one subject group, please provide the enrollment break-down for each group).
- Assignment of participants to groups – if participants will be assigned to groups within the research study (e.g., a control group and a treatment group), explain what the criteria are for assignment to the groups and what procedure will be used to assign individuals to the groups (randomization or other procedure).
- Sampling: If applicable, explain how sampling will occur.

Recruitment, Informed Consent, and Financial Information

- Provide specific details regarding recruitment strategies and make sure you have all of the recruitment documents uploaded into IRBNet. The IRB must review and approve all recruitment documents before you use them, including recruitment messages that will be posted online in social media.
- Provide a detailed explanation of the consent process. Who will obtain consent? How and where will it be done? Informed consent templates are posted on the USA IRB webpage, click [here](#) to access.
- Will you seek any waivers/alterations of informed consent, parental permission, or child assent?
- If you plan on using deception/incomplete disclosure, describe the information that will be withheld from research participants (or misinformation that will be provided to participants), and the justification for using deception/incomplete disclosure. Describe the plans for debriefing research subjects after their participation, and include any debriefing form/script with your IRB protocol submission.
- If subjects will be paid for participation, provide a detailed explanation of how much they will be paid, whether payments will be prorated over the course of study participation, and what forms of payment will be used (eg, cash, gift card, entry into a raffle, course credit, etc).

Risk Assessment

Consider all reasonably foreseeable risks of the study, including both physical and non-physical harms. Keep in mind that risks are not always immediate -- anger, emotional upset, or stress may appear later. Describe any reasonably foreseeable risks to psyche, reputation, employability, insurability, social status, criminal or civil liability that may occur as a result of participation. Describe precautions that will be taken to minimize risks/harms.

Address emotional and psychological risks, including risks of emotional discomfort from being asked about or discussing sensitive issues.

If there is a possibility that subjects will disclose abuse, neglect or intent to harm themselves/others, explain how you will respond in such situations, including what referrals to assistance or reporting of abuse/neglect to authorities may occur.

Data Confidentiality and Participant Privacy

- What identifiers will be included in any data collected? Will the researchers take any steps to de-identify the data?
- Where and for how long will the research data be stored? What security precautions will be taken to protect data confidentiality and participant privacy?
- Who will have access to the research data? Will the data be available to other researchers for future studies or not? If you are collecting biospecimens, will those specimens be included in any repository/biobank and shared with future researchers for other research projects?

Source: University of Chicago, Social & Behavioral Sciences IRB