IRB Submission Tips

Source: University of Chicago, Social & Behavioral Sciences IRB

Determine whether your study needs IRB review –

The IRB has jurisdiction to review "research" with "human subjects" – those terms are defined in the federal regulations that govern human subject's research. See IRB Determination Worksheet to help you assess if your research requires IRB review. In light of the IRB's mission to protect human subjects, and the potential regulatory consequences of not obtaining IRB review and approval for human subjects research, err on the side of caution and contact the IRB when you are uncertain whether your study is human subjects research or not.

Plan ahead –

Refer to USA IRB Committees for each committee scheduled review dates. Typically, the IRB Office will generate a IRB published board document (i.e., approval, modifications letter, etc). within 1- 3 days after the committee meeting date. NOTE: Exempt studies are administratively reviewed and approved by the IRB administrative staff.

Human Subjects Protection Training –

If your project is human subjects research and therefore will undergo IRB review and you have not taken human subjects protection training, you will need to complete human subjects training (as will anyone on the research team who will be obtaining informed consent, interacting with research participants, and/or analyzing data that contain identifiers). See USA IRB's human subjects training requirements.

Plan appropriate data security measures –

Consider the sensitivity of the data you will be collecting and the potential risks to research participants if there were a data breach.

Consent and assent forms –

Use the USA IRB consent templates as your starting point for developing consent forms / information sheet. You will save yourself considerable time using the templates rather than using obsolete versions of consent and assent forms or trying to develop such forms from scratch.

Types of Waivers –

A waiver of documentation of consent and a waiver/alteration of consent are not the same – be sure that you are requesting the correct type of waiver in the IRB submission form. A waiver of documentation of consent is a waiver of the need to obtain the research participant's signature on the consent form (ie, consent will be verbal or documented in other ways). A waiver/alteration of consent is a full or partial waiver of the elements of informed consent. Studies that will use deception or incomplete disclosure must request a waiver/alteration of particular elements of informed consent.

The Protocol –

Your IRB submission documents must explain in detail the "who, what, when, where, how and why" of your study (or with amendments, the changes you are proposing to your study). Many new submissions are delayed during the IRB review process because the research team did not provide sufficient detail on research procedures, subject population, recruitment methods, compensation plans, consent and assent procedures, etc. Keep in mind that the IRB reviews hundreds of studies and does not have your expertise about your particular study – we need you to explain your research plans to us in detail. For further detail related to Social Science research, see guidance Key Elements of a Social Science Research Protocol.

Payment for research participation –

Recruitment materials (including flyers, emails, etc.) should not emphasize the payment or amount to be paid by such means as larger or bold type. It is appropriate to describe the payment for research participation in recruitment materials but the payment/amount to be paid should not be emphasized. Payment cannot be described in consent and assent forms/procedures as a "benefit" of study participation – instead, payment should be discussed in a separate section on "financial information."

Remuneration includes cash or cash equivalents (such as checks and gift cards) provided to research subjects as compensation for the time and effort they spend participating in a research study. The Internal Revenue Service (IRS) treats remuneration as taxable income to the recipient. This means the recipient is supposed to report the payment when he or she files a personal tax return at the end of the year. If the University pays $600 or more to a research participant during the calendar year, then the University is required to report the payments to the IRS and issue the recipient a Form 1099 (payments to foreign nationals are reported on a Form 1042-S).
Reimbursement (payments to research subjects to cover out-of-pocket expenses they incur while participating in research, e.g., reimbursement for taxi fare or parking) based on receipts is not considered taxable income.

Amendments –

When you have received IRB approval for your study, any subsequent changes you make to research procedures, subject population, compensation, recruitment, consent/assent, etc. must be reviewed and approved by the IRB before you can implement changes to your study. If your study received an Exempt approval and afterward you want to make changes to your study, you must still submit an amendment to the IRB so the IRB can determine whether your study continues to qualify for Exempt status. You must revise the consent form / information sheet, as applicable.

Continuing Review –

Studies that are Exempt do not undergo continuing review, as well as most Expedited (minimal risk) studies. These type of studies must, at the time of notice, complete an annual check-in form as request by the IRB. For federally funded studies and studies that are more than minimal risk, the IRB must review the study at least once a year.

It is your responsibility to keep track of the date on which IRB approval will expire. If IRB approval expires, all research activities involving human subjects MUST STOP, including subject contact, data collection, and data analysis. The only exception to this requirement is for activities that should be continued for reasons of participant safety. No new subjects may be enrolled after IRB approval lapses.

Educational Research –

There are laws that can impact research carried out in schools and with educational records (e.g., the Family Educational Rights and Privacy Act (FERPA) and the Protection of Pupil Rights Act (PPRA)). For a discussion of FERPA and PPRA and how those laws can impact the informed consent process, contact the USA IRB @ irb@southalabama.edu