

Study Outline

Look for this information in initial and continuing review applications in a way that is available for ALL IRB members (not just primary reviewers)

- Purpose of the research [II.4.A, II.5.A]
- The scientific or scholarly rationale (background and hypothesis) [II.4.A]
- Procedures to be performed [II.4.A]
- A description of the procedures being performed already for diagnostic or treatment purposes [II.4.A]
- Risks [II.4.A]
- Potential Benefits [II.4.A]
- Inclusion and exclusion criteria [II.5.A]
- Setting of the research [II.5.A]
- Provisions to monitor the data for the safety of participants [II.4.B]
- Whether the research will involve populations vulnerable to coercion or undue influence. [II.4.C, II.5.A]
- When some or all participants are vulnerable to coercion or undue influence a description of additional safeguards included to protect their rights and welfare [II.4.C, II.7.B]
- Method of identification of participants [II.5.A]
- Recruitment method [II.5.A]
- Advertising [II.5.B]
- Amount and schedule of all payments [II.5.B]
- Provisions to protect the privacy interests of participants [II.6.A]
- Provisions to maintain the confidentiality of data [II.6.B]
- Consent process [II.7.A]
 - The person who would conduct the consent interview
 - The person who would provide consent or permission
 - Any waiting period between informing the prospective participant and obtaining consent
 - Steps taken to minimize the possibility of coercion or undue influence
 - The language used by those obtaining consent
 - The language understood by the prospective participant or the legally authorized representative
- Consent document or consent script [II.7.A, II.7.C]

Consent Document

Basic

- A statement that the study involves research.
- An explanation of the purposes of the research.
- An explanation of the expected duration of the participant's participation.
- A description of the procedures to be followed.
- Identification of any procedures that are experimental. *(May be omitted if there are none.)*
- A description of any reasonably foreseeable risks or discomforts to the participant. *(May be omitted if there are none.)*
- A description of any benefits to the participant or to others, which may reasonably be expected from the research. *(May be omitted if there are none.)*
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant. *(May be omitted if there are none.)*
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. *(May be omitted if confidentiality will not be maintained.)*
- A statement that notes the possibility that the Food and Drug Administration may inspect the records. *(May be omitted for research that is not FDA-regulated.)*
- An explanation as to whether compensation is available if injury occurs. *(May be omitted if the research involves no more than minimal risk.)*
- If compensation is available when injury occurs, an explanation as to what it consists of or where further information may be obtained. *(May be omitted if the research involves no more than minimal risk.)*
- An explanation as to whether any medical treatments are available if injury occurs. *(May be omitted if the research involves no more than minimal risk.)*
- If medical treatments are available when injury occurs, an explanation as to what it consists of or where further information may be obtained. *(May be omitted if the research involves no more than minimal risk.)*
- An explanation of whom to contact for answers to pertinent questions about the research.
- An explanation of whom to contact for answers to pertinent questions about the research participants' rights.
- An explanation of whom to contact in the event of a research-related injury to the participant. *(Note: May not be omitted just because the research involves no more than minimal risk.)*
- Contact information for the research team for questions, concerns, or complaints. *(AAHRPP)*
- Contact information for someone independent of the research team for problems, concerns, questions, information, or input. *(AAHRPP)*
- A statement that participation is voluntary.
- A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.
- A statement that the participant can discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

Required for VA Research

- A statement that in the event of a research-related injury the VA had to provide necessary medical treatment to a participant injured by participation.
- A statement that a veteran-participant would not be required to pay for care received as a participant in a VA research project except in

accordance with federal law and that certain veterans were required to pay co-payments for medical care and services provided by VA.

Required for ICH GCP

- The approval/favorable opinion by the IRB.
- The probability for random assignment to each treatment.
- The participant's responsibilities.
- When applicable, the reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant.
- The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the participant.
- When there is no intended clinical benefit to the participant, the participant should be made aware of this.
- A statement that the monitors, the auditors, the IRB, and the regulatory authorities will be granted direct access to the participant's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the participant or the participant's legally authorized representative is authorizing such access.
- If the results of the trial are published, the participant's identity will remain confidential.

Additional

- A statement that the particular treatment or procedure may involve risks to the participant, which are currently unforeseeable. *(Look for when research involves investigational drugs/devices, novel procedures involving risk, or where a goal of the research is to define safety.)*
- A statement that if the participant is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. *(Look for when the research involves pregnant women or women of childbearing potential, and the effect of the procedures have not been evaluated in pregnancy or a goal of the research is to define safety in pregnancy.)*
- Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent. *(Look for when the protocol mentions this as a possibility.)*
- Any additional costs to the participant that may result from participation in the research. *(Look for when additional costs are expected.)*
- The consequences of a participant's decision to withdraw from the research. *(Look for when withdrawal from the research will have adverse consequence.)*
- Procedures for orderly termination of participation by the participant. *(Look for when such procedures are part of the protocol.)*
- A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant. *(Look for on long-term clinical trials.)*
- The approximate number of participants involved in the study.
- The amount and schedule of all payments. *(AAHRPP)*

Other

- No statements similar to "Compensation will not be provided."
- No signature line for legally authorized representative or parent, when the research is not approved for cognitively impaired adults or children.

Exemptions

- Reviewer's determination of category is documented.

Category #1 studies

- The activities are normal educational practices.
 - *That is practices that would be expected to go on anyway.*
 - *Randomized designs/cross-over designs are suspect.*
- The setting is an established or commonly accepted educational setting.
 - *Schools, medical offices, hospitals, boot camps are established or commonly accepted educational settings.*
 - *County fairs, shopping malls, trade shows are NOT established or commonly accepted educational settings.*

Category #2 studies

- If a survey or educational test, the survey or educational test is in the file.
- Check the survey/educational test for identifiers.
 - If there are identifiers recorded, any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- There are no interventions (manipulations of the subject or the subject's environment.)
 - *For example, asking someone take part in an activity (use this computer program, try this learning strategy, talk with another person) and then do a survey or observe them is not Category #2.*
- Children are not involved in survey research.
 - *If parents are surveyed about their children and private identifiable information is collected about the children, the children are the subjects.*

Category #4 studies

- The investigator has described the data that will be recorded.
 - *If there is no description of the data being recorded, Category #4 does not apply.*
- The recorded data includes no identifiers.
 - *Note that identifiers can be collected, but not recorded. For example, a hospital can provide access to medical records with identifiers. An insurance company can provide a tape of data with identifiers. As long as the investigator does not record identifiers or links to identifiers, this is exempt. Note that whether research involves human subjects depends on what data are collected. Whether the human subject research is exempt in Category #3 depends on what is recorded.*
 - *Note that if the investigator is provided anonymous information, the study is not human research.*
 - *Watch for links to identifiers that make a study not exempt:*
 - *Hospital number.*
 - *Student ID.*
 - *Phone number.*
 - *Date of surgery with a rare disease (heart transplant/brain tumor removal)*
 - It is clear from the protocol that the data existed at the time the research was proposed.
 - *If it simply states "we will collect the data" without indicating that the data already exist, Category #4 does not apply.*

Category #5 studies

Most Category #5 exemptions are wrong.

- Must be conducted or funded by a federal agency.
 - *Studies conducted by state agencies cannot be Category #5.*
 - *Studies that evaluate federal programs, but are not conducted or funded by a federal agency cannot be Category #5.*
- For DHHS funded research (E.g., Medicare//Medicaid evaluations, evaluations of federal funded drug treatment programs, CDC program evaluations) See whether OHRP made the decision about whether the research is exempt.

Contracts

- ❑ Indicates that the organization would follow the protocol and applicable law.
- ❑ Indicates who would provide care for research-related injury and who was responsible to pay for it. *[Not equivalent to indemnification for liability. It should be a statement specifically regarding medical care for research-related injury.]*
- ❑ Obligates the sponsor to promptly report to the organization any findings that could: *[For example: If the sponsor sends an on-site study monitor and the monitor finds serious problems with the research that affect participants (missing drug, no consent, incomplete screening tests), this would obligate the sponsor to notify the organization.]*
 - Affect the safety of participants.
 - Affect the willingness of participants to continue participation.
 - Influence the conduct of the study.
 - Alter the IRB's approval to continue the study.
- ❑ Obligates the sponsor to follow the organization's policies and procedures regarding the publication of findings from sponsored research. *[Not applicable if the organization has no such policy.]*
- ❑ Describes how results from a research study would be communicated to participants when those results directly affected their safety or medical care. *[For example: Two years after the study ends, the sponsor finds out the study drug increases risks of heart disease. In this case the sponsor would be obligated to notify the organization who can then determine whether and how to provide this information to current or former participants.]*