

UNI IRB - Consent Checklist

This document provides a list of the items that reviewers are looking for in consent documents, based on federal regulations and university IRB requirements. Not all items will apply to every study. The format and ordering of items is optional, and the form need not be long and involved, as long as all applicable items are addressed. Please use language that lay persons can read and understand (typically 8th grade level is appropriate).

General requirements

- Presented **on letterhead** or must state in the first paragraph that the project is being conducted by persons affiliated with the University of Northern Iowa
- No exculpatory language through which the participant is made to **waive** any of her or his **legal rights**, or releases the university or its agents **from liability for negligence** (a6)
- Presented in **additional language(s)**, when participants are not fluent in English (a3)
- If the study is an evaluation of a program or intervention that is or would be occurring anyway, consent **information should pertain only to the research-specific** activities/risks/benefits, not those pertaining to the program itself
- For written (signed) consent, a statement that **participants will be offered a copy** of the consent form and **signature lines** for participant, researcher, and advisor (if applicable)

Study description

- A statement that the study involves **research** (b1)
- An explanation of the **purposes of the research** (one concise sentence or two) (b1)
- The expected **time/duration** of the person's participation (b1)
- A description of the **procedures** to be followed (b1)
- Identification of any **experimental procedures** or **medical treatments** (b1)
- The **location** where the procedures will be done
- Information about **video/audio recordings and transcripts**, and who will see them
- The approximate number of subjects involved in the study, when appropriate (e.g., when the quality of the study or sample size may be relevant to the decision to participate) (c6)

Anonymity and confidentiality

- Information about whether or not any **direct or indirect identifiers** are being collected, and if/when they will be destroyed (or if/when the codes connecting the identifiers to the data will be destroyed) (b5, b9)
- A statement describing the extent, if any, to which **confidentiality** of any records identifying the participant will be maintained (b5)
- If study data, biospecimens, and/or artifacts will be **shared with others** or if they may be used in **future studies**, a statement to that effect (b9)
- If study is online, a **statement about technology** similar to this: *“Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data transmitted electronically.”*
- If narrative or oral responses are involved, note whether **direct quotes, without identifying information**, may be used in publications
- A statement regarding **any exceptions to confidentiality**, when applicable (b5)

Abuse: In studies that elicit information that could lead to a disclosure about abuse, neglect, or harm to self or others, a statement must be included in the consent regarding any exceptions to confidentiality. (If you are not a mandatory reporter, you must determine which exceptions to confidentiality, if any, you will make.)

Crime: In studies that are not anonymous and collecting information about illegal behavior, note that you would be required to respond in the unlikely event of a court subpoena (and how you might prevent this by keeping identifiers separate from other data and/or destroying identifiers as soon as possible after study completion).

Focus groups: In focus group research, note that confidentiality by other group members cannot be guaranteed.

Risks and costs

- A description of any reasonably foreseeable **risks** or discomforts (b2) – A study may have “minimal risk” or “risks not greater than those of day-to-day life” but it is not appropriate to say there is “no risk” (at a minimum, there is the “risk” of being inconvenienced).
- If applicable, a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable (c1)
- Any monetary costs to the subject that may result from participation in the research (c3)

Benefits

- A description of possible **benefits** to the participant, which may reasonably be expected from the research, or a statement that individual participants may not benefit from participation, but that there may be benefits to general knowledge or to society (b3)

Study compensation (which is not a benefit)

- An explanation of any **compensation** and, if appropriate, procedures to prorate compensation for participants who withdraw prior to completion of the study
- Statement that **compensation to individuals will be reported** to the UNI Business Office, if applicable - In some cases, researchers are required to inform the UNI Office of Business Operations (OBO) about compensation provided to research participants, for tax purposes. (See [UNI compensation policy](#).) When this applies, you must include a statement to that effect in the consent information, and note that: a) **actual data from the study will not be provided** (or even the title of the study, if appropriate) - only names and contact information, and b) **participants may decline the compensation** if they wish.
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions (c8)

Refusal, withdrawal, or termination by the investigator

- A statement that participation is **voluntary** (b8)
- A statement indicating that the **participant may refuse to participate or may discontinue participation** at any time during the project without penalty or loss of benefits to which the participant is otherwise entitled (b8)
- If applicable, the **consequences of a subject's decision to withdraw** from the research and procedures for orderly termination of participation by the subject (c4)
- If applicable, a statement that **significant new findings** developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject (c5)
- If applicable, anticipated circumstances under which the subject's **participation may be terminated** by the investigator without regard to the subject's or the legally authorized representative's consent (c2)

Whom to contact

- The name(s), title(s), telephone number(s) and/or email addresses of the person(s) to contact for **answers to questions about the research (PI and Faculty Advisor)** (b7)
- Title and email address for the person to contact for answers to questions about **research participants' rights**. (This should be the IRB Administrator at anita.gordon@uni.edu or 319-273-6148.) (b7)
- The name, title, and telephone number of the person to contact in the event of a **research-related injury**, if different from above (b7)

Additional Elements, required when applicable

For research involving biospecimens

- If applicable, a statement that the subject's biospecimens (even if identifiers are removed) may be used for **commercial profit** and whether the subject will or will not share in this commercial profit (c7)
- For research involving biospecimens, indicate whether the research will (if known) or might include whole **genome sequencing** (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen) (c9)

For educational research or special programs

- A statement about **whether or not the procedure is part of the regular curriculum** of a class or program. Specifically state what the normal activities are that participants will be completing, then explain which activities are being done for research. (Note that the research may simply involve analyzing the normal data or artifacts that are generated out of these standard activities.)
- A statement about **whether or not the participant will miss any regularly scheduled work/class** and if so, a statement about whether or not s/he will be allowed to make up this work
- A statement as to whether participation or non-participation will **affect the participant's grade** or status in a program, including any extra credit options
- An explanation of **what non-participants will do** while the research is taking place

For research involving more than minimal risk

- An explanation as to whether any **compensation** or cost reimbursement is available if injury occurs (b6)
- An explanation as to whether **medical or psychological treatment** is available if research-related injury occurs, what it would consist of, and where further information may be obtained (b6)

For studies involving physical activities or interventions

- A description of **training and/or experience of the researchers** in directing the study procedures
- An outline of which **procedures are part of normal or required activities** versus which are solely for research purposes
- A statement regarding whether or not participants' **performance may be observed** by others
- A statement that a written **emergency plan** is available for review, upon request, and that the **area is safe and clear** in the event of an accident or fall
- A brief description of the **emergency care credentials** of PI or another person who will be present

For research involving medical or psychological treatment

- A disclosure of appropriate **alternative procedures** or courses of treatment, if any, which might be advantageous to the participant (b4)

Note: Citations from 45 CFR 46 consent language (1/15/18 version) shown in parentheses.