Informed Consent Checklist

Informed Consent is a process. It must be conducted in language understandable to the persons being informed. Consent documents should be written in plain, everyday language and include the following.

Note – not every project's consent process will require every item from this checklist. Generally, those checklist items containing **bold and underlined** portions should be considered mandatory**.**

General

- ✓ Consent written in **first and second person** perspectives (e.g., I, me, my, you, we). From the FDA Information Sheet on Informed Consent – "Consent documents are more understandable if they are written just as the investigator would give an oral explanation to the subject, that is, the subject is addressed as 'you' and the investigator as 'I/we'. This second person writing style also helps to communicate that there is a choice to be made by the prospective subject. Use of the first person may be interpreted as presumption of subject consent, i.e., the subject has no choice."
- ✓ **Language at the level appropriate for the participants** (the mean adult reading level in the U.S. is 6-8th grade). Note - if you are working with children, reading level can change significantly between grades.
- ✓ Explanation that the study is a **research** study or project
- ✓ A place for **signature of the participant and date if obtaining written consent** is clearly labeled as such (e.g., "Signature of person obtaining consent")
- ✓ That the **participant will be provided with a copy of the consent document(s)**, including, if s/he wishes, the signed consent form.
- ✓ **NO use of "understand" phrases (e.g. "you understand," "I understand")** – Substitute "I have been informed", "It has been explained to me" or words to that effect. Note – try to limit the number of times sentences and paragraphs of consent documents being with the "I have been informed" phrase.

Researcher's Info

- ✓ Identify the researcher's "**affiliation**" with the institution (e.g., graduate student, faculty, staff, undergraduate).
- ✓ **Contact person(s).** Include the researcher's name, telephone number, and e-mail address (students must include faculty advisor's equivalent contact information).
- ✓

Procedures

- ✓ Explanations of the **nature, purpose, and duration of the study.** If it is experimental, participants must be informed of this.
- ✓ Explanation of **procedures** to be employed in the study (i.e., exactly what the participants are expected to do) and the **time commitment** required of the participants to complete those procedures.
    - ✓ Conditions of participation such as age, health status, etc.
    - ✓ Approximate total number of participants who will be enrolled in the study. If you are offering entry into a drawing or raffle as a participation incentive, provide some indication regarding the chances of winning. Base this upon your planned number of enrollees.
    - ✓ If working with adults, language stating that individuals must be 18 years of age or older to participate in the study.
- ✓ If appropriate, debriefing procedures.
- ✓ If appropriate, circumstances under which the P.I. may terminate subject participation without subject consent.

Risks & Benefits

- ✓ Description of **risks** (hazards, inconveniences, discomforts, stress) the participant may experience, as far asthey are known and how they will be minimized. Alternatively, state if the risks are minimal (i.e., no greaterthan those encountered in normal daily life). Also, if appropriate, identify resources that participants can makeuse of to help them deal with emotional distress, etc.
- ✓ The following statement, if there are possibilities of physical risk: "As in all research, there may be unforeseen risks to you as a participant. If an accidental injury occurs, appropriate emergency measures will be taken."
- ✓ If appropriate, that any significant new findings affecting risks will be reported to the participant.
- ✓ No language that would release or appear to release the researcher, the institution or its agents from liability for negligence (no exculpatory language).
- ✓ **Benefits** of the study in general (scholarly) and benefits to participants as individuals. All studies must have some benefit in order to receive HSRB approval. If participants will not get any direct benefit from their participation, it is appropriate to include language to that effect as well.

Voluntary Nature

- ✓ That **participation is voluntary** and that the **participant can withdraw** her/his consent or discontinue participation in the research at any time without penalty.
- ✓ If appropriate (e.g., subjects are students, members of an organization, etc.), that the decision to participate or not participate will have no impact on grades, class standing, or relationship to the institution in any way.

Confidentiality

- ✓ How **confidentiality** will be maintained and any limits to confidentiality. Any wording that "guarantees"confidentiality or anonymity is not appropriate. Also, if appropriate, indicate any limitations to confidentiality(for example, in situations where participants may be quoted – how quotes will be attributed to them; if excerpts of audio or video recordings will be included as part of presentation of study results – possibility that participants might be identifiable to viewers of the recordings).
- ✓ If you are using focus groups, remind focus group participants to keep confidential the information discussed during the session(s). This is particularly important when sensitive topics are discussed.
- ✓ If audio or videotaping is involved, the uses to which the tapes may be put, who will have access to them, how they will be secured and how long they will be retained by the researcher (ultimate disposition).
- ✓ If you are obtaining consent or participant information (e.g., survey responses, indications of interest in participation) via e-mail, you should inform participants that e-mail is not 100% secure.

Surveys

- ✓ For surveys for which written consent is not obtained (e.g., consent information is provided as a cover sheet/information page with no provision for participant signature), that completion and return of the survey indicates consent to participate.
- ✓ If you are conducting a web-based survey, remind participants that they should clear the browser cache and page history.
- ✓ If there is a possibility that your participants could be completing a web-based survey at work, remind them of the possible use of tracking software by their employer.

Experimental

- ✓ If the study is therapeutically related, disclosure of alternate procedures the subject might choose.

Common consent form word usage with corresponding alternatives

A major component of the informed consent process is language at an appropriate level for study participants. Following is a table that may be used as a reference tool to help translate complex words/phrases into simpler wording for average reading level requirements.

Complex words/phrases	Simpler words/phrases	Easy words/phrases
additional	extra	more
administer	dispense	give
adverse	negative	bad; harmful
appropriate	suitable	proper; right
approximately	nearly	about
available	present	Handy
categories	classes	Groups
combination	series	mix
compensation	payment	money
consequences	outcomes	results
empirical	evidence	research study
equivalent	equal	same
immediately	at once	now
initiate	begin	start
unique identifying information	personal information	IDs

Readability – Examples of increasing language complexity based on grade levels as determined by the Flesch – Kincaid Scale

4th grade – You don't have to be in this research study. You can agree to be in the study now and change your mind later. Your decision will not affect your grades. Your teacher's attitude toward you will not change.

6th grade – Taking part in this study is your choice. If you decide not to take part, this will not harm your relationship with your teachers or with the university.

8th grade – Participation in this study is entirely voluntary. You have the right to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

10th grade – Your participation in this study is voluntary and you are free to withdraw at any time. Participation or withdrawal will not affect any rights to which you are entitled.

12th grade – Your participation in this study is strictly voluntary. You have the right to choose not to participate or to withdraw your participation at any point in this study without prejudice to your future benefits or other services to which you are otherwise entitled.

College – You voluntarily consent to participate in this research investigation. You may refuse to participate in this investigation or withdraw your consent and discontinue participation in this study without penalty and without affecting your relationship to the university.