

Explanation Of The Informed Consent Requirements

1. All consent material should identify the Principal Investigator and provide a contact phone number (it is not advisable to show a home phone number), the investigator's academic affiliations or appointment, and the investigator's department. (FEDERAL REQUIREMENT) If the investigator is a graduate student, the institutional affiliation should clarify whether the student is a masters or doctoral candidate.
2. All consent material should show any associates connected with the project and/or the faculty sponsor for student investigators.
3. All consent material should **INVITE**, rather than assume participation.
4. All consents should always contain a statement advising subjects that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled. Non-participation statements should make it clear that subjects may elect not to complete/answer any portion of the task that they choose. Additionally, if participants are employees being recruited at or through their workplace; or students, the non-participation statement should specifically state that a decision to cease or decline participation will not negatively impact their employment status or class standing. (FEDERAL REQUIREMENT)
5. All consent material should include a statement that the study involves research and the purpose of the research. (FEDERAL REQUIREMENTS)
6. All consent material should contain a description of the procedures to be followed, and identification of any procedures which are experimental and the anticipated number of subjects. (FEDERAL REQUIREMENT)
7. All consent material should contain a statement clarifying the expected duration of the subject's participation. If the participation is multi-component or longitudinal, then the duration should detail the individual and total duration. EXAMPLE: "I have been advised that I will be asked to complete a questionnaire once a month for a year. Each month, it will take approximately one (1) hour. The total anticipated time commitment is twelve (12) hours." (FEDERAL REQUIREMENT)
8. All consent material should always contain a statement advising subjects of the risks of participation. It is not always the case that there will be risks, but the statement should inform participants either that there aren't any risks or what risks to expect. (FEDERAL REQUIREMENT)
9. All consent material should always contain a statement advising subjects of the benefits of participation. It is not always the case that there will be benefits, but the statement should inform participants either that there aren't any benefits or what benefits to expect. (FEDERAL REQUIREMENT)

10. All consent material should always advise subjects **HOW** anonymity or confidentiality will be maintained, it is not sufficient to tell them that it will be maintained. If the procedures involve audio or video taping, the confidentiality statement should address how the tapes will be stored to maintain confidentiality and how long the tapes will be stored. (FEDERAL REQUIREMENT)
11. All consent material should always advise subjects that the data will be used for publication and educational purposes. Usually, the investigator will also advise the subject that the data will not be identified with them.
12. All consent material should contain a statement which advises subjects about the subject of remuneration. Remuneration may be either monetary, class credit or rewards of another kind. The remuneration statement should clearly state if task completion is required in order to qualify, or if there is a pro-rated issuance of the reward. It should also clearly state how the payment is to be made and exactly when the subject can expect to receive the payment.
13. All consent material should contain a statement which advises subjects that their participation may be terminated by the investigator for due cause. The CPHS may, in some cases, require the investigator to include any circumstances that may cause a subject's participation to be terminated. (FEDERAL REQUIREMENT)
14. All consent material should always offer to answer any questions that the subject may have regarding the project. This offer should restate the investigator's contact phone number, academic affiliation or appointment, and the department. (FEDERAL REQUIREMENT)
15. Only projects with more than minimal risk should include a financial disclaimer regarding any injuries resulting from project participation in the consent material.
16. All consent material should contain a statement acknowledging the investigator's professional and ethical responsibility.
17. Only when subjects are impaired or unable to provide certification of their willingness to participate is a witness signature normally required.
18. All consent material should always contain the CPHS review statement. This statement should be shown in capital letters and should be in bold type or highlighted in some other manner to bring it to prominent attention.