

Invitation Letter vs. Signed Consent Form: Documenting the Consent Process

A formal signed consent document may not be necessary or appropriate in certain studies, such as studies involving surveys, interviews, focus groups, or other minimal risk research; or in research where the subjects will remain anonymous. In these cases, the investigator should prepare an invitation letter to inform the subjects about the study and invite them to participate. The format may vary from that of a coversheet, memo, letter, or a script to be read to the subject; whichever is most appropriate for the study.

In most cases, studies involving surveys, interviews, or focus groups of children will require the signed permission of the minor child's parent or legal guardian as well as assent of the child (unless the IRB grants a waiver). In such instances, an invitation letter should be prepared, with an attached permission form which should be signed by the parent and returned to the investigator. If the minor subjects are mature minors (14 – 17 years of age), they are considered capable of understanding the information contained in the letter and can indicate their assent by signing the same permission form as the parent/guardian.

Specific Instructions Regarding Writing an Invitation Letter:

Generally, the invitation letter should be written in simple terms and in second person (e.g., "you/your"). Do not use first person (e.g., "I understand that I will"). Headers are not recommended, but are shown below as an aid to the explanation. A **sample invitation letter** for use as a starting point for drafting an information letter follows the following specific instructions:

Section 1: Invitation to Participate

Introduce yourself, explain your connection to the University of South Carolina, and explain that you are inviting them to participate in a research study. If you are a student, disclose this, and include information about the degree that you are working on, and if the study is being conducted to fulfill degree requirements, state this. If you are a professor, please state your department. If the study is funded internally or by an agency, disclose this.

Section 2: Purpose

Describe what you are studying. This does not need to be re-stated if it is covered in the introduction paragraph.

Section 3: Description of Procedures

Describe all study procedures so that the subject knows what her/his participation will involve. You should include a description of the topics that the subject be asked about (especially if there are any sensitive topics), the length of time required to complete the activities, and whether the subject will be contacted again in the future.

Section 4: Risks and Inconveniences

Describe any risks (could be physical, psychological, social or economic) or inconveniences the subject may experience, including risks of breach of confidentiality.

Section 5: Benefits

If there are no benefits to the individual subject, you should identify the benefits to society. DO NOT include monetary reimbursement or compensation as a benefit of the research.

Section 6: Confidentiality

Describe how you plan to preserve the subject's confidentiality. Remember that there is a difference between confidentiality and anonymity. Confidentiality means that the subject's identity is known by the investigator and can be linked to their data, even if their identity is not reported. Anonymity means that there is no way for the investigator to ever link the data to the subject's identity.

Section 7: Costs/Payments (if appropriate)

Tell the subject whether s/he will be charged for any part of the study and/or whether she will be given any reimbursement for her/his time and/or travel expenses. Reimbursement should not be coercive in amount or method of distribution.

Section 8: Voluntary Participation

Explain that subjects are under no obligation to participate, and there will be no negative consequences if they withdraw.

Section 9: Questions

Provide the subject with your contact information, your faculty advisor's contact information (if applicable), and the phone number for the University of South Carolina's Office of Research Compliance (803) 777-7095) if they have any questions about their rights as a research subject.

Sample Invitation Letter:

Study Title:

Dear _____,

My name is (insert). I am a (professor/doctoral candidate/graduate student) in the _____ Department at the University of South Carolina. *(If appropriate)* I am conducting a research study as part of the requirements of my degree in _____, and I would like to invite you to participate. *(If appropriate)* This study is sponsored *(or)* funded by _____.

I am studying (describe purpose). If you decide (to allow your child) to participate, you (your child) will be asked to (describe procedures, e.g., complete some surveys about _____ *(or)* meet with me for an interview about _____ *(or)* participate in a group discussion about _____). In particular, you will be asked questions about *(or)* we will discuss (insert topics). The meeting will take place at _____ *(or)* a mutually agreed upon time and place, and should last about _____ minutes. *(If appropriate)* The session *(or)* interview will be audio *(or)* video taped so that I can accurately reflect on what is discussed. The tapes will only be reviewed by members of the research team who will transcribe and analyze them. They will then be destroyed.

(If appropriate) You may feel uncomfortable answering some of the questions. You do not have to answer any questions that you do not wish to. Although you probably won't benefit directly from participating in this study, we hope that others in the community/society in general will benefit by _____.

Participation is confidential. Study information will be kept in a secure location at the University of South Carolina. The results of the study may be published or presented at professional

meetings, but your identity will not be revealed. (or) Participation is anonymous, which means that no one (not even the research team) will know what your answers are. So, please do not write your name or other identifying information on any of the study materials.

(for focus groups) Others in the group will hear what you say, and it is possible that they could tell someone else. Because we will be talking in a group, we cannot promise that what you say will remain completely private, but we will ask that you and all other group members respect the privacy of everyone in the group.

(If applicable) You will receive ___ to reimburse you for your time and travel expenses (insert when). If you withdraw from the study prior to the conclusion, you will still be reimbursed the same amount/your reimbursement will be pro-rated (describe how).

Taking part in the study is your decision. You do not have to be in this study if you do not want to. You may also quit being in the study at any time or decide not to answer any question you are not comfortable answering. (If USC students involved) Participation, non-participation or withdrawal will not affect your grades in any way. If you begin the study and later decide to withdraw, you will still receive research credit (or) there are other research credit opportunities available to satisfy your research requirement.

We will be happy to answer any questions you have about the study. You may contact me at (insert phone number and e-mail address) or my faculty advisor, (insert name, phone number, and e-mail address) if you have study related questions or problems. If you have any questions about your rights as a research participant, you may contact the Office of Research Compliance at the University of South Carolina at 803-777-7095.

Thank you for your consideration. If you would like to participate, please (explain what they should do, e.g., open the attached survey packet and begin completing the study materials. When you are done, please (insert instructions about what to do with completed instruments). (or) please contact me at the number listed below to discuss participating. (or) Sign the attached form and return it to _____. (or) I will call you within the next week to see whether you are willing to participate.

With kind regards,
(Signature)
(Name)
(Address)
(Phone number)
(e-mail address)

Parental Permission Form

Study Title: (Insert)

Researcher: (Insert)

I have read the information contained in the letter/memo about the above titled study, which describes what my child will be asked to do if (s)he wants to participate in the study; and,

Yes – I give permission for my child to participate in the study.

-OR-

No – I do not give permission for my child to participate in the study.

Parent/Guardian Signature

Date

Child's Name

Age

Assent (for High School Aged Children)

I have read the information contained in the letter/memo about the above titled study, which describes what I will be asked to do if I decide to participate. My parent/guardian has given me permission to participate. I have been told that the decision is up to me, and that I do not have to participate, even if my parent/guardian says that it is okay. I have been told that I can stop participating at any time I choose, and no one will be mad at me.

Yes – I want to participate in the study.

-OR-

No – I do not want to participate in the study.

Child's Signature

Date

Age