Informed Consent and Confidentiality Template
International University for Graduate Studies

Visit the IUGS web page "Policy on Research Ethics Involving Human Participants and Personal Data" to download instructions on how to design your human subjects review procedures. https://iugrad.edu.dm/images/downloads/iugs-irb-standards.pdf

General Guidelines

Informed consent confirms that the subject understands the requirements and limits of their participation, that it is voluntary, and includes the right to withdraw. Tailor the wording to ensure that it fits for the group for whom you are seeking consent. Subjects should be given the opportunity to review their remarks in individual interviews and erase part or all of the recording or notes if they so desire. Informed consent, and confidentiality processes, may, in some cases be conducted verbally. This approach would be used in cases where, for example, the only thing that links a subject to the research would be a signed form. If, for example, the researcher has only one contact with a subject, asnd that contact is anonymous, then having a signed form actually reduces confidentiality. So, in such cases, informed consent procedures need to be developed to show that they would be conducted verbally. To assure that subjects understand the purpose of the study, use easily understood, common language, e.g., 8th grade terminology.

(Comments in italics are instructions. Use hard copy if mailed, or describe verbally using the basic outline if conducted face-to-face.)

SAMPLE Description of Informed Consent and Confidentiality for Participation in a Human Subjects Research Project

Note that this is a generic guideline for a typical Informed Consent and Confidentiality procedure. Given the details of your specific study, you may need to modify this outline, but the basic concepts should be addressed and standards met.

Student Researcher Name
International University for Graduate Studies
Personal Address
Email
Phone
Title of Study

This study explores *[describe the topic]*. It is performed in partial fulfillment of the requirements for the student researcher's *[degree information]* at the International University for Graduate Studies.

There are *[state level, e.g., no, little, great]* foreseeable risks with this research. The main potential benefit is in the contribution to scientific knowledge on this topic. *[give detail, e.g., No or amount]* costs or payment are associated with participating in this study. Participation is entirely voluntary. You may withdraw from the study at any point without penalty. If any discomfort should arise regarding any of the processes or materials addressed in the study, please speak to me personally to ask any questions and to discuss your feelings. You may also contact my mentor, [*fill in name and contact information]* or my committee chair, at *[fill in and contact information]*.

More complete information on the nature and purpose of the research will be available when the data collection is completed.

I [participant name] agree to participate in this research project and I understand that:
[Complete the information on what will be required, considering the example below. Items #5 - #8 should always be included. Add or delete other points as relevant to your study]
1. The time required for *[e.g., the initial interview will be -----]*.
2. The time required for follow-up interviews, as needed, will be .5 to 1 hour.
3. The nature of my participation includes interviews, 1 initial and possibly 1 to 2 follow-up interviews.
4. I understand these interviews *[will/will not/may be]* recorded.
5. My participation is entirely voluntary. I may terminate my involvement at any time without penalty. I may also choose not to answer any question(s) I do not wish to for any reason. I can also ask that any comments I make be excluded from the study.
6. All my data remain confidential. The recordings and the transcriptions of the interviews will be kept in secure storage after the research is complete.
7. All data are for research purposes only.
8. If I have questions about the research, or if I would like to receive a copy of the aggregate findings of the study when it is complete, I can contact the researcher at the address and phone number above.

Print Participant Name_____Date_____

Signed_____Date_____(Participant)

Signed_____Date_____(Researcher)

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SAMPLE Informed Consent Cover Letter/Verbal Description

(use hard copy if mailed, or describe verbally using the basic outline if conducted face-to-face)

Student Researcher Name
International University for Graduate Studies
Personal Address, Email, Phone

Dear……,

I am currently completing research for my dissertation in partial fulfillment of the requirements for my *[include degree and area of study*] at The International University for Graduate Studies. My research addresses *[briefly describe your research].*

Required informed consent statements, whether verbal, written or both:

- Your participation in this research is completely voluntary;
- You may discontinue your participation at any time without penalty;
- You may also choose to not answer any question(s) you do not wish to for any reason.

Discuss potential benefits of the study. Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question. Mention only those activities that will be actual benefits and not those to which subjects are entitled regardless of participation. Note that if any form of reimbursement is offered, it must be discussed and should be relevant to the level of participation, e.g., mileage costs, time lost at work, etc.

Your participation in this study will provide useful information about [briefly *describe your research*]. This study involves an interviewing process and may make seek clarification of selected information you have shared with me as written in your case notes. All information gathered remains confidential, in that identifying information will not be disclosed. Information that is used will only be used with your approval, and direct quotations will be confirmed and approved prior to their use. I will be conducting all aspects of the research process myself.

There are *[state level, e.g., no, little, great]* foreseeable risks with this research. The main potential benefit is in the contribution to scientific knowledge on *[topic]*. *[detail, e.g., No or amount]* costs or payment are associated with participating in this study. Participation is entirely voluntary. You may withdraw from the study at any point without penalty. If any discomfort should arise regarding any of the processes or materials addressed in the study, please speak to me personally to ask any questions and to discuss your feelings. You may also contact my mentor, *[fill in name and contact information]* or my committee chair, at *[fill in and contact information]*.

Modify the following according to whether this is a face-to-face discussion or is done by mail, but it should be something like:

If you are willing, please sign one copy of the [enclosed] **Consent for Participation in Research Project** and return it to me in the envelope provided. Please keep the other copy. I will then contact you to set up a time for interview(s).

Thank you for your assistance.

Sincerely,

SAMPLE Confidentiality/Anonymity Statement: (student researcher and study name)

[The following language is typical of Confidentiality Statement requirements. Either this, or other similar language tailored to your specific study must be present in the consent form.]

*Tell participants if their information and/or participation will be kept confidential or anonymous. A **confidential** study means that while participants' identities potentially could be determined from the information they give, the researcher has taken steps to ensure that they will not be identified. An **anonymous** study means there is no way to tell if a particular person participated in the study and no way to identify that person from the information given even to the investigator.*

If a confidential study, briefly describe to participants the steps you are taking to ensure confidentiality. A typical procedure is that if a subject's identifying information is somehow needed (e.g., for follow-up) then the person's name and related information would be linked to a code that would appear on any data collected. The identifying informaiton would be kept separate from the data with the linking code. The code sheet will be destroyed after the study is complete. Confidential data will be kept in a secure location until they are no longer scientifically useful and then also destroyed. Remember that a study cannot be both confidential and anonymous. If you cannot ensure confidentiality/anonymity, you should clearly state this under the "risk" section of the informed consent form.

Group processess provide a particular challenge to confidentiality because once something is said in the group it becomes common knowledge. Explain to the subject that you can and will encourage group participants to respect confidentiality, but that you cannot guarantee it.

Provide your plan for sharing findings, usuaally this includes that findings are only presented in aggregate form, with nothing that could indeitify individual subjects. If you have a plan and a timeline for the sharing of information, include the details. You may also inform the subject that the research findings will be shared more broadly, for example, through publications and conferences.

The IRB will approve a protocol if confidentiality will only be broken to protect the research participant or others (e.g., if information arises in the course of the research that suggests a participant may intend harm to him/herself or others).

SAMPLE Confidentiality Statement Template

All documents and information pertaining to this research study will be kept confidential in accordance with all applicable laws and regulations, such as storage, other issues, and reporting of only aggregate data. I understand that records and data generated by the study may be reviewed by the IUGS Institutional Review Board to assure proper conduct of the study and compliance with relevant laws and regulations. I understand that if the results of this study are published, neither I nor any other subjects will be identified.

In the unlikely case that something happens to cause the researcher concern that there may be risk of the present danger of child abuse, suicide, and/or serious physical harm and/or homicide, he or she may disclose, without a participant's consent, relevant information that would identify a participant of the research project.

Your participation is voluntary. If you choose to take part in this study, you may stop at any time *(if any compensation is involved, explain whether stopping will alter the benefit/compensation to be received).* You may skip any questions you do not wish to answer.

(For a mail/internet survey): Return of the survey implies consent to participate.

Confidentiality Signature

Obtain a dated signature from the subject. Include signature lines for both the participant and the student researcher. A signature for a witness is not required, but may be useful in certain circumstances. If this is an anonymous study, do not obtain a signature. Do not record any information that could identify the participant, and inform them that no such information will be collected.

Print Participant Name_____ Date_____ (Participant)

Signed_____ Date_____ (Participant)

Signed_____ Date_____ (Researcher)

Special Note on Research with Child Subjects

NOTE: If your study involves children (less than 18 years old), the consent letter is written to Dear Parent/Guardian, and reference to "your child" or "your son/daughter" is used.

For studies involving children, an additional ***assent*** script is required. Children with permission to participate in a research study also have the right to be informed about the study and choose whether they wish to participate. Create a script that describes the study, what they'll be asked to do, confidentiality issues, etc. Use age-appropriate language! Children do not sign any documents.

SAMPLE Assent Consent Script for Child Subjects

Below is a very basic sample script that could be used with most young children. For middle school children, you may include more information and increase the reading level slightly. You should test your assent script on children you may know to see if they understand what you are asking. For high school students under 18, it is acceptable to use the parent/guardian consent form you created and modify it to reflect that it is an assent script directed at them and not their parent.

Hi, my name is _____, and I'm from the International University for Graduate Studies. I am here today because I am doing a project to learn about _____.

I would like to ask you to _____ *(explain in very simple language the activities the child will be asked to do)*. If you say "yes," you can still stop at any time by just telling me you want to stop. No one will be upset if you don't want to do this, or if you want to stop after you have started. If I ask you a question and you don't want to answer it, that's ok. Your parents (guardians) have said it is ok for you to be in the project if you want to.

Your answers will be private and only used for my project. Would you like to be in my project?

NOTE: Depending on the type of study, additional information may be required, e.g., "some questions could make you sad" (risk statement).