**Letter Style Informed Consent Document**

**Instructions, Checklist & Template**

**RECOMMENDED FOR ALL SOCIAL-BEHAVIORAL RESEARCH**

**The numbers in this checklist refer to the sections of the Informed Consent document.**

|  |  |
| --- | --- |
|  | **Required Elements** |
| 1 | A statement that this is research. |
| 2 | An explanation of the purpose(s) of the research |
| 3 | An explanation of the expected duration of the participant’s participation. |
| 4 | A description of the procedures to be followed. |
| 5 | A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. |
| 6 | A description of any reasonably foreseeable risks or discomforts to the participant. |
| 7 | A description of any benefits to the participant or to others which may reasonably be expected from the research. |
| 8 | A description of any payments to participants and, if appropriate, anticipated prorated payment (if any) should the participant withdraw from the study. |
| 9 | For research involving more than minimal risk, an explanation concerning treatment available or where further information may be obtained. |
| 10 | A statement that participation is voluntary and that the participant may withdraw at any time. |
| 11 | A statement that refusal to participate or withdrawal from participation will not involve any penalty or loss of benefits to which the participant is otherwise entitled. |
| 12 | An explanation of whom to contact about the research including an explanation of whom to contact for answers to pertinent questions about the research review process and participants’ rights. |
|  | **Add these items if appropriate** |
| 13 | For deception studies: a statement that the participant may not be told everything about the research at this time, but will receive full information at the end of the study. |
| 14 | A statement that the particular treatment or procedure may involve risks to the participant (or embryo, or fetus, or nursing infant if the participant is or may become pregnant) which are currently unforeseeable. |
| 15 | Anticipated circumstances under which a participant’s participation may be terminated by the investigator without regard to the participant’s consent. |
| 16 | Any additional costs to the participant that may result from participation in the research. |
| 17 | The anticipated prorated payment, if any, to the participant for participating in the research. |
| 18 | The alternative procedure(s) or course(s) of treatment that may be available to the participant, and their important potential benefits and risks. |
| 19 | European Union General Data Protection Regulation (GDPR) compliance. See [GDPR SOP](http://research.cofc.edu/administration/documents/policies-documents/irb_sop_gdpr.pdf). |

**INSTRUCTIONS FOR PREPARING CONSENT FORMS**

Instructions appear in italics; suggested language in regular type; red numbers refer to the checklist items.

It is very important to write your consent form in layperson’s language that can be easily understood by your participants. – an 8th grade reading level is recommended for the general population. This template includes language suggested by the IRB. Please adapt it as necessary to be sure your consent form explains your individual research clearly. It is important that the consent form be prepared in language that is easily understandable by your participant population

To check the reading grade level

**MS Word 97-2003:**

Enable readability statistics: 1) go to *Tools;* 2)click on *Options*; 3) click *Spelling and Grammar*; 4) check the boxes *Check Grammar with spelling* and *Show readability statistics*; 5) click OK.

Check readability level: Run Spell check. The readability statistics will come up after the spell check is complete.

**MSWord 2010**:

Enable readability statistics: 1) click the File tab; 2) click Options (in left menu); 3) click Proofing; 4) under When correcting spelling and grammar in Word, make sure Check grammar with spelling is selected; 5) select Show readability statistics; 6) click OK.

Check readability level: 1) Click on Review tab; 2) Click on Spelling and Grammar. When Word finishes checking the spelling and grammar, it displays information about the reading level of the document.

**OR use an Internet Readability Checker**.

UPLOAD TWO COPIES OF THE CONSENT FORM:

ONE COPY with the numbers, AND

ONE COPY exactly the way your participants will see it. DELETE all instructions, checklist numbers, and suggested language that is not applicable. This will be the official copy that will be stamped and must be used for all participants.

**Consent to Participate in Research**

You are invited to participate in a research study (1). This research, to be conducted by *(name, title, department), [If student, add* under the supervision of *(name, title, department)]*, is designed to *(briefly explain what the study is about in layperson’s language - but not in a way which might bias your participants)*.(2)

Participation in this study will require about *(amount of time; include details if there are multiple sessions or time commitments)*.(3) As a participant in this research, you will be asked to *(clearly explain exactly what you will do and what you expect your participants to do, including whether you will be audio or videotaping)*.(4)

[*For all deception studies include*: Research designs often require that the full intent of the study not be explained prior to participation. Although we have described the general nature of the tasks that you will be asked to perform, the full intent of the study will not be explained to you until after the completion of the study. At that time, we will provide you with a full debriefing which will include an explanation of the hypothesis that was tested and other relevant background information pertaining to the study. You will also be given an opportunity to ask any question you might have about the hypothesis and the procedures used in the study.(13)*]*

*Option 1.*  This research is anonymous. No information will be collected would identify you. (5) OR

*Option 2.*  I will keep your information strictly confidential. All notes and questionnaires will receive a code number and be kept separate from your signed consent form. The list which has your name and code number will be kept in a locked file in the *(name of department)* at the College of Charleston and destroyed when the research is complete. At no time will you be able to be identified in any reports or publications which result from this research. (5)

OR

*Option 3.*  *If you will be identifying people by name and/or title include the following.* I will keep your information strictly confidential. However, If you are willing to permit me to quote you in the report of my research, please check the item just above the signature line. You will be given an opportunity to review the section of my report in which your quote appears before completion of my research.(5)

*Additional statements which may be included if appropriate.*

The *(audio or video)*tape will be destroyed after it is transcribed.

OR

The *(audio or video)*tape will be kept for *(amount of time)* *(location)* for use in this research only OR for future research use OR for educational purposes.

Although it is not anticipated that you will benefit directly through your involvement in this study, this research is expected to benefit *(define the larger population)* by *(describe potential benefits to the larger population)***.**(6)

OR

Benefits that you may experience through participation in this study include *(describe potential benefits to the individual research participant, including any compensation to participant such as cash payment, gifts, free services, or extra credit in academic courses, and how it will be prorated if the participant withdraws).*(6)(7)

I know of no risk or discomfort associated with this research.(8)

OR

*[Explain potential risks and what remediation is available, for example, provide information about counseling services.]* (8)

Your participation is completely voluntary, and you may discontinue participation at any time. (10) Your consent is voluntary and may be withdrawn at any time. (19) *If appropriate add:* Your decision to participate or not, or to discontinue participating, will not result in any loss of benefits to which you are entitled OR will not have any effect on your grades in this class.(11)

Your personal data collected for this research will be stored until *[period for which the data will be stored OR if undetermined, method for determining length of data storage]*. Projected future use of your personal data includes *[details about any projected future use]*. (19)

If you have any questions concerning this research study please contact *(name of PI)* at (*telephone number)* or *(e-mail)*. *[If PI is a student, add* or my faculty advisor at (*telephone number)* or *(e-mail)]*. You may also contact Research Protections & Compliance on the Office of Research and Grants Administration, at 843-953-5885 or e-mail [compliance@cofc.edu](mailto:compliance@cofc.edu) if you have questions or concerns about research review at the College of Charleston or your rights as a research participant.(12) You will be given a copy of this form to keep.

**This research study has been approved by College of Charleston Institutional Review Board for the Protection of Human Research Participants and covers all relevant requirements of the EU General Data Protection Regulations.**

*OR - if the research qualifies under one of the EXEMPTION CATEGORIES:*

**This research has been reviewed by the Human Research Protections Program at the College of Charleston and covers all relevant requirements of the EU General Data Protection Regulations.**

***For ORAL CONSENT*** *(no participant signature) add only* I understand that mycompletion of the interviewOR survey OR questionnaire OR *[specify]* signifies my consent to participate in this research project.

OR

***For SIGNED CONSENT*** *include the section below.*

I have read this consent form, and I agree to participate in this research study. *If appropriate, add* and certify that I am at least 18 years old.

OR

The information in this consent form has been explained to me, and I have been given the opportunity to ask questions. *If appropriate, add* and certify that I am at least 18 years old.

*If appropriate, add*

In any reports or publications which result from this research,

I permit you to quote me \_\_\_ no \_\_\_ yes

AND/OR

You may use \_\_\_my name, \_\_\_ job title, \_\_\_pseudonym or \_\_\_other identifier *(specify appropriate identifier)*.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant Date

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Signature of Person Obtaining Consent Date

*OPTIONAL:* If you would you like to receive a copy of the results of this study, please print your contact information (mailing address or e-mail):