Virginia Department of Social Services
Consent Form Standards and Language
For Non-Medical Research

This Guidance document provides:

1. General Instructions about how to prepare and format the consent form.
2. Method-specific suggestions for types of research procedures.
3. Section-specific notes for each section of the consent form template.

General Instructions

The intent of the consent form standards is to provide clear consent information to increase potential research participants' understanding of research studies and better enable them to make decisions about participation. Follow these general instructions to help facilitate informed decision-making by participants:

- **Recommended Formatting**: Use reader-friendly formatting so the consent form looks easy to read.
    - Leave a 1-inch margin around the entire document.
    - Leave ample white space between headings and paragraphs, but do not double space within paragraphs.
    - Use subheadings, bullet lists and/or tables when appropriate.
    - Use black Arial or similar font, preferably 12-point size or larger.
- **Required VDSS Formatting**:
    - Footer: Leave the footer of the consent form blank, except for page numbers. The IRB will insert the assigned study number and IRB approval period in the footer.
    - Footer, right corner: Include page numbers ("Page X of Y" format). Also include any additional information (e.g., sponsor protocol number, version) as needed. A header is not necessary on the first page.
- **Required VDSS consent language**: If participants will be recruited from among VDSS/LDSS clients, include the following statement at the end of the first paragraph to underscore that participation in the research will have no impact on benefits or social services received. Also include the statement on assent form, information sheet and/or recruitment materials.

  "It is your decision whether or not to participate in the study. Your social services benefits will not change based on what you decide about the study. You can walk away from the study at any time. There is no penalty."

- **Question and Answer Format**: The question and answer format is considered best practice for consent forms. Write the consent form in conversational style, as if you were speaking to the reader. Section headings should be in question format. Answers should be in second person ("You" instead of "I") and active voice (e.g., "the researchers will ask you to…" instead of "you will be asked to…") whenever possible to engage the reader.

- **Reading level**: Write the consent form so it is understandable to a lay audience, e.g., 8th grade reading level or lower. The reading level of a document is more difficult if it contains long complex sentences. Whenever possible use words with three syllables or less, non-scientific words, simple sentences and break up the text into short straightforward sections. If using Microsoft Word, readability statistics are provided with the "Spelling & Grammar" check on the Review Ribbon. Other document readability tools are available via Internet[1]
- The **consent form** is for adult participation in research.
- **Parent permission** and proxy consent are for persons, such as legal guardians or appointed proxies, to provide legally authorized consent for minors or persons who cannot consent for themselves.
- **Parental permission/child assent forms:**
    - **Adolescents ages 13-17**: Create a single document addressed to the adolescent with signature lines for assent and parental permission. Two forms can be used when parents and adolescents are being asked to undergo different procedures, or for research involving older adolescents.
    - **Children ages 7-12:** Create two documents, one for parental permission and a separate simplified assent form for children. **Note:** Children are not required to sign the assent form. In some circumstances children may not be able to sign the assent form, but investigators are required to document in the research record that child assent is obtained. Every effort should be made to ensure that the assent form reading level is age appropriate.
- If the study involves using different consent forms for different populations, identify the population group as the subtitle of the form.
- The use of subheadings helps to organize long descriptions of procedures or risks and increases readability.
- Scientific terms should be defined and explained. Define in lay language all technical terms, concepts, and terminology throughout the consent form. Lay language is language that can be easily understood by the general public.
- An Investigator's Signature block is not required if a one-on-one consent process will not occur. (Examples include questionnaires that are distributed and returned via mail with a consent form/letter enclosed, or surveys posted on the web).

Method-Specific Suggestions

FOR FOCUS GROUPS

- Include in the "Confidentiality" section information about the limits to participants' confidentiality which are presented by participating in a group discussion for example, "All

[1] Readability statistics may include Flesch Kincaid Reading Ease, Flesch Kincaid Grade Level, SMOG Index, passive language, and Automated Readability Index (ARI)

participants will be asked to keep what is said during the group discussion between the participants only. However, complete confidentiality cannot be guaranteed."

FOR SURVEYS, INTERVIEWS, QUESTIONNARIES, OBSERVATIONS

- Add the following statement to this section if the research procedures involve or include surveys, questionnaires, or interviews: "You may refuse to answer any questions that you do not want to answer and still remain in the study."
- If individual interviews will be audio- or video-taped, consideration should be given to the option of offering participants the right to review, edit or erase the research tapes. If you think this option should be offered you may insert the following statement in the confidentiality" section: "You have the right to review the tapes made as part of the study to determine whether they should be edited or erased in whole or in part."
- Also explain who will have access to the tapes, if they will be used for educational or other purposes, and if/when they will be erased.

WHEN PARTICIPANTS ARE MINORS

- Include the following statement in the "Procedures" sections of assent forms ONLY if participants' parents' permission will be obtained: Please talk this over with your parents before you decide whether or not to participate. We will also ask your parents to give their permission for you to take part in the study. But even if your parents say "yes" you can still decide not to do this.
- If you are requesting that the IRB waive the requirement for parental permission, do not include the above statement in the youth or child assent forms.

WHEN RESEARCH WILL INVOLVE DECEPTION OR WITHHOLDING OF INFORMATION

- If you intend to withhold information about the real purpose of the study or purposely give subjects false information about some aspect of the research, include one of the following statements in the introductory paragraph of the consent form:

  For scientific reasons, this consent form does not include complete information about the study hypotheses and the research questions being tested. You will be fully debriefed following your participation in the research.

  OR

We cannot tell you every detail of this study ahead of time, but if you are willing to participate under these conditions, we will explain the procedure to you fully after your participation.

OR

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 questions you might have about the hypothesis and the procedures used in the study.

WHEN YOU INTEND TO RECONTACT FOR FUTURE RESEARCH

- If you wish to ask participants to consent to future contact for additional studies, provide check boxes before the "Subject's Signature" block for participants to accept or decline to be contacted for other studies in the future. See example below:

CONTACT FOR FUTURE STUDIES

Please check the appropriate box below and initial:

___ I agree to be contacted for future research studies

___ I do NOT agree to be contacted for future research studies

POTENTIAL USES OF DATA / IMAGES

If you wish to ask participants to consent to various potential uses of their data:

- Include the following statement in the "Confidentiality" section of the consent form:

On the checklist at the end of this consent form, you will be asked to indicate if you would permit the researchers to include <insert type of data, (e.g., videos, transcripts) > of your study participation in <insert potential uses of data (e.g., articles, conference proceedings >).

- Provide check boxes before the "Subject's Signature" block for participants to accept or decline to allow the various potential uses of their data. Format according to example below:

Please check the appropriate box below and initial:

___ I agree to allow <insert TYPE of data> to be used for <insert USE of data>

___ I do NOT agree to allow <insert TYPE of data> to be used for <insert USE of data>

SECTION-SPECIFIC NOTES

INTRODUCTORY PARAGRAPH

- If Principal Investigator is a student, include a statement that the research is being conducted for your senior project, thesis or dissertation, and identify your faculty sponsor.

POTENTIAL BENEFITS TO PARTICIPANTS AND/OR TO SOCIETY section

- As benefits are not known prior to completion of the research, use "may" instead of "will" when describing potential benefits. (e.g., The results of the research may benefit you/society ...;

PAYMENT FOR PARTICIPATION

- Section - All consent and assent forms: Note that remuneration provided to participants should be described only in the "Payment for Participation" section, and not in the "Benefits" section.
- If subject will receive payment, describe method and amount. Describe payment (may be prorated if appropriate) should the subject decide to withdraw or be withdrawn by the investigator. For example:

  You will receive $10 payment for participation. If you start but do not complete the survey, or if you skip any questions, you will still receive $10.

  You will receive $25 payment for participation in the focus group discussion. If you choose to leave before the discussion ends, you will receive full payment for participation.

  You will receive $50 payment for participation in the focus group discussion. If you choose to leave before the discussion ends, you will receive a partial payment of $____ for participation.

CONFIDENTIALITY

- Audio- or Video-taping: If individual interviews will be audio- or video-taped, consideration should be given to the option of offering participants the right to review, edit or erase the research tapes. If you think this option should be offered you may insert the following statement in the “Confidentiality” section: “You have the right to review the tapes made as part of the study to determine whether they should be edited or erased in whole or in part.”

- Also explain who will have access, if they will be used for educational purpose, and if/when they will be erased.
- Focus Groups: Include in the “Confidentiality” section information about the limits to participants’ confidentiality which are presented by participating in a group discussion. e.g., “All participants will be asked to keep what is said during the group discussion between the participants only. However, complete confidentiality cannot be guaranteed.”
- When research data is collected anonymously: If participation in the research will be anonymous, the following statement included in the "Confidentiality" section of the consent form template should be removed: Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Instead, the Confidentiality section should include a statement indicating that participation will be anonymous. e.g., "Your participation in this research will be completely anonymous. No personally identifiable information will be collected from you at any point in this study."
- When appropriate, the "Confidentiality" section should also include a statement advising the participants not to include any identifiable information on the research instruments. e.g., "Please do not write your name or any other identifiable information on the survey."
- When research data is shared with other researchers: If information will be released to any other party for any reason, identify the person/agency to whom the information will be furnished, specify the nature of the information released, and the purpose of the disclosure.

PARTICIPATION AND WITHDRAWAL

- Surveys, Questionnaires, Interviews: Add the following statement to this section if the research procedures involve or include surveys, questionnaires, or interviews: "You may refuse to answer any questions that you do not want to answer and still remain in the study."
- Include the following sentence only if there are circumstances in which the investigator would withdraw participants from participation in the research (e.g., no longer meets eligibility criteria, condition changes such that continuing participation in the research would pose undue risk to the subject, etc.).
- The investigator may withdraw you from this research if circumstances arise which warrant doing so.
- If you include the sentence, also describe the anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's assent. If there are no such circumstances, do not include this sentence in the consent or assent form.
- Inform participants about how to withdraw from the study.

IDENTIFICATION OF INVESTIGATORS

- If Principal Investigator is a student, identify your faculty sponsor in the "Identification of Investigators" section.

SIGNATURE OF INVESTIGATOR

- The "Signature of Investigator" section is intended to be used by the investigator (or designated member of the research team) to document that as part of the informed consent process the investigator/designee has ascertained that the subject has understood the information provided in the informed consent process.
- If an in-person consent process is not conducted (e.g., consent letter is mailed to subject, who is asked to mail completed survey if they agree to participate), the "Signature of Investigator" section should not be included on the consent document.
- **Please note**: The consent form should be signed by the member of the research team who conducts the informed consent process with the subject, and all persons who will conduct the consent process must be identified in the "Process of Consent" section of the IRB application and approved by the VDSS IRB.
- Ensure that you have a process in place to provide participants a copy of the fully signed consent document.