**VALENCIA COLLEGE: Sample Forms**

**Human Research Protection (HRP) Institutional Review Board (IRB)**

Participant Informed Consent Form (for Internal and External Investigators)

Informed consent means that research participants need to have sufficient information about the project in which they are being asked to become involved so that they have a general understanding of the research before they volunteer to participate. **The information given to prospective participants (and/or their representatives) must be in language they can understand.**

**The information contained in your Participant Informed Consent Form should provide sufficient details about what the participant will be asked to do and must match what you have stated in your IRB Protocol Initial Submission Form (or, if applicable, reflect modifications as described in your IRB Continuing Review/Termination Form or IRB Addendum/Modification Form). The following suggestions are offered as guidelines; the exact language of the informed consent form is the decision of the researcher and should be age and language-appropriate.**

**SECTION 1 - SAMPLE INFORMED CONSENT FORM:**

The following sample Participant Informed Consent Form includes a side-by-side table that lists the required components of informed consent along with some suggested wording.

SAMPLE PARTICIPANT INFORMED CONSENT FORM

[Date]

Dear [Student/Parent/Sir/Madam]:

| **Required Components of Informed Consent** | **Sample Wording** |
| --- | --- |
| 1. Statement of purpose of the study. | We are conducting a study to determine \_\_\_\_\_. |
| 2. Short description of methodology and duration of participant involvement. | In this study, [you/your child] will be asked to \_\_\_\_\_\_\_. Participation should take about \_\_\_ minutes/hours/days/weeks/months]. |
| 3. Statement of risks/benefits to the participants (including remuneration, if applicable). | There are no risks to [you/your child].  ***OR***  The only risks to [you/your child] include \_\_\_\_\_. |
| 4. Statement of data confidentiality. (Note: “confidential” means that the researchers will know the names of the participants, whereas “anonymous” means that the researchers will not know the names of the participants.) | All information will be handled in a strictly confidential manner, subject to the disclosure requirements of Florida Sunshine Laws, so that no one will be able to identify [you/your child] when the results are recorded/reported.  ***OR***  All information will be submitted anonymously, so that no one will be able to identify [you/your child] when the results are recorded/reported.  ***AND***  All information is subject to the Family Educational Rights and Privacy Act (FERPA) of 1974, which is designed to protect the privacy of educational records. |
| 5. Statement regarding the right of the participant to withdraw from the study at any time without negative consequences. | [Your/your child's] participation in this study is totally voluntary and you may withdraw at any time without negative consequences. To withdraw at any time during the study, simply contact [name, title of Principal Investigator] at [phone number, email address], or [mailing address] |
| 6. An offer to answer any questions the participant may have. | Please feel free to contact [name(s), title(s) of all investigators] at [phone number(s)] if you have any questions about the study. |
| 7. Contact information for Valencia’s IRB. | Or, for other questions, contact the Chair of Valencia’s Institutional Review Board at irb@valenciacollege.edu. |
| 8. Line for signature of participants and/or parents or legal guardian, and statement that participant is 18 years of age or older unless parent or legal guardian has given consent | *If the participant is of age (18 years old or older), use:*  I understand the study described above and have been given a copy of the description as outlined above. I am 18 years of age or older and I agree to participate.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Participant Date  ***OR***  *If the participant is not of age so parent/guardian will be signing, use:*  I understand the study described above and have been given a copy of the description as outlined above. I agree to allow my child to participate with his/her assent when possible.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Parent/Guardian Date  ***AND***  *ASSENT format (see Section 4):*  I understand what I must do in this study and I want to take part in the study.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Child Date  ***OR***  *If the research is minimal risk and anonymous and you are requesting a waiver of documentation of consent (see Section 2), use:*  I am at least 18 years of age and completing this [survey] constitutes my informed consent. |

A copy of the Participant Informed Consent Form must be given to the signatory, along with copies of any research materials that are provided to the participants and/or their parents/guardians (e.g., recruitment materials, description of the research, lists of questions).

If you will only be seeking participants who are 18 years of age or older, it is recommended that you include the statement “You must be 18 years of age or older to participate in this research” at the top of your Participant Informed Consent Form so that it is clearly visible.

**SECTION 2 - WAIVER OF DOCUMENTATION OF CONSENT:**

You may request a waiver of documentation of consent (just state this in Section 4 of your IRB Protocol Initial Submission Form) if your research is minimal risk, truly anonymous, and you do not need to know who completed which survey. By using the waiver of documentation of consent, you must still provide participants with a consent form/letter, but participants do not have to sign the form. You may convert the sample consent form above to a waiver of documentation of consent by removing the signature lines and removing any reference to signing. The title of the form should remain “Participant Informed Consent Form.”

Federal regulations provide for seven (7) “minimal risk” categories, and four (4) of those categories are related to medical research. Because Valencia does not typically conduct medical research, only the three (3) non-medical-related minimal risk categories are described below. If your activity is related to medical research, please contact the IRB Chair. The three (3) non-medical-related minimal risk categories are:

1. research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
2. collection of data from voice, video, digital, or image recordings made for research purposes.
3. research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

**SECTION 3 - DECEPTION:**

In situations where participants will be **intentionally deceived as part of the research process**, items 1 and 2 of the sample informed consent in Section 1 areomitted and participants are told (on the signed form) that disclosure of the purpose and/or methodology could bias the outcome of the study. In this case, **after the study is complete,** each participant must be presented with a description of the purpose and methodology as carried out and a debriefing document must be signed by the participants “after the fact” in order to guarantee informed consent. If deception is part of your research, the following is suggested debriefing format:

SAMPLE DEBRIEFING DOCUMENT FOR DECEPTION RESEARCH

Thank you for your participation in this experiment. As you may have gathered from the activity, we are interested in \_\_\_\_\_\_\_\_\_. The research activity that you participated in was designed to \_\_\_\_\_\_\_. We will be combining your results with the results of others to determine \_\_\_\_\_\_\_\_\_\_\_\_.

If you do not wish for your results to be part of this study, please inform the experimenter at this time. If you have any questions, comments, or concerns, or would like a copy of the final results, contact \_\_\_\_\_\_.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_**

Participant’s Signature Participant’s Printed Name Date

(or Parent/Guardian)

**SECTION 4 – CHILDREN:**

For participants less than 18 years of age, the researcher must obtain the informed consent of a parent or legal guardian and all reasonable attempts must be made to obtain each participant's ***assent***, which is defined as the participant's agreementto participate in the study. Documentation of this assent must be signed by the child (or the parent/guardian if the child is too young to sign) and a witness (not the person obtaining the assent).

If your participants will be children of elementary age or younger, you should consider obtaining the child’s assent by reading the informed consent information to prospective participants instead of presenting only a written document.

SAMPLE CHILD’S ASSENT SCRIPT

My name is \_\_\_\_\_\_ and I am \_\_\_\_\_\_ at Valencia College. I am interested in how students like you \_\_\_\_ and I would like to ask you some questions. You may stop at any time and you will not have to answer any questions you do not want to answer. If you don’t want to do this, it is OK and your [parent/teacher] will find something else for you to do. Would you like to do this?

If the child is old enough to sign his/her name, have your script printed out on a piece of paper with the following:

I want to participate in \_\_\_\_\_\_\_’s research project.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_**

Student’s Signature Student’s Printed Name Date

(or Parent/Legal Guardian)

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

Witness’ Signature Witness’ Printed Name

If the child is not old enough to sign his/her name, the child must clearly say “Yes” and you must document in writing on the assent form that the child said “Yes.” A witness should sign this written documentation. A nod of the head or other physical gesture alone is NOT acceptable as evidence of assent.

**SECTION 5 – VERBAL RESEARCH:**

If your methodology involves verbal questioning (such as telephone surveys) where obtaining written consent is difficult, here is some suggested wording:

SAMPLE ADULT VERBAL CONSENT SCRIPT

(Telephone survey sample)

Hi, my name is \_\_\_\_\_\_\_. I am a \_\_\_\_\_\_\_ at Valencia College and we are doing a survey for \_\_\_\_\_\_\_\_\_. The survey is really short and only takes about 5 minutes. I can only interview people who are 18 years of age or older. Are you at least 18? (If yes, continue; if no, May I please speak to anyone in the household who is at least 18)

(Add as necessary to assure respondent) Let me stress that your participation in this survey is completely voluntary and confidential, subject to the disclosure requirements of Florida Sunshine Laws. Do you have any questions you want to ask about the survey? You will not be identified by name in any document we produce. We are interviewing approximately \_\_\_\_ people and your answers will be combined with everyone else’s. You have the right to refuse to answer any question you want. You may also terminate the interview at any time.

Proceed with survey questions approved by the IRB.

**SECTION 6 – ONLINE RESEARCH:**

If the research process involves an online survey, the survey should open up with a consent letter being displayed first and instructions for the participant to click the accept button if they want to participate. An https-type secured site is preferred for confidentiality purposes (subject to the disclosure requirements of Florida Sunshine Laws).