

DOCUMENTING INFORMED CONSENT

Each application submitted to the HSRRC for review must include a thorough description of the process by which consent will be obtained from subjects, as well as a copy of the consent form which the investigator proposes to use. The Committee will review the form to ensure that it meets federal and University requirements (*see “Elements of Informed Consent,” “Model Consents” and “Informed Consent Checklist,” this section*) and, once approved, neither the process or form may be altered without Committee approval. In the case of signed informed consent, the investigator must not only provide each participant with a signed copy, but keep one for his or her records, as well.

Signed informed consent must be obtained from all prospective subjects or their legally authorized representatives, unless this requirement is waived by the HSRRC. The Committee is likely to grant a waiver of signed consent if a) the only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality; each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or b) the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Such a waiver does not eliminate the need for subjects to give their informed consent, however. In cases in which the signature requirement is waived, the IRB will require the investigator to provide subjects with a cover letter, which must contain all the elements of a consent form, but does not have any identifiers or other information which could link the subject to the study, nor does it require a signature.

ELEMENTS OF INFORMED CONSENT

- The consent should be written in the second person (*see “Model Consents” below*), as first person may be considered too suggestive or coercive
- The name of the researcher and his or her affiliation must be clearly stated
- The study and its purpose should be briefly explained
- All procedures and activities to be conducted during the course of the research by participants, including their duration, frequency and locale must be explained
- All potential risks or discomforts, along with their respective safeguards, must be clearly stated
- Benefits to participation, whether direct or indirect, should be outlined
- A statement indicating that participation is voluntary and that the subject may withdraw at any time without penalty should be included
- The extent to which confidentiality can or will be maintained should be clearly defined
- Contact info, including address and telephone number, for both the researcher *and* the HSRRC must be included
- There must be an indication that the subject will receive a copy of the form for his/her own records
- If the researcher is working with children or a vulnerable population, “Special Topics” must be consulted for additional informed consent elements (*see section VI, “Special Topics”*)
- The entire consent must be written in language that is readily understandable to the average subject (for adults, this usually means the 7th grade level)
- Faculty and staff should consider printing informed consents and cover letters on organizational letterhead

MODEL ADULT CONSENT*

(letterhead stationary as appropriate)

Title of Study

You are invited to participate in a research study conducted by [*name of investigator*] from Portland State University, [*departmental affiliation*]. The researcher hopes to learn [*state what the study is designed to discover or establish; if you are a student, please also indicate that the study is being conducted in partial fulfillment of the requirements for a master's or doctoral degree, and indicate that it is under the supervision of a specific faculty member at PSU*]. You were selected as a possible participant in this study because [*state why subject was selected*].

If you decide to participate, you will be asked to [*describe procedures and activities, their purpose, duration, location and frequency; if these activities are to be audio- or videotaped, please indicate this*]. While participating in this study, it is possible that [*describe all possible risks, discomforts and inconveniences, and explain how you will safeguard against them; describe any alternative procedures or courses of treatment, if applicable*]. You may not receive any direct benefit from taking part in this study, but the study may help to increase knowledge which may help others in the future. [*If this is not the case, then include a statement about likely benefits, including any compensation which will be offered to participants.*]

Any information that is obtained in connection with this study and that can be linked to you or identify you will be kept confidential [*If this is not the case, and subjects will be identified by name or otherwise in a paper, thesis, dissertation, journal or newspaper article, on the web or in a presentation, a statement must be added to that effect. If information will be released to any other party for any reason, please state the nature of such information, identify the person or agency to whom it will be furnished, and the purpose of such a disclosure*]. This information will be kept confidential by [*describe coding methods (if any) and data storage procedures*].**

Your participation is voluntary. You do not have to take part in this study, and it will not affect your [*course grade or relationship*] with [*name the institution or organization with which the researcher is affiliated*]. You may also withdraw from this study at any time without affecting your [*course grade or relationship*] with [*institution or organization mentioned above*].

If you have concerns or problems about your participation in this study or your rights as a research subject, please contact the Human Subjects Research Review Committee, Office of Research and Sponsored Projects, 600 Unitus Bldg., Portland State University, (503) 725-4288 / 1-877-480-4400. If you have questions about the study itself, contact [*researcher's name*] at [*address and telephone number*].

Your signature indicates that you have read and understand the above information and agree to take part in this study. Please understand that you may withdraw your consent at any time without penalty, and that, by signing, you are not waiving any legal claims, rights or remedies. The researcher will provide you with a copy of this form for your own records.

Signature

Date

*Please note that this is a model only and should be tailored to fit your own project specifications. Use this, together with the "Elements of Informed Consent" and "Informed Consent Checklist" to build your own consent form.

**Limits to confidentiality must be stated clearly, as well. The State of Oregon requires that all suspected or confirmed cases of child and elder abuse must be reported to authorities, and subjects must be informed of this limit if the nature of the research makes it likely that such a topic will be discussed.

MODEL CHILD ASSENT

Title of Study _____

Child's name _____

Your parents (or guardian) have said that it is okay for you to take part in a project about *[insert brief description of project here]*. If you choose to do it, you will be asked to *[insert description of the activities which participation will require, as well as an estimate of the amount of time involved]*.

If you want to rest, or stop completely, just tell me—you won't get into any trouble! In fact, if you don't want to do it at all, you don't have to. Just say so. Also, if you have any questions about what you will be doing, just ask me to explain.

If you do want to try it, please sign your name on the line below. Remember—you can stop to rest at any time, and if you decide not to take part anymore, let me know.

Signed _____ Date _____

MODEL COVER LETTER

Title of Study _____

Dear *[prospective subject's name]*:

My name is *[researcher's name]*, and I am a *[student/faculty member]* at *[institutional affiliation]*. I am beginning a study on *[brief description of research project]*, and would like to invite you to participate.

You are being asked to take part because *[explain why subject was selected]*. As part of the study, I am interested in your opinions and attitudes about *[list the theme or focus of research]*, and hope that the information I collect will help us to better understand *[insert subject or theme]*. If you decide to participate, you will be asked to *[provide a complete description of the activities required for participation]*, which involves answering questions about *[provide specifics, such as "substance abuse" or "second language acquirement"]*. It should take approximately *[provide a time estimate]* to complete.

As a result of this study, you may *[describe any risks involved]*. However, I assure you that *[detail safeguards which will be implemented in order to prevent risk]*. You may not receive any direct benefit from taking part in this study, but the study may help to increase knowledge that may help others in the future. *[If this is not the case, then include a statement about likely benefits, including any compensation which will be offered to participants.]*

Any information that is obtained in connection with this study and that can be linked to you or identify you will be kept confidential *[If this is not the case, and subjects will be identified by name or otherwise in a paper, thesis, dissertation, journal or newspaper article, on the web or in a presentation, a statement must be added to that effect. If information will be released to any other party for any reason, please state the nature of such information, identify the person or agency to whom it will be furnished, and the purpose of such a disclosure]*. Subject identities will be kept confidential by *[describe coding methods (if any) and data storage procedures].***

Participation is entirely voluntary. Your decision to participate or not will not affect your relationship with the researcher or with *[name of sponsoring institution]* in any way. If you decide to take part in the study, you may choose to withdraw at any time without penalty. Please keep a copy of this letter for your records.

If you have concerns or problems about your participation in this study or your rights as a research subject, please contact the Human Subjects Research Review Committee, Office of Research and Sponsored Projects, 600 Unitus Bldg., Portland State University, (503) 725-4288 / 1-877-480-4400. If you have questions about the study itself, contact *[researcher's name]* at *[address and telephone number]*.

Sincerely,
[Name of Investigator]
Affiliation

MODEL CONSENT FOR USE WITH SENSITIVE POPULATIONS

BE PART OF AN IMPORTANT PROJECT **The Mental Health and HIV Medication Adherence Study**

The Center for the Study of Mental Health Policy and Services at Portland State University's Regional Research Institute is doing a research study on how people who are living with HIV infection and a mental health condition are managing their healthcare, especially when it comes to medications.

What Will I Have To Do?

If you decide to take part in this project, we will ask you to talk with us for about 90 minutes. The interview will be on these topics:

- ▶ Your experience of living with HIV
- ▶ Your experience of living with a mental health condition
- ▶ Your experience of managing the medications that may have been prescribed for you
- ▶ Your relationship with your medical and mental health providers

Are There Any Risks?

HIV infection and mental health issues are very personal, we know. You do not have to take part in this study. If you do agree to take part, you may feel uncomfortable, angry, sad, guilty, scared or embarrassed because of some of the questions we ask. You don't have to answer any questions you don't want to. And if you don't want to go on, you can stop. If you are upset after the interview and need to talk with someone, you can call (insert name) _____ at the Regional Research Institute; she's the person leading the project in Portland. You will also get a list of organizations that may be able to help you with certain problems.

What Will I Get In Return?

1. \$25 for taking part in this study
You will get \$25 if you decide to be part of this study. You'll get the money as soon as the interview is done. The money is our way of saying Thank You For Your Time.
2. Money for transportation and/or childcare
You will get money, up to \$10, to pay for your transportation to and from the interview. If you have children, you will also get money, up to \$10, to pay for a babysitter.
3. Knowing you are helping others
Many people feel good about helping others. We can learn so much from you, and teach others how to live with HIV and a mental health condition.

What Are You Doing To Protect Me?

Your privacy is very important to us. We have done many things to protect you:

- ▶ We won't tell anyone if you take part in this study or not
- ▶ You will be interviewed alone. What you tell us will be kept private.
- ▶ Your name and what you tell us in the interview will be kept private to the extent allowed by law. (By "kept private" we mean that the names of people who take part in the study will not be given to anyone else. And it means that we will only reveal what you say in a way that no one could ever guess or know it was you who said it.) If, in the course of the interview you disclose that you are, or are intending to, harm yourself or others, we are ethically and legally required to notify the appropriate authorities.

- ▶ Only staff from the research project will know what you say. If you found out about this project at a clinic or through a social service agency, no one from the clinic or the agency will know what you say.
- ▶ Your name and other personal information, which we need in order to keep track of who we talk to, will be kept in a locked file cabinet or in a locked file on the computer so that no one other than the research staff will be able to see it. For example, this form (which has your name on it) will be kept in a locked file cabinet.
- ▶ When we write or talk about what we learned in this study, we will leave things out so no one will be able to tell who we are talking about.

Any Questions?

If you have any questions about this study, this form, or the interview, you can talk to your interviewer or to the person leading the project in Portland. (Insert name of P.I. and telephone #). You can also contact the Chair of the Human Subjects Committee of Portland State University about your rights as a research participant (someone who takes part in a study). Hours are 9:00 a.m. to 5:00 p.m. The office is located at Portland State University, Unitus Bldg., 6th floor, 2121 SW 4th Avenue, Portland, OR 97201. The telephone number is (503) 725-4288 / 1-877-480-4400, or send e-mail to: hsrrc@lists.pdx.edu.

If I Sign, What Does It Mean?

This is a consent form. Your signature below means that:

- ▶ You have read and understand what this form says.
- ▶ You are willing to take part in the study by talking with us in an interview.
- ▶ You know that you do not have to take part in this study. And even if you agree, you can change your mind and stop at any time. No problem
- ▶ If you found out about this study at a clinic, you know that taking part in this study has nothing to do with the care you get there. If you agree to take part or if you say no, they won't know and it won't matter. They will treat you the same.
- ▶ You will get a copy of this form to keep for yourself.

Participant Signature	Date	Participant name, printed
Interviewer Signature	Date	Interviewer name, printed