Informed Consent Template

This is a suggested template based on federal regulations, and should be adapted to be appropriate for your study. (See Informed Consent Tips.)

HHS regulations at 45 CFR 46.116 state that no investigator may involve a human being as a subject unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative.

Please feel free to contact the GSU -IRB at IRB@gram.edu about the changes to the form that may be best for your research. Please provide the contact information for the IRB Chair on your form so that participants have the option to contact someone not directly involved in the study.
INFORMED CONSENT

BE SURE TO INCLUDE THE FOLLOWING INFORMATION IN THE INFORMED CONSENT

DESCRIPTION OF THE RESEARCH: You (or “Your child”) are invited to participate in a research study on (describe project in non-technical language; include types of questions that will be asked if applicable; explain the purpose of the research). You will be asked to (describe procedures, mention video and audio-taping, if applicable, and what will become of tapes after use, e.g., shown at scientific meetings - sometimes, but not always, it is appropriate to destroy tapes). The research will be conducted by (e.g. researcher, researcher assistant, etc.) The research will be conducted at (specify location(s))

(If applicable) An interpreter will be used in this study (Describe: 1. How you will guarantee that the bilingual interpreter will maintain the confidentiality of the subjects? 2. Who the interpreter works for; and 3. How the interpreter was recruited for your study)?

RISKS AND BENEFITS: The risks and possible benefits associated with this study are (describe foreseeable risks or discomfort to subject). Explain any benefits of the study, even if those benefits are of indirect consequence to the subject. Also explain what will happen if the subject does not want to participate in all aspects of the study. (For instance, in a classroom if a student does not want to participate in an activity, will there be an alternative to the activity?)

Please note: The IRB does not consider any research to be “free of risk” or “no risk.” For example, use such language as “The research has the same amount of risk students will encounter during a usual classroom activity.”

PAYMENTS: (if applicable) What you will receive (describe reimbursement; where there is none, state so) as payment for your participation.

DATA STORAGE TO PROTECT CONFIDENTIALITY: The investigator should explain how subject confidentiality will be preserved, how data will be kept confidential and used for professional purposes, whether charts will be coded, and kept in locked files, etc. Remember that in a small college setting such as Bowdoin, even anonymous surveys may contain combinations of demographic information such that the subject is identifiable. Please state explicitly how these data will be protected.

TIME INVOLVEMENT: Your participation will take approximately (amount of time and duration of study in total).

HOW RESULTS WILL BE USED: The results of the study will be used (explain if result of the research will be used for your dissertation, conferences, if data will be presented at meetings, will data be published in journals, or articles, or used for educational purposes).
Grambling State University
SAMPLE

PARTICIPANT’S RIGHTS

Principal Investigator: _____________________________________________________________

Research Title: ______________________________________________________________

• I have read and discussed the Research Description with the researcher. I have had the opportunity to
ask questions about the purposes and procedures regarding this study.

• My participation in research is voluntary. I may refuse to participate or withdraw from participation at any
time without jeopardy to future medical care, employment, student status or other entitlements.

• The researcher may withdraw me from the research at his/her professional discretion.

• If, during the course of the study, significant new information that has been developed becomes available
which may relate to my willingness to continue to participate, the investigator will provide this information
to me.

• Any information derived from the research project that personally identifies me will not be voluntarily
released or disclosed without my separate consent, except as specifically required by law.

• If at any time I have any questions regarding the research or my participation, I can contact the
investigator, who will answer my questions. The investigator's phone number is (____)___________.

• If at any time I have comments or concerns regarding the conduct of the research or questions about my
rights as a research subject, I should contact the Grambling State University Institutional Review Board
Chair, Dr. Carolyn Jackson at jacksoncr@gram.edu or (318)274-2509. Dr. Jackson can also be reached
at IRB@gram.edu.

• I should receive a copy of the Research Description and this Participant's Rights document.

• If video and/or audio taping is part of this research, I ( ) consent to be audio/video taped.

• I ( ) do NOT consent to being video/audio taped.

• The written, video and/or audio taped materials will be viewed only by the principal investigator and
members of the research team.

• Written, video and/or audio taped materials

( ) may be viewed in an educational setting outside the research

( ) may NOT be viewed in an educational setting outside the research.

• My signature means that I agree to participate in this study.

Participant’s signature: ________________________________ Date:____/____/____

Name: ________________________________

If necessary: Guardian’s Signature/consent: ________________________________

Date:____/____/____ Name: ________________________________
Grambling State University
SAMPLE

Assent Form for Minors (8-17 years-old)

I ________________________________ (child’s name) agree to participate in the study entitled: _________________________________. The purpose and nature of the study has been fully explained to me by __________________________ (investigator’s name). I understand what is being asked of me, and should I have any questions, I know that I can contact __________________________ (investigator) at any time. I also understand that I can to quit the study any time I want to.

Name of Participant: ____________________________________

Signature of Participant: ________________________________________

Witness: _________________________________

Date: _______________________________

Investigator’s Verification of Explanation

I certify that I have carefully explained the purpose and nature of this research to __________________________ (participant’s name) in age-appropriate language. He/She has had the opportunity to discuss it with me in detail. I have answered all his/her questions and he/she provided the affirmative agreement (i.e. assent) to participate in this research.

Investigator’s Signature: ________________________________________

Date: _______________________________