INSTRUCTIONS FOR INFORMED CONSENT DOCUMENTS

The informed consent document is one part of the informed consent process. Thus, it is vital that the consent form be clear and understandable. Delays in the approval of IRB applications most commonly result from inadequate consent forms. These instructions are intended to assist researchers in the creation of their consent form documents.

General Requirements:

- All red text on the consent form template is for instructional purposes. PLEASE REMOVE RED TEXT prior to submission to the IRB, or in the case of the confidentiality section, change the color of text that is applicable to your research.
- The consent form template is the IRB's preferred format for subjects ages 16 and older.
- Consent forms should be written in second person's voice (e.g., you will be asked to complete questionnaires) EXCEPT the "Documentation of Informed Consent" section located just above where subjects sign the form that should be in first person.
- DO NOT use exculpatory language through which the subject is made to waive or appear to waive any of their legal rights, or releases or appears to release the researchers, the sponsors, the institution or its agents from liability for negligence.
- Correct all grammatical and typographical errors.
- The IRB requires the use of an "approved" consent form indicated by an approval stamp in the upper right-hand corner of the consent document.
- Please provide a space for subject's to initial and date at the bottom of all non-signature pages.

Readability:

- Consent forms should be written in simple lay language understandable to the subject. For adults, this is generally considered to be at the 8th grade reading level. DO NOT use jargon. To view examples of informed consent text written at various grade levels, please see the following: Readability Standards for Informed Consent Documents: (from the New England Journal of Medicine) http://content.nejm.org/cgi/content/full/348/8/721/T1

- Use at least a 12 point font. Certain populations (e.g., elderly populations) may require a larger font to improve readability.
- Spell out all acronyms and abbreviations, at least initially in the form.
- Use complete sentences except as noted in the bullet below.
- When explaining research procedures that are either numerous or complex, consider using either a bulleted list, sub-headings, flow chart, or diagram to improve subjects' comprehension of what they are asked to do.

Heading/Title:

- When using multiple consent forms for different subject groups, it is helpful for both IRB reviewers and researchers to change "Research Participant Consent Form" to something more descriptive of the subject population such as "Teacher Consent Form", "Student Consent Form Age 18 and Older", "Student Assent Form Grades 4-6", "Parent Consent Form", "Control Group Consent Form".
- The Title of Project typically matches the title of the IRB protocol. However there are times when this is inappropriate because it could compromise the research or otherwise would not be understandable by the subject population. When this occurs, please explain the reasoning within the protocol application narrative.
- Principal Investigator should be the PI listed on the IRB protocol.
- Research Project Number should reflect the reference number assigned to the IRB protocol once it has been submitted to the IRB. When the PI receives the consent forms stamped with the IRB's approval, the PI should include the reference number in the header.
- Once approved, the IRB will stamp the consent form with an approval stamp stating both the approval date and expiration date. The form cannot be used to recruit subjects after the expiration date. The PI will receive a copy of the stamped consent form and should make copies from that form to recruit subjects. Subjects should receive a copy of the consent form to keep for their own records.

Purpose of Research:

- Provide a non-technical explanation of the research project's purposes. Be clear that this is research. Explain why the subject is being recruited for the study (e.g., you are being asked to participate in the research project because…).

Specific Procedures:

- Provide a non-technical step-by-step explanation of the research project's procedures and number of sessions.
- When explaining research procedures that are either numerous or complex, consider using either a bulleted list, sub-headings, flow chart, or diagram to improve subjects' comprehension of what they are asked to do.
- Identify all data to be collected as well as how and where it will be collected.
- Identify any procedures that are experimental.
- Identify any alternative procedures or treatments that might be available to subjects.
- When conducting blood draws, biopsies or administering a procedure using metric measurements, translate the measurements into a commonly recognized measurement (e.g., 15cc of blood equals 1 tablespoon). If exposing a subject to radiation, identify the exposure in terms understandable to the subjects, such as the amount relative to a routine dental X-ray. If hearing experiments are conducted, compare the noise level to common noises (e.g., the decibel level is comparable to the sound of a vacuum cleaner).

Duration of Participation:

- Describe the amount of time subjects will be required to devote to the procedures (e.g. 3 hours per week for 12 weeks).
- Make certain the proposed duration is realistic for subjects to perform the procedures.

Risks:

- Describe any reasonably foreseeable risks, stressors or discomforts. The risks can be physical, psychological, economic, social, or legal. The consent form should address any risks that are noted in the IRB protocol.
- Describe what will be done to minimize these risks.
- When appropriate, a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus if the subject is or becomes pregnant) that are currently unforeseeable.
- When appropriate, a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

- If applicable, include any additional resources (e.g., counseling centers) available to assist subjects.
- If risks are minimal, please explain that they are no greater than the subject would encounter in daily life or during the performance of routine physical or psychological examinations or tests.
- If conducting research in areas that may trigger mandatory reporting requirements, this must be disclosed as a risk to subjects (e.g., child abuse and neglect, etc.).

Benefits:

- Describe any potential benefits to the subject which may reasonably be expected from the research, or a statement that there are no direct benefits to subjects, but that there may be benefits to general knowledge or to society.
- Benefits cannot be guaranteed or be implied to be guaranteed. Do not overstate benefits.
- If research involves treatment, disclose any appropriate alternative procedures or courses of treatment that might be available.
- Compensation or other incentives to participate in research are not considered benefits to subjects.

Compensation:

- Describe payments or other incentives (e.g. class credit, extra credit, gifts). Explain any schedule of payments.
- For research involving multiple sessions, payments should be pro-rated and not contingent upon study completion.
- If your payment procedures require a subject to sign a log or provide name, address and social security number to a Purdue University business office for the purpose of facilitating payment, please disclose this information. If uncertain about this, consult your department's business office.
- State whether pro-rated payments will be made if a subject withdraws from the study.
- When utilizing compensation that includes a drawing, identify the odds of winning

Extra Costs to Participate:

- Identify any costs related to the research that subjects may be required to pay (e.g., travel expenses, costs of medicines or other treatments, cost of study related supplies).

- If there are no extra costs to participate in the research, please state this.

Injury or Illness:

- This section is only required for studies that present greater than minimal risk to subjects. However its inclusion is optional for all other studies.
- Researchers should determine costs related to the injury or illness of a subject will be covered by the study and how those expenses will be paid. The Human Research Protection Program does not pay for these expenses.
- If researchers determine that the study will not cover such costs, the language "Purdue University will not provide medical treatment or financial compensation if you are injured or become ill as a result of participating in this research project. This does not waive any of your legal rights nor release any claim you might have based on negligence." should be used.

Confidentiality:

- Describe the extent, if any, to which confidentiality of records identifying the subjects will be maintained.
- Describe how identifiable research records, data, specimens, etc. will be stored and for how long. The IRB generally recommends locked storage, such as a cabinet, for identifiable information.
- Describe if research records, data, specimens, etc. will be de-identified and/or destroyed at a certain time. If records, data, specimens, etc. will be de-identified, disclose if a code key will be stored and when, if ever, it will be destroyed.
- This section must include the language, "The project's research records may be reviewed by [external funding agency, Food and Drug Administration (if FDA regulated), Office for Human Research Protections (if funded by DHHS)] and by departments at Purdue University responsible for regulatory and research oversight."
- When appropriate, disclose the approximate number of subjects involved in the study. For example, if there will be a low number of enrollees, there may be an increased risk of breach of confidentiality. Thus disclosing this added consideration would be appropriate.
- State where, how, and to whom results will be disseminated.

Voluntary Nature of Participation:

- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- When appropriate, the consequences of a subjects decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- When appropriate, anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
- If the study is conducted in a specific environment (e.g. school, health care facility, workplace, etc.), include a statement that the decision to participate or not participate in research will have no effect on the subject's relationship with that specific research site (e.g., school, workplace, health care facility).
- When appropriate, disclose the point where a subject would be unable to withdraw their data from the study. For example, if the data will be de-identified after the data collection and code key destroyed, please state that.

Contact Information:

- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research related injury to the subject.
- Add the following contact statement, "If you have any questions about this research project, you can contact [insert PI name and phone number plus any additional research personnel who participants may need to contact and their contact information. If more than one person is listed, please indicate the first point of contact]. If you have concerns about the treatment of research participants, you can contact the Institutional Review Board at Purdue University, Ernest C. Young Hall, Room 1032, 155 S. Grant St., West Lafayette, IN 47907-2114. The phone number for the Board is (765)494-5942. The email address is irb@purdue.edu."

Documentation of Informed Consent

- A statement that subjects have read the consent form and had the opportunities to ask questions and have the research explained.
- A statement they are prepared to participate in the research.

- A statement explaining they will receive a copy of the consent form.

Optional Elements:

- Future Use – When data from the research will be used for future research, future educational endeavors, or other future uses, that information must be disclosed to subjects. Such uses can be a requirement of participating in the study. However, it is often beneficial to both researchers and subjects to allow subjects the option to consent specifically for the future use. This can be done by adding a checkbox and language indicating the subjects consent to the future use. This language and checkbox should be placed after the signature portion of the consent form since it is requesting permission for activities other than the original research project.