MEMORANDUM

TO: Deans, Chairs, Directors, Faculty, Staff and Students

FROM: George A. Hedge, Vice Provost for Research

SUBJECT: University Policy Regarding the use of Human Subjects in Projects

Federal and university policies require that all projects conducted by faculty, staff and students using human subjects must be reviewed. The overall intent of the policy is to ensure that human subjects are treated physically, psychologically and socially in such a way as to minimize embarrassment and stress, and to avoid harm or other negative effects.

A project using human subjects must have Institutional Review Board (IRB) approval of the project's protocol. Prior to initiating any portion of the project, approval from the IRB must be received. It is especially important that students who use data gathered from human subjects for theses and dissertations be fully aware of university policies. Failure to comply with university review procedures may make it impossible for the Graduate School to accept theses or dissertations.

Protocols should be reviewed by department level committees prior to being submitted to the IRB for either an exempt review, expedited, or full board review. A Human Subject Workshop is offered each semester which explains the review criteria and procedures. Departmental reviewers, faculty and staff who are conducting projects that involves human subjects should attend.

Approval is valid for only ONE year and must be renewed if the protocol lasts longer or is modified during that period of time. An annual review may be initiated by the investigator or by OGRD. This review requires a summary of the current status of the project including what is left to be accomplished and an anticipated completion date. A copy of the current consent form should also be submitted. Whatever the initial review category was, the same review procedure will be followed for annual reviews.

If you have questions concerning these procedures, or the classification of a protocol, please contact OGRD for clarification. A summary of the current policy and the review forms are attached.
WASHINGTON STATE UNIVERSITY HUMAN SUBJECTS FORM

To receive approval from the WSU Institutional Review Board (IRB) for the use of human subjects, submit the following packet of materials to your department for initial review and signatures. Your department will forward the packet to the IRB for final review and approval. When your packet has been received by the IRB it will be checked for completeness. If not complete, it will be returned with a request for additional materials necessary for the review. To determine the level of review needed for your protocol turn to Section 2, Page 6.

PACKET CHECKLIST

EVERY PACKET MUST INCLUDE THE FOLLOWING MATERIALS.

1. Completed and Signed WSU Human Subjects Forms ___
2. Documentation of Consent Procedures (one or more of the following):
   a. Consent Form, ___
   b. Verbal Consent Script, ___
   c. Cover letter, ___
   d. Waiver Request ___
3. Any survey instruments or questionnaires to be used. ___
4. A list of interview questions or topics, in as much detail as possible. ___
5. If you are accessing protected health information (PHI), complete and attach a completed HIPAA Authorization Form & HIPAA Appendix A ___
6. Any advertisement or recruiting materials ___
7. Exempt protocols: Signed original ___
   Expedited Protocols: Signed original and two copies of items 1-5. ___
   Full Board Protocols: Signed original and 16 copies of items 1-5. ___
8. Original must be single-sided and not stapled. Copies may be stapled and double-sided.

AVOID THE TOP 5 MISTAKES PEOPLE MAKE WHEN SUBMITTING AN APPLICATION!

1. Stating that the data is anonymous when it is actually confidential (See Section 5, Definitions).
2. Not giving enough information as to who will have access to the data.
3. Stating there are no risks to a project. Even though the risks may be low, they need to be listed on the form.
4. The signature page does not have all the required signatures.
5. Consent forms and survey or interview instruments are not attached for review.

REVIEW TIMETABLE

Exempt reviews are reviewed as the packets are received and will take no more than 10 working days for approval once they have arrived at OGRD.

Expedited reviews are reviewed as the packets are received and will take about 12 working days for approval once they have arrived at OGRD.

Full Board reviews will be reviewed at the next monthly meeting of the IRB, if and only if the packets are received at OGRD at least 10 working days prior to the meeting date.

ELECTRONIC VERSIONS OF THIS FORM

Use contact number below to request copy.

WORLD WIDE WEB SITE at www.research-compliance.wsu.edu under IRB.

HOW TO CONTACT THE IRB

Phone: (509) 335-9661, Research Compliance Office
Campus Mail: campus zip 3140
Fax: (509) 335-1676
Email: irb@wsu.edu
Mail: WSU IRB, PO Box 643140, Pullman, WA, 99164-3140
SECTION 1

PLEASE TYPE. If you use an electronic version of this form, use a different font for your responses.
DO NOT leave a question blank. If a question does not apply to your protocol write “n/a.”

Principal Investigator(s) (PI):_____________________________________________________________

Department:___________________________________ Campus:___________________   Campus Zip:__________

Campus Building & Room #:___________________________________________________________

Status: Faculty______Adjunct Faculty______Staff______Graduate Student_____Undergraduate_____

Contact Phone Number:_____________________________  Contact Email Address:_____________________________

Mail Correspondence To:______________________________________________________________

Project Title:_____________________________________________________________

TYPE OF REVIEW:   EXEMPT___       EXPEDITED___ FULL BOARD___

Estimated project start date:____      ______
Estimated data collection completion date:____________

Is there, or will there be extramural funding that directly supports this research? YES ____             NO____

If yes, funding agency (s):_____________________________  PI on grant:_____________________________

OGRD# __________________

ABSTRACT:  Describe the purpose, research design and procedures. Clearly specify what the subjects will do.

I. DATA COLLECTION

A. Check the method(s) to be used (underline all items in the columns on the right that apply):

___ Survey: Administered by: investigator subject mail phone in person internet/email

___ Interview: one-on-one focus group oral history other

If you are using a survey or doing interviews, submit a copy of the survey items/ interview questions

___ Observation of Public Behavior: in classroom at public meetings other

___ Examination of Archived Data or Records: academic medical legal other (briefly describe)

___ Taste/Sensory Evaluation: food tasting olfactory

___ Examination of Pathological or Diagnostic Tissue Specimens

___ Therapeutic: biomedical psychological physical therapy

___ Experimental: biomedical psychological other

___ Other: Briefly Describe ____________________________

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WSU Human Subjects Form, Page 3
B. Data: Anonymous ___ Confidential ___ Intentionally identified___ (Please See Definitions, Section 5).

C. What form of consent will be obtained? (Please see Section 6 for sample consent and assent templates)
   a. Implied ___ (Please attach cover letter or describe terms.)
   b. Verbal ___ (Please attach consent script.)
   c. Written ___ (Please attach consent form.)
   d. Seeking Waiver of Consent ___ (Contact the IRB for further information.)
   e. Consent Not Applicable ___ (On a separate page explain why not.)

D. If anonymous or confidential, describe how anonymity or confidentiality will be maintained (e.g., coded to a master list and separated from data, locked cabinet, office, restricted computer, etc.). List all sites where data might be stored.

E. Who will have access to the data? Please be specific.

F. Will video tapes ___ audio tapes ___ photographs ___ be taken? YES ____ NO____
   If yes, where will tapes or photographs be stored?

G. When will all research materials be destroyed?

II. DESCRIPTION OF THE POPULATION (See Definitions, Section 5, Page 9)

1. Approximate number: __________ Age Range: __________
   How will subjects be selected or recruited and how will subjects be approached (or contacted)?

2. Will subjects be compensated* (include extra credit)? YES ____ NO____
   If yes, how much, when and how. Must they complete the project to be paid?

*NOTE: If students will be receiving extra credit for participation, they must be able to complete an alternative assignment for extra credit should they choose not to participate. This assignment must be comparable, with respect to time and effort, as participation in the research.
3. Are any subjects under 18 years of age?  

   YES____  NO____

4. Are any subjects not legally competent to give consent?  
   If yes, how will consent be obtained? From whom? Are there procedures for gaining assent?  
   (Please attach assent form.)

   YES ____ NO____

5. Will any ethnic group or gender be excluded from the study pool?  
   If yes, please justify the exclusion.

   YES ____ NO____

6. Is this study likely to involve any subjects who are not fluent in English?  
   If yes, please submit both the English and translated versions of consent forms and surveys, if applicable.

   YES ____ NO____

7. Does this study involve subjects located outside of the United States?  
   If yes, on an attached page please explain exactly “who the subjects are,” and the identities (if possible) and responsibilities of any additional investigators.

   YES ____ NO____

8. Does this study involve the use or creation of protected health information?  
   (See Section 5 for a definition of protected health information.) If yes, complete and submit HIPAA Appendix A, the HIPAA Authorization Form along with the completed human subjects application.

   YES ____ NO____

III. DECEPTION  (See Definitions, Section 5, Page 9)

   If any deception is required for the validity of this activity, explain why this is necessary.  Please include a description of when and how subjects will be debriefed regarding the deception, and attach a debriefing script.

IV. RISKS AND BENEFITS  (See Definitions, Section 5, Page 8)

   A. Describe any potential risks to the subjects, and describe how you will minimize these risks. These include stress, discomfort, social risks (e.g., embarrassment), legal risks, invasion of privacy, and side effects.

   B. In the event that any of these potential risks occur, how will it be handled (e.g., compensation, counseling, etc.)?

   C. Will this study interfere with any subjects' normal routine?  

      YES____  NO____
D. Describe the expected benefits to the individual subjects and those to society.

E. If blood or other biological specimens will be taken please address the following.

   Brief Description of Sampled Tissue(s): ___________________________________________

   Describe the personnel involved and procedure(s) for obtaining the specimen(s). Note that the IRB requires that only trained certified or licensed persons may draw blood. Contact the IRB for more details on this topic.

V. USE OF DATA COLLECTED (Check all that apply)

1. ___ Thesis/Dissertation
2. ___ Journal Article/Publication/Presentation
3. ___ Grant Activities
4. ___ Other: Briefly Describe: ________________________________________________

VI. PROJECT CHECKLIST (Attach additional pages as necessary.)

A. Will any investigational new drug (IND) be used? YES___ NO___

B. Will any other drugs be used? YES___ NO___
   If yes to A or B, on a separate page, list for each drug:
   1. the name and manufacturer of the drug,
   2. the IND number,
   3. the dosage,
   4. any side effects or toxicity, and
   5. how and by whom it will be administered.

C. Will alcohol be ingested by the subjects? YES___ NO___
   If yes, on a separate page, describe what type and how will it be administered. Refer to the guidelines for administration of ethyl alcohol in human experimentation (OGRD Memo No. 18 available at OGRD).

VII. FINANCIAL CONFLICT OF INTEREST

Does the researcher or any other person responsible for the design, conduct, or reporting of this research have an economic interest in or act as an officer or director of any outside entity whose financial interest would reasonably appear to be affected by the research? YES___ NO___

If yes, please answer the following:

If the economic interest involved is a "significant economic interest" as defined in WSU’s Conflict of Interest Policy, has a plan for managing, reducing or eliminating any conflict been established by the Conflict of Interest committee? YES___ NO___
SECTION 2

Is your project EXEMPT?

Federal regulations specify that certain types of research pose very low risks to subjects, and therefore requires minimal review from the IRB. To determine if your project is exempt, answer the following questions.

1. Will subjects be asked to report their own or others’ sexual experiences, alcohol or drug use, and will their identities be known to you? YES__ NO__

2. Are the subjects’ data directly or indirectly identifiable, and could these data place subjects at risk (criminal or civil liability), or might they be damaging to subjects' financial standing, employability or reputation? YES__ NO__

3. Are any subjects confined in a correctional or detention facility? YES__ NO__

4. Are subjects used who may not be legally competent? YES__ NO__

5. Are personal records (medical, academic, etc.) used with identifiers and without written consent? YES__ NO__

6. Will alcohol or drugs be administered? YES__ NO__

7. Will blood/body fluids be drawn? YES__ NO__

8. Will specimens obtained from an autopsy be used? YES__ NO__

9. Will you be using pregnant women by design? YES__ NO__

10. Are live fetuses subjects in this research? YES__ NO__

If you answered YES to any of the questions above, then your project is NOT exempt, but may still qualify for expedited review (see Section 3, Page 7).

If you answered NO to the questions, your research might be EXEMPT if it fits into one of the following categories.

(Circle or Underline all that apply)

1. Educational Research: Research conducted in established or commonly accepted educational settings, involving normal educational practices. This is for research that is concerned with improving educational practice.

2. Surveys, Questionnaires, Interviews, or Observation of Public Behavior. To meet this exemption, the subject matter must not involve “sensitive” topics, such as criminal or sexual behavior, alcohol or drug use on the part of the subjects, unless they are conducted in a manner that guarantees anonymity for the subjects.

3. Surveys, Questionnaires, Interviews or Observation of Public Behavior. Surveys that involve sensitive information and subjects’ identities are known to the researcher may still be exempt if: (1) the subjects are elected to appointed public officials or candidates for public office; or (2) federal statute(s) specify without exception that confidentiality will be maintained throughout the research and thereafter.

4. Archival Research. Research involving the collection or study of existing data, documents, records, pathological or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. These data/samples must be preexisting, which means they were collected prior to the current project.

5. Research Examining Public Benefit or Public Service Programs. To qualify for this exemption, the research must also be conducted by or subject to review by an authorized representative of the program in question. Studies in this category are still exempt if they use pregnant women by design and their purpose is to examine benefit programs specifically for pregnant women.

6. Taste Evaluation Research. Studies of taste and food quality evaluation. Studies of taste evaluation qualify for this exemption only if (1) wholesome foods without additives are consumed; or (2) if a food is consumed that contains a food ingredient at or below the level of and for a use found to be safe.

FINAL QUESTION: Are any subjects under 18 years of age? YES__ NO__

If your study uses subjects under 18 years of age, and you plan to use surveys, questionnaires or do interviews, then your project is NOT exempt. All other exemptions apply even if subjects are under the age of 18.

If you answered NO to the questions and your study fits into one of the six categories, then your project is EXEMPT.
SECTION 3

Does your study qualify for EXPEDITED review?

Expedited Reviews

Expedited reviews are for studies involving no more than minimal risk or for minor changes in previously approved protocols. To meet expedited review criteria your protocol must meet the following conditions: no more than minimal risk to the subjects, subjects must not be confined in a correctional or detention facility, and one or more of the following types of participation on the part of subjects.

(Circle or Underline any that apply to your project)

1. **Collection of excreta and external secretions**: sweat, saliva, placenta, and/or amniotic fluid. None of these may be collected by "invasive" procedures, such as those that use cannulae or hypodermic needles, such as in amniocentesis.
2. **Recording of data using noninvasive procedures routinely employed in clinical practice**. This includes but is not limited to the use of "contact" recording electrodes, weighing, tests of sensory acuity, electrocardiography and electroencephalography, and measures of naturally occurring radioactivity. This does NOT include procedures which: a) impart matter or significant amounts of energy to the subjects, b) invade the subjects’ privacy, or c) expose subjects to significant electromagnetic radiation outside the visible range (e.g. Ultraviolet light from tanning beds).
3. **Collection of hair or nail clippings, teeth from patients whose care requires the extraction or collection of plaque and/or calculus** using routine procedures for the cleaning of teeth.
4. **Voice recordings** made for research purposes such as investigations of speech defects and speech pathology.
5. **Moderate exercise** by healthy volunteers.
6. **Experimental research** on individual or group behavior or on the characteristics of individuals, such as studies of perception, cognition, game theory or test development. This does NOT include studies...
   ...that involve significant stress to the subjects.
   ...that are intended to produce a relatively lasting change in behavior.
7. **Studies of archived data, records or diagnostic specimens** that are not exempt.
8. **Studies involving the collection of blood samples** by venipuncture, in amounts not exceeding 550 ml (about a pint) in an eight week period and no more often two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

If your study fits into one of the eight types of participation and required criteria, then your project can receive EXPEDITED REVIEW.

SECTION 4

If your study does not meet exempt or expedited review criteria, then it qualifies for FULL BOARD review.

Full Board Reviews

Protocols that require full board review have the potential for high risks to subjects (physical, psychological or social) or those that have special population consent considerations (research on Native Americans, prisoners, persons who are not legally competent, ethnic considerations).
INVESTIGATOR’S ASSURANCES

This investigation involves the use of human subjects. I understand the university's policy concerning research involving human subjects and I agree...

1. ...to obtain voluntary and informed consent of persons who will participate in this study, as required by the IRB.
2. ...to report to the IRB any adverse effects on subjects which become apparent during the course of, or as a result of, the activities of the investigators.
3. ...to cooperate with members of the IRB charged with review of this project, and to give progress reports as required by the IRB.
4. ...to obtain prior approval from the IRB before amending or altering the project or before implementing changes in the approved consent form.
5. ...to maintain documentation of IRB approval, consent forms and/or procedures together with the data for at least three years after the project has been completed.
6. ...to treat subjects in the manner specified on this form.

Principal Investigator: The information provided in this form is accurate and the project will be conducted in accordance with the above assurances.

Signature_________________________ Print Name_________________________ Date________

Faculty Sponsor: (If P.I. is a student,) The information provided in this form is accurate and the project will be conducted in accordance with the above assurances.

Signature_________________________ Print Name_________________________ Date________

Chair, Director or Dean: This project will be conducted in accordance with the above assurances.

Signature_________________________ Print Name_________________________ Date________

When Section 1 is filled out and fully signed, review the Packet Checklist (Page 1) to complete the packet for review and submission.

Institutional Review Board: These assurances are acceptable and this project has adequate protections for subjects. This project has been properly reviewed and filed, and is in compliance with federal, state, and university regulations.

Signature_________________________ Print Name_________________________ Date________

IRB ONLY: This protocol has been given- Exempt___ Expedited___ Full Board___ status.
SECTION 5

DEFINITIONS

ANONYMOUS: Subjects’ names are unknown to the investigator, not requested and not given. If the only time the investigator asks for a name is for a signature on a consent form, the investigator should use implied consent, to preserve anonymity.

ASSENT: Agreement by subjects not competent (e.g., children or cognitively impaired people) to give legally valid informed consent to participate in a study.

BENEFIT: A valued or desired outcome to the study that will be an advantage to the subjects participating.

CONFIDENTIAL: Subjects’ names are known to the investigator and are usually coded to a master list and/or kept separately from the data and results. This is usually used, for example, when the investigator must match test results with surveys or if there will be a follow-up survey. The investigator has a real need to know subjects’ names.

DECEPTION: The protocol is designed to withhold complete information when consent is obtained.

DIRECTLY or INDIRECTLY IDENTIFIABLE: Identities of individual subjects are kept by the investigator. If subjects’ identities are inseparable from data, then data are directly identifiable. If subjects’ identities are kept separate from data, with information connecting them maintained by codes and a master list, then data are indirectly identifiable. In either case, investigator must assure that confidentiality will be maintained, and must explain how subjects’ identities will be protected.

INFORMED CONSENT: Subjects’ voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in a study or to undergo a diagnostic, therapeutic or preventive procedure.

INTENTIONALLY IDENTIFIED: Subjects’ names are to be used in connection with their data when project results are presented to the public. This procedure is common for journalistic-type interview studies, where subjects are public figures or in oral histories. In these cases, the investigator should seek explicit consent from the subjects for the use of their names in connection with their data.

MINIMAL RISK: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed study is not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. The definition of minimal risk for research involving prisoners differ somewhat from that given for noninstitutionalized adults.

POPULATION: A group of people in society meeting certain criteria to be eligible as subjects in a project’s protocol.

PRINCIPAL INVESTIGATOR: The individual (s) with primary responsibility for the design and conduct of a project’s protocol.

PROTECTED HEALTH INFORMATION: health information, recorded in any form or medium that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual."

PROTOCOL: The formal design or plan of a study’s activity; specifically, the plan submitted to an IRB for review and to an agency for support. The protocol includes a description of the design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen (s), and the proposed methods of analysis that will be performed on the collected data.

RISK: The probability of harm or injury (physical, psychological, social or economic) occurring as a result of participation in a study. Both the probability and magnitude of possible harm may vary from minimal to significant.

SIGNIFICANT RISK: A study’s design that presents a potential for serious risk to the health, safety or welfare of the subjects.

SUBJECTS (HUMAN): Individuals whose physiologic or behavioral characteristics and responses are the object of study in a project. Under the federal regulations, subjects are defined as living individual(s) about whom an investigator conducting a study obtains: data through intervention or interaction with the individual; or identifiable private information.
SECTION 6

FREQUENTLY ASKED QUESTIONS CONCERNING CONSENT PROCEDURES

1. Do I need to get consent? Can I get a waiver from the consent requirements?

If you are using archived data, consent may not be necessary or even possible. Some data do not meet the definition of “archived data,” but researchers may still seek a waiver of consent requirements. Only studies with a restricted set of conditions may use this option, and each waiver request is separately reviewed and considered by the IRB.

2. What if I want to give my subjects anonymity?

You should not use a written consent form. Instead you can use a consent script (e.g., phone surveys) or a cover letter (e.g., mail surveys). These documents do the same basic job as a written consent form does informing subjects about the study and their rights. The only difference is that subjects do not sign their name.

3. Do I need to get consent if my project is exempt?

The requirement for some form of consent applies to ALL research, although most exempt projects (particularly mail or phone surveys) can use a consent script or cover letter (for implied consent).

4. What if I audio or video tape my subjects?

You will need to get written consent. The consent procedure needs to specify WHEN the tapes will be destroyed, WHERE they will be stored, and WHO will have access to the tapes. Use a version of the WRITTEN CONSENT FORM.

5. What if I want to intentionally identify individuals in my research report(s) (i.e., quote individuals who you interviewed and gave their identities)?

Then you will be required to get their written consent.

6. What if my project is BIOMEDICAL in nature?

Use the sample for written consent forms and the BIOMEDICAL CONSENT FORM CHECKLIST.

7. What are the special consent considerations for children?

If a child is between the ages of 7 and 18, then you should seek both written parental consent and child assent. The assent form language should be at about the same grade level as the child. If the child is between the ages of 3 and 7, then you should use a VERBAL ASSENT, which is a consent script with language appropriate for the child’s age. A child younger than age 3 is considered incapable of participating in the consent process. At all age levels, the final power of consent is usually left to the parents or guardians. More than one age-appropriate assent form may be necessary if the study covers a wide age span.

8. Are there laws that affect the consent process?

In the course of your research, if you become aware that any specific individual is in imminent danger of harming himself or others (i.e., due to acute depression) or is currently suffering mental or physical abuse, or abusing another individual, you are required by Washington state law to inform the appropriate authorities. If there is a reasonable chance that you may discover such information about your subjects, you must tell them of this requirement when you ask for their consent, because the law requires you to break confidentiality in these circumstances.
WASHINGTON STATE UNIVERSITY
CONSENT FORM

[TITLE OF ACTIVITY]

Researchers: [List names, academic/staff positions, divisions/departments, telephone numbers of investigators and co-investigators.]

24-hour emergency telephone number with name or position [when relevant, for studies involving more than minimal risk]

Researchers’ statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called ‘informed consent.’ We will give you a copy of this form for your records.

PURPOSE AND BENEFITS

[Provide a brief background and describe the purpose of the activity. For drug studies, state how many people will be in the study. Describe the expected benefits to individual subjects and/or society. State if subjects will not benefit from being in this study.]

PROCEDURES

[Describe the procedures involved. Include the commitment of time for each, the total amount of time involved, and how long the study will last. As appropriate, specify size of samples to be taken and names and doses of substances to be given. Describe questionnaires, surveys, and interviews and describe or provide examples of the most personal and sensitive questions you will ask. State that subjects may refuse to answer any question or item in any test, inventory, questionnaire, or interview. Include the use of medical, academic, or other records, photographs, audio, or visual recordings.]

RISKS, STRESS, OR DISCOMFORT

[Include information on the psycho-social and physical risks, including side effects, stress, discomforts, breach of confidentiality, or the invasion of privacy that might result from each procedure. Do not state that there are no risks or that risks “should be” minimal. If appropriate, state how side effects will be handled and whom the subject should contact in the event of an adverse reaction. If drugs are used, state that there may be unanticipated side effects. If investigational drugs are used, state that any information developed during the study that might affect subjects' willingness to participate you will provide it to them.]

OTHER INFORMATION
In studies involving interventions (educational, social, medical, or other) include descriptions of alternative procedures or standard care that are available if a subject chooses not to be in the study. State whether data will be confidential (linked to identifiers) or anonymous (no links). State who or what other agencies will have access to identifiable data. Describe how the data will be used and how long they will be retained. For drug and medical device studies regulated by the U.S. Food and Drug Administration, add: "The U.S. Food and Drug Administration (FDA) reserves the right to review study data which may contain identifying information." State that subjects may refuse to participate or may withdraw from the study at any time without penalty or loss of benefits to which they are otherwise entitled. Include a description of inducements (money, service, course credit) subjects may receive for participation. Indicate what costs subjects may immediately or ultimately have to bear. If applicable, state: "If you are injured as a direct result of study procedures, you will be (cared for by a member of the investigating team OR referred for appropriate treatment)." State who will be responsible for the cost of such treatment. If applicable, state that a copy of the consent form will be placed in the subject's medical, educational, personnel, or other record.

MEDICAL RECORDS ACCESS

In studies involving access to medical records or protected health information include a description of health information to be obtained/collected, how the information will be used, how long it will be retained, who will have access, how the information will be protected and stored and the participant’s right to revoke their authorization to access their health information. Authorization to access medical records can be obtained separately from the informed consent.

Printed name of researcher                        Signature of researcher                        Date

Subject’s statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have general questions about the research, I can ask one of the researchers listed above. If I have questions regarding my rights as a participant, I can call the WSU Institutional Review Board at (509)335-9661. This project has been reviewed and approved for human participation by the WSU IRB. [If relevant, add: I give permission to the researchers to use my medical records as described in this consent form.] I will receive a copy of this consent form.

Printed name of subject                        Signature of subject                        Date
Following are two sample assent forms. They are included as guides to you in construction of a child’s assent to be used in your project. Fill in the appropriate information and adjust to the specifics of your research.

NOTE:
*Do not include a statement to the effect that “your parent has agreed to allow you to take part in the study”. This implies the possibility of parental pressure for the child’s participation. Instead use “your parent is aware of this project”.
*Make sure you use age appropriate language. For example, do not use the same language for a third grade student as you would a graduate student.

#1

Sample Minor Assent Document

WASHINGTON STATE UNIVERSITY
ASSENT FORM
[TITLE OF ACTIVITY]

Researchers: [List names, academic/staff positions, divisions/departments, telephone numbers of investigators and co-investigators.]

24-hour emergency telephone number with name or position [when relevant, for studies involving more than minimal risk]

Your parent knows we are going to ask you to participate in this project/fill out this survey. We want to know about kids’ attitudes/experiences about topic of research. It will take amount of time of your time to complete the task. Your name will not be written anywhere on the research instrument. No one will know these answers came from you personally.

If you don’t want to participate, you can stop at any time. There will be no bad feelings if you don’t want to do this. You can ask questions if you do not understand any part of the study.

Do you understand? Is this OK?

Name (Please print):______________________________________________________

Signature: ______________________________________________________________

Date: ___________________________

Investigator’s Signature: ________________________________Date:_______________
Sample Minor Assent Document

WASHINGTON STATE UNIVERSITY
ASSENT FORM
[TITLE OF ACTIVITY]

Researchers: [List names, academic/staff positions, divisions/departments, telephone numbers of investigators and co-investigators.]

24-hour emergency telephone number with name or position [when relevant, for studies involving more than minimal risk]

We are doing a research study about purpose in simple language. A research study is a way to learn more about people. If you decide that you want to be part of this study, you will be asked to description, including time involved.

There are some things about this study you should know. There are procedures, things that take a long time, other risks, discomforts, etc.

Not everyone who takes part in this study will benefit. A benefit means that something good happens to you. We think these benefits might be description.

If you do not want to be in this research study, we will tell you what other kinds of treatments there are for you. This statement applies to research projects that offer treatment or intervention.

When we are finished with this study we will write a report about what was learned. This report will not include your name or that you were in the study.

You do not have to be in this study if you do not want to be. If you decide to stop after we begin, that’s okay too.

This study has been reviewed and approved by the WSU Institutional Review Board (IRB). If you have questions about this study, please contact the researcher at (phone #). If you have questions about your rights as a participant, please contact the WSU IRB at 509-335-9661.

If you decide you want to be in this study, please sign your name.

I, ___________________________________, want to be in this research study.
(Print your name here)

___________________________________  _______________
(Sign your name here)     (Date)

Parts in Italics should be modified for your specific project. Other parts may need to be modified as well depending on your research methods.
GUIDELINES FOR COMPOSING A BIOMEDICAL PROJECT CONSENT FORM

Determine if the consent form is going to be written using first person (I) or second person (you). The language should avoid technical medical terminology; use uncomplicated and understandable words. If technical terms must be used, clearly explain in simple language. (e.g., Placebo is an inactive medication or “sugar pill” or a placebo contains no medication.) Consider attaching a glossary of terms. The consent form should be tailored to the particular procedure and participant, avoiding irrelevant references, gender confusion, etc. The name of the investigator and telephone number should appear in the consent form.

BIOMEDICAL CONSENT FORM CHECKLIST

__Title of study
__Investigator name, title and phone number
__Investigator affiliation

HEADINGS FOR CONSENT FORM

Introduction
__Description of the study
__Role of participant

Purpose
__What is being studied
__Why it is being studied
__Purpose of research
__Indicate experimental/research

Procedures
__List of all procedures
__Intervals of procedures
__Length of time participant in study
__What will be given or received and how administered
__Length of hospital stay, if required
__Prior experience with drug or device

Risks
__Describe all risks in detail
__Describe all possible side effects
(in consent form or as attachment)

Benefits to Participant
__Describe in detail
__State if none

Alternative Treatment/Procedures
__Describe in detail

Exclusions for Nonparticipation
__Describe in detail

Participant Costs/Payment
__Payment to be received by participant
__Costs to participant, if any
__Insurance coverage, if any

Reimbursement/Compensation for Illness/Injury During Study
__Name/phone number of treating doctor
__Where will treatment be given
__Other forms of compensation, if any

Confidentiality
__Indicate records are confidential
__Safeguards used if data published
__Who will have access to records

Patient Rights
__Name/phone number of investigator
__Listing of WSU IRB (509) 335-9661

Voluntary Participation/Withdrawal
__Statement regarding voluntary participation
__Statement regarding withdrawal by participant during study
__Statement regarding withdrawal of participant by physician

Legal Rights/Patient Consent
__Statement regarding legal rights
__All questions answered
__Emergency phone number
__Copy of consent form given to participant
__Signature and date line for participant (or guardian)
__Signature and date line for investigator
__Signature and date line for witness

Other
__Written in first person/second person
__Technical medical terminology explained