CONSENT FORMS

A. FREQUENTLY ASKED QUESTIONS CONCERNING CONSENT PROCEDURES

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

Written consent is used with any face-to-face research activity whether minimal risk or greater than minimal risk studies in both Biomedical and Social Behavioral research. Obtaining a signature on a consent form is standard. 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 EUIRB.

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, 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 or take pictures of my subjects?**

You will need to get a written consent. The consent procedure needs to specify WHEN the tapes or photographs will be destroyed, WHERE they will be stored, and WHO will have access to the tapes or photographs. 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 I have interviewed and give 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 8 and 17, you should seek both written parental and child assent. One parent must give permission if the research is minimal risk or greater than minimal risk but holds prospect of direct benefit. If the research is greater than minimal risk and holds no prospect of direct benefit, both parents must give permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. The assent form language should be written 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.

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 him/herself or others (e.g., due to acute depression, etc.) or is currently suffering mental or physical abuse, or is/has been abused by others, or is abusing another individual, you are required by Pennsylvania 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. Contact IRB for more information on this topic, including specific language to be used.

B. CONSENT FORM TEMPLATES

[CONSENT FORM]
[Insert Title of Study]

[Your name]
[Contact information]

I am a [graduate/undergraduate] student pursuing a [Your Degree] in the [Program] at Eastern University.

You are invited to be in a research study of [general statement about study]. You were selected as a possible participant because [explain how the subject was identified]. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

Background Information:

Currently, I am working on a research study for a [course/thesis]. The study is designed to [describe the study briefly].

Procedures:

If you agree to be in the study, I/we will ask you to do the following things: [describe tasks and
procedures: subjects should be told about video or audio recording, photographs that may be taken, length of time for participation, frequency of procedures and make assurances about anonymity/confidentiality/etc.].

Confidentiality:

Participation in this study is voluntary and [confidential/ anonymous – see “Definitions” p. 45 of IRB manual]. Any identifying information will be removed from the final research report. [if the study is conducted at a place of employment, indicate that employer will not have access to the files/surveys/etc. and that participation will not affect their employment in any way] Research records [video or audio recordings/photographs] will be stored securely [indicate where and how] and only researchers will have access to these records. These records will be maintained [confidentially/anonymously] for 3 years and then destroyed on [date of destruction]

In any sort of report I/we might publish, we will not include any information that will make it possible to identify a subject.

Risks and Benefits of participating in the Study:

The risks of this study are [insert risks] (Risk must be explained, including the likelihood of the risk). [If there are risks, please indicate how they will be handled].

The benefits of this study are [insert benefits].

Compensation:

You will receive payment/extra credit [indicate if there is/is not compensation. If so, explain how much, when and how they will be compensated, and explain whether they must complete the study in order to be paid or if they will receive partial compensation for completing a percentage of the study. If subjects receive class points you must explain how students who do not participate may earn extra credit through alternative means].

Voluntary Nature of the Study: Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relations with Eastern University [or with other cooperating institutions, insert names here] and will result in no penalty. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships and without penalty.

Contacts and Questions:

The researcher(s) conducting this study is/are: [name of researcher(s)]. You may ask any questions you have now. If you have questions later, you are encouraged to contact [the researcher(s)] at [phone number and email of researcher(s)]. (If the researcher is a student, include advisor’s name, telephone number and email address here.)

This project has been approved by Eastern University’s Institutional Review Board as indicated
You will be given a copy of this information to keep for your records.

CONSENT STATEMENT:

I have read the above information and agree to participate in this research study. I understand that if I have any questions or concerns regarding this project, I can contact the investigator at the above location or the Eastern University Institutional Review Board at IRB@eastern.edu. I consent to participate in the study.

____________________   __________
( Participant’s Signature) (Date)

________________________  __________
( Parent or Guardian Signature, if a minor) (Date)

__________________________  __________
( Investigator Signature) (Date)
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 name of the investigator and telephone number should appear in the consent form.

BIOMEDICAL CONSENT FORM CHECKLIST

___ Title of study
___ Investigator name, title and contact information
___ Investigator affiliation

HEADINGS FOR CONSENT FORM

Introduction/Background Information:
___ Description of the study
___ Role of participant

Purpose:
___ What is being studied
___ Why it is being studied
___ Purpose of 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

Voluntary Participation/ Withdrawal:
___ Statement regarding voluntary participation
___ Statement regarding voluntary withdrawal by participant
___ Statement regarding voluntary withdrawal of participant by physician (in consent form or as attachment)

Confidentiality:
___ Indicate records are confidential
___ Safeguards used if data published
___ Who will have access to records
Indicate the date records will be destroyed

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

Reimbursement/Compensation for Illness/Injury During Study:
- Name/phone number of treating doctor
- Where will treatment be given
- Other forms of compensation

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

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

Contacts and Questions:
- Name/phone number of investigator
- Listing of EU IRB: irb@eastern.edu