INSTRUCTIONS FOR PREPARING CONSENT DOCUMENTS

The Institutional Review Board of Howard University requires that each consent document contain a written statement of exactly what is to be said to a participant in order to obtain consent for participation in a research project. This statement should be outlined under Item #2 of the attached sample informed consent form, which is the standard form to be used at this Institution for all projects involving humans. The "Explanation to the Participant" should be worded in lay terminology targeted for individuals with an eighth grade education, and not for a peer review committee/or a scientist.

The Informed Consent form should contain the following elements (see attached form):

Item #1: Title of Research Project
Listing of Tests and/or Procedures to be Performed:
(a) Provide a brief description of each
(b) Indicate the amount of time required to complete each

Item #2: "Explanation to the Participant" should be written in lay terminology under this heading. It should contain the following basic information:

(a) statement of the purpose(s) or objective(s) of the project and identification of the investigator(s), including students, as appropriate, and his/her institutional and departmental affiliation
(b) description of the tests and/or procedures to be employed
(c) discussion of alternative methods or procedures, if appropriate.
(d) discussion of risks, both known and anticipated (Please be aware, "minimal" is the smallest increment of risk.)
(e) discussion of benefits to the participant or society
(f) statement of assurance regarding protection of data collected on the participant (confidentiality safeguards)

(g) Statement regarding use of placebo(s). If a project calls for a placebo, the percent probability of a participant receiving a placebo should be stated.

(h) Statement of whether the participant will receive remuneration for any inconvenience incurred by participating in this study.

(i) For clinical or drug studies, include a statement explaining whether the participant will incur any financial obligations by participating in the study.

(j) Statement regarding availability of medical treatment or compensation for physical injuries incurred as a result of participation in the research.

(k) Statement of agreement to participate in project, upon adequate explanation of investigator, and assurance that all reasonable precautions will be taken to reduce risks and provide care.

(l) Statement advising participant that he/she is free to withdraw consent and discontinue participation in the project at any time without jeopardizing the right to receive health care at this Institution.

(m) Statement of agencies or individuals who will have access to the records, including the Howard University Institutional Review Board.

Item #3 The principal investigator or designee should be identified by name and his/her office telephone number and/or cell phone number should be included in the event of an emergency. If the principal investigator is not a physician, the name and telephone number of the clinician to whom the participant would be referred in the event of an emergency should be included.

Finally, the consent form should be signed and dated by the participant parent, or guardian, in the presence of the physician/investigator, who will also sign and date the form. All consent forms must be kept on record with a project with for at least three (3) years after termination of the study or the last IRB approval date.

****IT MUST BE EMPHASIZED THAT THE "EXPLANATION TO PARTICIPANT SECTION" MUST BE WRITTEN IN CLEAR, LAY TERMINOLOGY****

TYPES OF CONSENT DOCUMENTS:

Consent for Investigative Procedures – standard consent form used for a participant to consent for himself/herself. Can also be used for third party/next-of-kin consent with the proper modifications.

Parental Consent Form – Used for parents to consent for their child/children to participate in a study.

Oral History Consent Form – Used when interviews or sessions will be video or audio taped.

Venipuncture Consent Form – Used when blood is to be drawn.

Preamble – Used when it is not necessary to know the identity of the participants. A preamble is also appropriate for verbal consent (i.e., web posting, telephone script, etc.)

SAMPLE CONSENT FOR INVESTIGATIVE PROCEDURES
HOWARD UNIVERSITY
WASHINGTON, DC 20059

1. The following tests and/or procedures are needed for the project entitled:
"_____
_____."

Tests and/or Procedures to be Performed

_____
_____
_____

2. Explanation to the Participant:
(As per the instructions for preparation of informed consent form.)

In the event of physical or other injury resulting from the research test(s) or procedures(s), emergency medical treatment will be provided at Howard University Hospital, but financial compensation will not be available (unless it is).

Some of the test(s) or procedure(s) described may be novel or experimental, but they do not involve any risk(s) other than those described in the first paragraph. Your participation in this study is voluntary. All reasonable precautions have and will be taken to reduce risk(s) and to provide for your care.

You are free to withdraw this consent and discontinue participation in this project at any time without affecting either your right to receive on-going care or your relationship with Howard University or Howard University Hospital.

The Howard University Institutional Review Board will have access to the records of this project.

Dr. [faculty advisor/principal investigator] can be reached at the following number _____ or the following cell phone number:_____ in the event you have any questions regarding your participation in this project. If you have questions any time that you would like to discuss with someone other than the investigators on this project, you are free to contact the Howard University Institutional Review Board at 202-865-8597 between 8:30 a.m. and 5:00 p.m. You may also contact _____ [faculty advisor/principal investigator] at any time for answers to pertinent questions about this research and your research-related rights. You should contact him/her in the event of a research-related injury.

3. I have read the above description of the research project and anything I did not understand was explained to me by_____ and my questions were answered to my satisfaction. I agree to participate in the above-referenced project.

I acknowledge that I have received a personal copy of this consent form.

_____

Participant's Signature Date

4. I, the undersigned, have defined and fully explained the test(s) or procedure(s) involved in this investigation to the above participant or parent or guardian.

_____ _____

Investigator's Signature Date

STATEMENT ON BLOOD DRAWING
Minimal Requirements

DESCRIPTION OF PROCEDURE

1. Lay terminology, should be used, e.g., use “drawing blood” rather than “venipuncture” and express volume as ounces or teaspoons rather than cc’s or mls.

2. State the volume and number of times that blood will be drawn during the project. Relate risks to the amount of blood taken if it exceeds standards set by the Red Cross (five hundred cc’s or mls [1 pint] over 6-7 weeks).

3. State who will draw the blood, e.g., physician, nurse, phlebotomist (technician; medical, dental, nursing or other student).

4. State the site from which blood will be taken, e.g., artery, vein, arm, finger.

5. State how it will be taken (syringe and needle or lancet).

6. It is not necessary to describe details of tourniquet application or cleaning of skin.

RISKS AND HAZARDS

It is only necessary to describe in lay terminology the local reactions to the blood drawing procedure, e.g., bruising, leakage or infection in the site from which the blood will be drawn.

SAMPLE VENIPUNCTURE CONSENT FORM

IRB #:

Consent for Investigative Procedures
Howard University
Washington, DC 20059

1. **The following tests or procedures will be performed on blood obtained from you for the project entitled:**
"_____
_____"

Tests or Procedures to be Performed on the Blood.
_____
_____

2. **Explanation to Participants**

(Investigator's Name) is conducting a research project to examine _____
_____.
For this purpose, approximately (state volume tsp./pints) of your blood will be drawn (number of sessions that blood will be drawn). The procedure involves placing (name of instrument) in a (identify the vessel or its location) after cleaning with _____ to take the blood and will require (indicate amount of time). There are physical risks associated with this procedure. Occasionally, minor complications, such as, bruising, swelling, infections, and/or black and blue marks develop at the blood drawing location. (Name of person who will draw blood), (Identify his/her occupation or status), is experienced in this technique. It is believed that knowledge from this study will benefit _____
_____
_____. You will receive (dollar amount/nothing) for any inconvenience that you may incur as a result of your participation in this study.

In the even of physical or other injury resulting from the research tests or procedures, emergency medical treatment will be provided at Howard University Hospital, but financial compensation will not be available.

Participation in this project does not involve any risks other than those described. Precautions have and will be taken to reduce the risks and to provide for your (/your child's – if appropriate) care.

You can withdraw this consent and discontinue participation in this project at any time without affecting your relationship with Howard University or Howard University Hospital.

The Howard University Institutional Review Board will have access to the records of this project.

Dr. [faculty advisor or principal investigator] can be reached at the following number _____ in the event I have any questions regarding your (/your child's – if appropriate) participation in this project. If you have questions at any time that you would like to discuss with someone other than the investigators on this project, you are free to call the Howard University Institutional Review Board at 865-8597 between 8:30 a.m. and 5:00 p.m., Monday through Friday. You can also contact [faculty advisor or principal investigator] at any time for answers to pertinent questions about this research and your research-related rights. You should contact him/her in the event of a research-related injury.

3. I have read the above description of the project. Anything I did not understand was explained to me by _____ and I had my questions answered to my satisfaction. I agree to participate (and/or to have my child participate) in this project.

   I acknowledge that I have received a personal copy of this consent form.

_____ _____
Participant's Signature or Parent/Guardian's Signature Date

4. I, the undersigned, have defined and fully explained the tests or procedures involved in this investigation to the above participant, parent, or guardian.

_____ _____
Investigator's or Designee's Signature Date

USE OF A PREAMBLE TO OBTAIN INFORMED CONSENT

1. Definition:

   A preamble is an informed consent procedure that does not require the signature of a study participant.

2. A preamble is appropriately used in place of a written consent under the following conditions:

   a. The participant is not required to place any identifying information on data collection instruments. Such identifiers include name, social security number, student identification number, specific birth data, telephone number, address, etc.
   b. The participant will be given the data collection instrument at a single session and will not be re-contacted for any reason.
   c. The research procedure requires completion of written or verbal responses only (i.e., no blood drawing, or physical activities are required).
   d. The data collection procedures do not include audio- or video taping or home visits.

3. A preamble is generally not accepted for special populations, i.e., minors, prisoners, retarded or institutionalized individuals, pregnant women, etc.

4. The contents of the preamble should have the same informational elements as a written consent form, for example:

   a. The name of the principal investigator/faculty advisor (PI)/(FA), and the name of the student investigator(s), if appropriate.
   b. The name of any tests, questionnaires, or procedures and a description of these tests in general lay terms.
   c. Inclusion or exclusion criteria for participation should be stated.

d. A description of the general purpose of the research with special note as to whether it is part of the requirements for a degree.
e. An estimate of the time it will take to complete the procedures.
f. A brief statement on anticipated risks and benefits. "Minimal anticipated risk" is the lowest risk category, a statement of "no known risks" is not acceptable.
g. Any incentive should be explained clearly, i.e., grade points, money, etc.
h. A guarantee of confidentiality by not requiring any identifying information, such as, name, social security number, birth date, telephone number, etc.
i. Contact telephone numbers for the PI/FA, the student investigator(s), if it is a student project, and Howard University Institutional Review Board (202-865-8597).

IRB #

SAMPLE
Preamble
For Investigative Procedures
Howard University
Washington, DC 20059

This is an investigation in the department of _____. This study is being conducted by (name of PI/FA) and (student, if applicable), a doctoral/master's candidate. You will be asked to complete (number) questionnaire(s), the (name the tests), which require (minutes) to complete. This questionnaire(s) will be administered at (place).

The benefit to you for participating in this study is that _____. We anticipate minimal psychological risks, and personal time inconvenience. You will be given $ _____to cover the cost of transportation and any inconvenience that you may incur as a result of your participation in this study.

The results of this research will be useful to _____. Procedures for maintaining confidentiality are as follows. [Individuals result will be pooled with group results. Do not place any identifying information on the questionnaire, such as, name or student identification number.] You may withdraw from this study at any time without jeopardizing [your status in this class or] your relationship with Howard University or Howard University Hospital.

The participants should be 18 years of age or older and in good health. If you are younger than 18, please contact the investigator immediately.

If you would like any further information about this study, please contact (PI/FA) at _____. You may also call the Howard University Institutional Review Board at 865-8597, from 8:30 a.m. to 5:00 p.m., Monday through Friday, if you would like to discuss this study with someone other than the investigators.

SAMPLE ORAL HISTORY FORM

IRB#:

CONSENT FOR INVESTIGATIVE PROCEDURES
HOWARD UNIVERSITY
WASHINGTON, DC 20059

1. The following tests or procedures are needed for the project entitled,
"_____
_____
_____"

Tests and/or Procedures to be Employed

_____
_____
_____

2. Explanation to Participant:

State the purpose(s) or objective(s) of the project and identify the investigators and their institutional and departmental affiliation.

Describe the methods for obtaining the history.

Describe the process for maintaining the confidentiality of the data.

State the risks that may accrue to the participant(s) from his/her participation in the interview.

State of the benefits that may accrue to the participant(s), or society from his/her participation in the study.

The Howard University Institutional Review Board will have access to the records of this project.

You can withdraw this consent and discontinue participation at any time.

You have the choice to allow or not allow the interview to be taped. Your choice is indicated as follows:

☐ "I will allow this interview to be taped."

☐ "I will not allow this interview to be taped."

You have the choice to review or not review a transcription of the tape. Your choice is indicated as follows:

☐ "I wish to review a transcription of the tape."

☐ "I do not wish to review a transcription of the tape at any time."

The interviewer, _____ may be contacted at telephone number _____ in the event I have any questions regarding your participation in this project. If you have questions at any time that you want to discuss with someone other than the interviewer, you are free to call the Howard University Institutional Review Board at 202-865-8597, from 8:30 a.m. to 5:30 p.m. Monday through Friday. Payment for long distance calls will be the responsibility of _____.

3. I have read the above description of the project. Anything that I did not understand was explained to me by _____ and I had my questions answered to my satisfaction. I agree to participate in this interview and to allow my name to be associated with this interview if publications result from this study.

I acknowledge that I have received a personal copy of this consent form.

_____

Interviewee's/Guardian's Signature Date

_____

Interviewer's Signature Date

INSTRUCTIONS FOR PREPARATION OF ASSENT FORM

FOR CHILDREN AND MINORS

Parents, legal guardians or a legally authorized representative must sign parental consent forms permitting minors to participate in research projects. An Informed Assent Documentation for young adults (13-17 years of age) and minors (12 and under) must be prepared. The following are samples of Assent Forms. Language must be simplified as appropriate for the age of the participants.

For children unable to read and sign the written assent form, a verbal script should be used in lieu of the written Informed Assent Form.

Assent of the Child Form Date: _____ IRB Number: _____

Assent Form for Young Adults
13 -17 years of age
Howard University
Washington, DC 20059

Study Title:	
Name of Investigator(s):	
School/College and/or Department:	

This study is being conducted by the person(s) listed above. You will be asked to: _____.

It will require (minutes/hours) to complete. The (questionnaire/test/procedures) will be administered at (location)_____.

The benefit to you for participating in this study is that _____. We anticipate minimal psychological risks, and personal time inconvenience. You will be given (gift card/remuneration). The results of this research will be useful to _____ _____.

You may withdraw from this study at any time without jeopardizing your status in your class/school/etc., or your relationship with Howard University and/or Howard University Hospital.

If you would like any further information about this study, you may contact Dr(s). (PI/FA)_____ at _____. You may also call the Howard University Institutional Review Board at (202) 865-8597, from 8:30 a.m. to 5:00 p.m., Monday through Friday, if you would like to discuss this study with someone other than the investigators.

Sign your name if you agree to take part in this study.

_____ _____

Signature Line Date

Assent of the Child Form Date: _____
IRB Number: _____

Assent Form for Children
less than 12 years of age
Howard University
Washington, DC 20059

Addendum Consent Form IRB:

Study Title:	
Name of Investigator(s):	
School/College and/or Department:	

I have been told that my mom/dad/or the person who takes care of me, has said that it is okay for me to take part in this study about _____
_____

The people in charge have explained to me what the study is about and what will happen.

I am taking part because I want to. No one will get angry with me if I say no. I have been told that I can stop at any time that I want to and nothing will happen to me if I want to stop.

Sign your name if you agree to take part in this study.

_____ _____
SIGN YOUR NAME ON THIS LINE DATE

Assent of the Child Form Date: _____
IRB Number: _____

Waiver of Assent for Children less than 12 years of age

Howard University
Washington, DC 20059

Addendum Consent Form IRB:

I have determined that this child does not have the capacity to give assent because of the following:

☐ Maturity ☐ Psychological state of the child

_____	_____	_____ / _____ / _____
Signature of Investigator	Typed or Printed Name	MM / DD / YY