CONSENT FORM FOR RESEARCH PARTICIPATION

STUDY TITLE:

PRINCIPAL INVESTIGATOR:

STUDENT RESEARCHER: [if applicable]

IRB STUDY NUMBER: [this is the protocol number that is assigned to your study]

INTRODUCTION

Example:

- I am a [faculty member OR student] at Howard University, in the School or Department of _____. I am [We are] planning to conduct a research study, which I invite you to take part in.
- I am doing this study with colleagues at [name other institutions, if this is a multi-institutional study.]
- This form contains key information about the reason for doing this study, what we will ask you to do if you decide to be in this study, and the way we would like to use information about you if you choose to be in the study.

DESCRIPTION

Example: You 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 **purpose** of the research]*.
- You will be asked to *[describe **procedures**; mention video/audio taping, if applicable, and what will become of tapes after use, e.g., shown at scientific meetings; describe the final disposition of the tapes]*.
- *[Note: If the study involves deception or incomplete disclosure which necessitates a debriefing process, a general statement may be added here that more information will be given to subjects at the conclusion of the study, e.g., "At the end of the study, we will explain in greater detail what we hope to learn from this research." If the investigator believes that such a statement would bias study results, he/she should discuss this in the protocol as part of the justification for use of deception or incomplete disclosure.]*

WHAT WILL I DO IF I CHOOSE TO BE IN THIS STUDY?

Example:

You will be asked to

- [describe **procedures**; *mention video/audio taping, if applicable, and what will become of tapes after use, e.g., shown at scientific meetings; describe the final disposition of the tapes]*.
- Provide a clear, concise but complete description of what subjects will do or experience.

- Describe activities in chronological order to the extent possible.
- If there are many procedures, use a table, lists, or subheadings to organize this information.

TIME INVOLVEMENT

Example: Study participation will take approximately [insert expected length of time--include the total time commitment, the number of visits/sessions involved, and the length of each visit/session].

STUDY LOCATION

Example:

- All study procedures will take place at [explain study location[s] –
- [If different procedures will take place at different locations, specify accordingly].
- [If you will be audio-recording or video-recording subjects, include the following]
- I would like to audio-record [or video-record] this interview to make sure that I remember accurately all the information you provide. I will keep these tapes in [explain where you will keep them] and they will only be used by [explain who will have access to the tapes]. If you prefer not to be audio-recorded, I will take notes instead.
- [If audio/video recording are not optional, then clearly state that it is required for participation]
- Indicate ***Yes*** or ***No***:

[If applicable] I give consent to be audiotaped during this study.

☐ Yes ☐ No

[If applicable] I give consent to be videotaped during this study:

☐ Yes ☐ No

[If applicable*]* I give consent for tapes resulting from this study to be used for [describe proposed use of tapes]:

☐ Yes ☐ No

[If applicable] I give consent for my identity to be revealed in written materials resulting from this study:

☐ Yes ☐ No

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS?

Example:

- The risks associated with this study are:
  - [describe foreseeable risks]
- [Explain any foreseeable risks to subjects here].
- [Keep in mind that risks are not always immediate -- anger, emotional upset, or stress may appear later.].
  - Your participation in this study may involve the following risks… *[describe any reasonably foreseeable risks to psyche, reputation, employability, insurability, social status, criminal or civil liability that may occur as a result of participation.]*
- (Address emotional and psychological risks, including risks of emotional discomfort from being asked about or discussing sensitive issues].

- You may feel emotional or upset when answering some of the questions. Tell the interviewer at any time if you wish to take a break or stop the interview.
- You may be uncomfortable with some of the questions and topics we will ask about. If you are uncomfortable, you are free to not answer or to skip to the next question.

- As with all research, there is a chance that confidentiality of the information we collect from you could be breached – we will take steps to minimize this risk, as discussed in more detail below in this form.

WHAT ARE THE POSSIBLE BENEFITS?

Example:

- The benefits which may reasonably be expected to result from this study are *[describe any **benefits**; if none, state as such].*
- **We cannot and do not guarantee or promise that you will receive any benefits from this study.**
- This study is designed to learn more about [insert purpose/topic of study].
- The study results may be used to help other people in the future. *[If applicable]*
- Your decision whether or not to participate in this study will not affect your *[choose as appropriate]: employment; medical care; grades in school.*

HOW WILL YOU PROTECT THE INFORMATION YOU COLLECT ABOUT ME, AND HOW WILL THAT INFORMATION BE SHARED?

Example:

- Results of this study may be used in publications and presentations.
- Your study data will be handled as confidentially as possible.
- If results of this study are published or presented, individual names and other personally identifiable information will not be used [if appropriate, add phrase such as "unless you give explicit permission for this below"].
- To minimize the risks to confidentiality, we will... [Explain data security measures to be taken, e.g., storage, coding, encryption, limited access to study records, etc].
- If disclosure of faces or voices is necessary to understanding the research, and therefore, identifying information may be used in reports/presentations [explain this and provide "I agree" "I do not agree" options at the end of the consent form]
- We may share the data we collect from you for use in future research studies or with other researchers – if we share the data that we collect about you, we will remove any information that could identify you before we share it. [Adjust this data-sharing language as needed to fit your study – for example, if you might share data that potentially could be identifiable, such as videotapes, then you should make that clear].
- If we think that you intend to harm yourself or others, we will notify the appropriate people with this information.

ARE THERE PAYMENTS/COMPENSATION?

Example:

- You will receive *[describe reimbursement; where there is none, state as such]* as payment for your participation.

- Participation in this study will involve no cost to you. You will not be paid for participating in this study.

OR

- [If subjects will be paid, explain the amount and terms of payment/reimbursement. If payments will be prorated if a subject withdraws from the study, explain the conditions for payment]

WHAT ARE MY RIGHTS AS A RESEARCH PARTICIPANT?

Example:

- If you have read this form and have decided to participate in this project, please understand your **participation is voluntary** and you have the **right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled**.
- **The alternative is not to participate.**
- You have the right to refuse to answer questions.
- The results of this research study may be presented at scientific or professional meetings or published in scientific journals.

PRIVACY and CONFIDENTIALITY

Example:

- Your individual privacy will be maintained in all published and written data resulting from the study.
- All data will be coded by identification number assigned to you and are known only by the investigators on this project.
- Your name will not be associated with the results.
- Results of blood work (excluding genetic test) and physical measurements (such as height, weight and blood pressure) obtained in this study may be shared with you and sent to your personal physician if you provide written request.
- *[If identities will be disclosed, provide details*: With your permission, your identity will be made known in written materials resulting from the study.]
- *If this research study collects identifiable private information, include one of the two following statements:
- After the removal of identifiers from identifiable private information, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

OR

- Your private information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

WHO CAN I CONTACT IF I HAVE QUESTIONS OR CONCERNS ABOUT THIS RESEARCH STUDY?

Examples:

- ***Questions:*** If you have questions, you are free to ask them now.
- If you have questions later, concerns or complaints about this research, its procedures, risks and benefits, contact the Principal Investigator, *[name and phone number of PI]*.
- ***Independent Contact:*** If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Howard University Institutional Review Board to speak to someone independent of the research team at (202)-865-8597.
- You can also write to: The Institutional Review Board
  Howard University
  1840 7th Street, NW Suite 309
  Washington, DC 20001
  Phone: (202)-865-8597

NEW ELEMENTS of INFORMED CONSENT (Medical Sciences)	
WHEN YOUR PROJECT WILL INVOLVE...	**Include in the Informed Consent (Examples)**
The collection of identifiable private information or biospecimens	A statement whether: • Identifiers may be removed, and • if the de-information or biopspecimens **may or may not** be used for future research or shared with other investigators [46.116 (b)(9)]
Use of biospecimens	A statement that the subject's biospecimens (**even if identifiers are removed**) • may be used for commercial profit and • whether the subject will or will not share in the commercial profit [46.116 (c)(7)]
Clinically relevant research results	A statement regarding whether the clinically relevant research results, including individual research results, will be disclosed to subjects, and if so under which conditions [46.116 (c)(8)]
Whole genome sequencing (i.e., sequencing of human germline or somatic specimen with the intent to generate the genome or exome sequence of the specimen	A statement indicating that the research will (if known) or might include whole genome sequencing [46.116 (c)(9)]

UNIVERSITY STATEMENT

Example:

- If you suffer physical injury during your participation in this research, the Howard University Hospital will provide acute and necessary medical treatment and subsequently provide referrals to appropriate health care facilities.
- Acute treatment cost will be charged to your insurance carrier, and or to any other party responsible for your treatment costs.
- Neither the Howard University Hospital nor Howard University College of Medicine can provide any financial compensation due to any injury suffered during this research study.

OPTIONAL STUDY ELEMENTS

Example:

- [This section should include other explicit consents for optional elements of the research procedures, such as contacting participants again in the future about participation in other research studies.] e.g.

  e.g. Future Use of samples:

  - You have my permission to use my blood in other projects as they are approved by the IRB and I will check the "yes" box below or if I do not wish for my blood to be used in the future IRB approved research studies, check the "no" box below.
    (a) Yes☐ (b) No☐
  - I permit my sample to be stored, but Howard University must ask me before it is used.
    (a) Yes☐ (b) No☐
  - I do not permit my sample to be stored but I may still take part in the study.
    (a) Yes☐ (b) No☐

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

  e.g. Participation in Future/Other Studies

  - Initial one of the following to indicate your choice:
  - _____ [initial] I agree to allow the researchers to use my contact information collected during this study to contact me about participating in future research studies.
  - _____ [initial] I do not agree to allow the researchers to use my contact information collected during this study to contact me about participating in future research studies.

CONSENT

I have read this form and the research study has been explained to me. I have been given the opportunity to ask questions and my questions have been answered. If I have additional questions, I have been told whom to contact. I agree to participate in the research study described above and will receive a copy of this consent form.

_____ _____

Participant's Name [printed] Signature and Date

_____	_____
Witness Name [printed]	Signature and Date
_____	_____
Participant's Signature	Signature and Date

Note:

i) IF YOU ARE SEEKING WAIVER OF DOCUMENTED [SIGNED] CONSENT, DELETE THE LINES ABOVE FOR THE PARTICIPANT'S NAME AND DATED SIGNATURE and substitute instead the wording "If you agree to participate, please say so. You will be given a copy of this form to keep for your records."

ii) Red fonts and b*ullet points are used in this example for clarity. You should only use bullets if appropriate for your ICF*

iii) For items that may not be relevant to your type of research such as in Medical Sciences Vs. Behavioral Sciences, you may ignore.

Who **Approves**, **Signs** and or **Receive Copies of ICF**?			
	Written Informed Consent (Standard)	**Short Form Written Informed Consent**	**Short Form Written IC Summary**
IRB	Approve	Approve	Approve
Subject or legally authorized representative	Present/copy/**sign**	Present/copy/**sign**	Present/copy
Person administering consent	Present/copy/**sign**	Present/copy	Present/copy/**sign**
Witness		Present/**sign**	Present/**sign**