Burrell College of Health Sciences – Informed Consent Template

Principal Investigator:

Department:

Study Title:

Instructions to Researcher: Please modify this consent form as appropriate for your study. In general, you will need to address the highlighted areas. Please remove the highlighting as you complete the consent form.

Informed Consent:
You are being asked to participate in a research project that is being conducted by investigators at the Burrell College of Health Sciences. It is important that you understand this research so that you can decide whether or not you want to take part in the project. This process is called "Informed consent". To make your decision, you must consider all the information provided.

You should especially consider:

- The purpose of the research project
- How the research is conducted, including the collection of information, or any medications, devices, interventions, or techniques to be used.
- The risks of participating in this research.
- The benefits of participating in this research.
- Whether the possible benefits of taking part in the project make it worth the risks you might face.
- The alternatives to taking part in this research. If applicable, how this research differs from any standard of medical care that you or others in your community would commonly receive.

Voluntary Participation:
You do not have to take part in this research. It is your choice. If you choose not to take part or to stop taking part in this research at any time, there will be no penalty to you or loss of benefits which you might otherwise receive.

Purpose:
The purpose of this research is (please explain the purpose of the study in common conversational language that a 6th grade student would understand. Do not use jargon or highly technical terms or abbreviations in explaining the purpose. Isn't 8th grade the typical standard, for example, for news media?)

Number of Participants:
The research will be conducted in approximately XXX people who volunteer for the research project.

Duration of the Study:
You will be in this research study for about (indicate the length of time that the person will need to participate in the project. For more complex study designs with multiple study days, you may include a flow chart diagram.)

Procedures:
While you are in the study you will have different (tests, evaluations and/or procedures) performed on you which involve certain risks. An explanation of each of these will be provided through this informed consent process. It is important that you understand the procedures that will be performed.
(Describe the experimental procedures and parts of this study in common conversational terms that are understandable by a layperson. Indicate what the subject will be required to do and what will be done to them. Indicate how the study differs from standard of care and any drugs/devices that are not approved or not approved for this particular use. Include a table or list of interventions and timelines that the volunteer needs to be aware of. Also describe if the procedures will produce any pain or discomfort.)

Risks:
Taking part in this study involves certain risks. In addition to the risks described below, there may also be risks that are not known at this time. (Describe the known risks to the subject in all aspects of the project that will involve them. These risks should be explained in common conversational language that is accessible to a layperson.)

In you have any medical issues during this study, contact an investigator. The Investigator Contact Information is provided under the section of this informed consent form titled **"Contacts"**. *If you are having a medical emergency, call 911 or seek immediate medical care. You should let the emergency medical personnel know that you are participating in this study.*

Reproductive Risks:
Taking part in this study may involve certain reproductive health risks to male or female participants and/or risks to a pregnant woman, embryo, fetus, or nursing child. (Please indicate known risks. If there are no known risks, then please indicate this as well.)

Benefits:
(Describe the possible benefits of the research in conversational terms accessible to a layperson. Do not overstate the benefits of the research. You may also use the following statement if the research benefits are broad: "You may not personally benefit from taking part in this research, but other people may be helped by what is learned".)

Alternatives:
You do not have to participate in this study. There are options other than taking part in this study. (If the alternatives are brief, then state them here. If the list of alternatives is extensive, then include them in a separate section. –OR- The alternative to being part of this study is choosing not to participate. There is no penalty for choosing not to participate.)

Medical Issues:
There is a possibility that you could have a physical injury or illness that is directly caused by the study procedure (or drug that is different from your standard medical care). If this happens, you will receive the necessary and available medical care. (Describe in detail, if appropriate, medical issues that could arise and how they will be treated).

Costs:
(Describe any costs that the subject will have if they choose to participate in the study.)

Payment:
(Describe any payment and/or reimbursement that will be made to the subject. -OR- You will not receive any payment or reimbursement for taking part in this study).

Ending Study Early:
You may decide that you no longer wish to participate in this study after you have begun. You may be asked to stop the study early, even if you do not want to. You and the research team will discuss the reasons if it becomes necessary to end your participation. (Describe any other actions that will occur if the subject has to leave the study. This may include an exit interview or examination.)

Privacy and Confidentiality:
Information will be collected about you for this study. The information will be viewed by the people involved with this research. Steps will be taken to protect your identity and personal information. However, it is important that you understand that the information collected about you can never be 100% secure. (Optional Additional Information about how the researchers will handle privacy may be included here. Again, keep this information conversational and accessible to the reader.)

OR – please incorporate and expand relevant text provided below, as appropriate:

Privacy and Confidentiality: HIPAA Authorization
In order to take part in this study, we need to obtain your health information from your medical providers. Your signature on this form which includes this HIPAA Authorization will allow us to get access to that information. We are committed to respecting your privacy and to keeping your personal and health information confidential. When choosing to take part in this study, you are giving us permission to use your personal information that includes health information in your health care records and information that can identify you. For example, personal information may include your name, address, phone number, medical diagnoses, or social security number. Your health information and personal information we may collect and use for this study includes:

(List all information being collected for this study. Examples: demographics including race and ethnicity (required if the research is federally funded), labs, imaging results (e.g., x-rays), questionnaires, photos, video, audio, and any other information/results collected for this study).

This also includes any information collected about a medical issue caused by a study activity.

For this study, certain people will need access to your personal information. All the people who will need access to your personal information may not be required by law to protect it. However, they will all protect it to the best of their ability.

The following people may have access to your personal information (Examples Provided, Contact ORSP for additional guidance):

- Research Personnel employed at the Burrell College of Health Sciences
- Other members of the research team
- The Institutional Review Board of the Burrell College of Health Sciences
- The research sponsor (if clinical trial) or source of funding for the project
- A safety monitoring committee

Statements like the following examples may also be necessary:
"You can see your health care records at any time. However, you will typically not be able to see your study records or the study results until the study is completed. A copy of this signed form, information about this study and the results of any study test or procedure may be included in your health records and may be seen by your insurance company."

"Your personal information will be used as long as necessary for this study. Contact the investigator, preferably in writing, if you want to end your permission to use your personal information. If you do this, no more information will be collected, but the information already collected will still be used. If you end your permission to use your personal information, you will not be able to continue in this study."

"The information from this study may be published in scientific journals or presented at scientific meetings, but you will not be personally identified."

"A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

The following statements may also need to be included if appropriate to the research:
"Identifiers might be removed from the identifiable private information or identifiable specimens and then the information or specimens could be used for future research studies or distributed to other researchers for future research studies without your additional permission."

- OR -

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

Disclosure of Financial Interest:
(Complete if Applicable) The Burrell College of Health Sciences is being paid by (Insert Sponsor Name) to conduct this study.

New Information:
New information may come out during this study. You will be given any new information that could change your decision to take part. You will be given any research results that could affect your health. (Modify this section as appropriate and include any conditions whereby new information would not be made available to the participants.)

Additional Sections with More Detailed Information:
Other Information that may need to be included. The following sections may need to be added using similar headings as above with specific information addressed as necessary. Please create appropriate headings and information if required. Contact the IRB or Office of Research should you need additional guidance on the following topics:

Procedures and their risks: (Insert table or lists showing evaluations/tests/procedures and the administration/use of drugs/devices at each time point (e.g., the schedule of events/study events table from the protocol)). Include the following for each procedure/test/evaluation:

Name of Procedure/Test/Evaluation:
Description:
Risks:

Include the following statement if applicable: "This research includes or might include whole genome or exome sequencing. This is like taking an inventory of your DNA which contains your genetic information."

Drugs/Devices and their Risks: (If not already provided, include a table or description of the timing of drug/device intervention. If applicable, describe the different groups that a subject may be assigned to. Also describe the probability of being assigned to each of the different groups.) Include the following for each:

Name of Drug/Device:
Description:
Method of Administration/Use:
Risks:

Additional Risks: (Describe any additional risks that have not already been mentioned in this consent form.)

Risks to Pregnant Women and Unborn or Nursing Children and/or Reproductive Risks for Males: (Contact the Office of Research for Guidance)

Contacts:
If you are having a medical emergency, call 911 or seek emergency medical care right away. You should let the emergency medical provider know that you are taking part in this study.

	Person or Office to Contact	Contact Information
If you have questions about the Study or Research related medical issues.	Main Investigator: NAME Investigator: (Duplicate as Necessary for Key Investigators)	Phone: XXX-XXX-XXXX Email: xxx@burrell.edu Mailing Address: XXXXXX
If you need to contact someone other than the study personnel about a concern or your rights as a research subject.	Burrell Office of Research and Sponsored Programs. Burrell Institutional Review Board (Ethics Committee)	Office of Research: Research Administration (575)-674-2307 IRB Chairperson: (575) 674-2327 or (575) 674-2335

Signatures:

By signing this form, you agree that:

- You were given the opportunity to read this form.
- This form was read to you if you are unable to read the form.
- All the information contained in this form was discussed with you by investigator or other research personnel unless you are being asked to complete a survey or participate in a project with no more than minimal risk.
- All your questions have been answered to your satisfaction.
- You were not pressured to participate in the research project.
- You voluntarily agree to take part in this research.

_____	_____	_____
Your Name (printed)	Your Signature	Date
_____	_____	_____
Name of Person Obtaining/ Assisting with Consent (printed)	Signature of Person Obtaining/ Assisting with Consent	Date
_____	_____	_____
Name of Investigator (printed)	Signature of Investigator	Date
_____	_____	_____
Name of Witness (printed)	Signature of Witness	Date

(Witness required if the only language the subject speaks and understands is English, but the subject cannot read English, or if the subject is blind or cannot physically sign the consent form.)

☐ **Copy of Signed and Dated Consent Form Given to the Subject/Parent/Legally Authorized Representative**