**South College Consent to Participate in Research**

**Study Title:** ADD STUDY TITLE HERE (NOT IN ALL CAPS, THE CAPS IN THIS DOCUMENT ARE DIRECTIONS FOR YOU, THE RESEARCHER, TO GENERATE THE CONSENT FORM FOR YOUR RESEARCH STUDY). FOLLOW THE CAPITALIZED INSTRUCTIONS IN EACH SECTION THEN DELETE THE INSTRUCTION.

**Researcher:** ADD PRINCIPAL INVESTIGATOR’S NAME AND CONTACT INFORMATION HERE.

* **You are being asked to participate in a research study.** This consent form contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.
* **Your participation is voluntary.** Your participation in this research is voluntary. You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you or loss of benefits to which you are otherwise entitled. Your decision will not affect your future relationship with South College. If you are a student or employee at South College, your decision will not affect your grades or employment status.
* **Purpose of the research.** ADD TEXT HERE ON THE PURPOSE(S) OF THE RESEARCH. USE PLAIN LANGUAGE WITH NO JARGON. PROVIDE THE INFORMATION THAT A REASONABLE PERSON WOULD WANT TO HAVE IN ORDER TO MAKE AN INFORMED DECISION ABOUT WHETHER OR NOT TO PARTICPATE, AND GIVE THE SUBJECT AN OPPORTUNITY TO DISCUSS THE INFORMATION.
* **Number of people being asked to participate in the research.** ADD TEXT HERE ON THE APPROXIMATE NUMBER OF SUBJECTS INVOLVED IN THE RESEARCH.
* **Duration of your participation.** ADD TEXT HERE ON THE AMOUNT OF TIME, NUMBER OF ENCOUNTERS, ETC., IT WILL TAKE FOR THE SUBJECT TO PARTICIPATE IN THE RESEARCH.
* **Description of procedures to be followed in the research.** ADD TEXT HERE ON THE PROCEDURES YOU ARE ASKING THE SUBJECT TO FOLLOW IN THE RESEARCH.
* **Reasonably foreseeable risks or discomforts.** ADD TEXT HERE ON ANY REASONABLE RISKS OR DISCOMFORTS, IF ANY, THAT THE SUBJECT MAY EXPERIENCE AS A RESULT OF PARTICIPATING IN THE RESEARCH. IF THE RESEARCH INVOLVES MORE THAN MINIMAL RISK, SEE BELOW FOR ADDITIONAL INFORMATION THAT MUST BE INCLUDED.
* **Benefits to you or others that may reasonably be expected from the research.** ADD TEXT HERE ON THE BENEFITS THAT THE SUBJECT OR OTHERS MAY REASONABLY EXPECT AS A RESULT OF THE SUBJECT PARTICIPATING IN THE RESEARCH.
* **Alternative procedures.** ADD TEXT HERE ON APPROPRIATE ALTERNATIVE PROCEDURES OR COURSES OF TREATMENT, IF ANY, WHICH MIGHT BE ADVANTAGEOUS TO THE SUBJECT.
* **Confidentiality of records identifying you.** ADD TEXT HERE DESCRIBING THE EXTENT, IF ANY, TO WHICH CONFIDENTIALITY OF THE RECORDS IDENTIFYING THE SUBJECT WILL BE MAINTAINED. IF YOU WILL NOT COLLECT IDENTIFYING INFORMATION THEN STATE SO HERE. IF YOU WILL COLLECT IDENTIFIABLE PRIVATE INFORMATION OR IDENTIFIABLE BIOSPECIMENS, SEE BELOW FOR ADDITIONAL SECTION(S) THAT MUST BE ADDED TO YOUR CONSENT FORM.
* **Answers to your questions.** For questions, concerns, or complaints about the study you may contact the researcher. His/her name and contact information are listed at the top of this consent form. For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Institutional Review Board, Chair; Dr. Michelle Barnett at (865) 288-8219.

# Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

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| **Printed name of subject** |  | **Signature of subject** |
|  |  |  |  |
|  |  | **Date** |  |
|  |  |  |  |
|  |  |  |
| **Printed name of person authorized to consent for subject (when applicable)** |  | **Signature of person authorized to consent for subject** **(when applicable)** |
|  |  |  |  |
| **Relationship to the subject** |  | **Date** |  |

**Investigator**

I have explained the research to the participant or his/her representative before requesting the signature(s) above. A copy of this form has been given to the participant or his/her representative.

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| --- | --- | --- |
|  |  |  |
| **Printed name of person obtaining consent** |  | **Signature of person obtaining consent** |
|  |  |  | **AM/PM** |
|  |  | **Date and time** |  |

**IF ANY OF THE FOLLOWING SECTIONS ARE APPLICABLE TO YOUR RESEARCH PROJECT, INCLUDE THEM ON YOUR CONSENT FORM (IN THE LOGICAL PLACE ON THE FORM BEFORE THE SECTION LABELED “ANSWERS TO YOUR QUESTIONS”). DELETE THE FOLLOWING SECTIONS THAT ARE NOT APPLICABLE TO YOUR RESEARCH PROJECT. DELETE THIS INSTRUCTION.**

* **Reasonably foreseeable risks or discomforts.** FOR RESEARCH INVOLVING MORE THAN MINIMAL RISK, INCLUDE AN EXPLANATION AS TO WHETHER ANY COMPENSATION AND AN EXPLANATION AS TO WHETHER ANY MEDICAL TREATMENTS ARE AVAILABLE IF INJURY OCCURS AND, IF SO, WHAT THEY CONSIST OF AND WHERE FUTHER INFORMATION MAY BE OBTAINED. THE FOLLOWING SOUTH COLLEGE INJURY COMPENSATION CLAUSE MUST BE INCLUDED:

“South College has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.”

IN STUDIES THAT INVOLVE GREATER THAN MINIMAL RISK AND ARE SPONSORED, INCLUDE A STATEMENT REGARDING THE SPONSOR’S INJURY COMPENSATION POLICY. THE SPONSOR’S INJURY COMPENSATION POLICY MUST BE INCLUDED IF THE SPONSOR WILL PAY FOR COMPENSATION TO INJURED RESEARCH PARTICIPANTS, OR PAY FOR TREATMENT OF RESEARCH-RELATED INJURIES (NOTE: INVESTIGATOR MUST PROVIDE VERIFICATION OF SPONSOR’S INJURY COMPENSATION CLAUSE WHEN SPONSOR WILL PAY). IF THE SPONSER WILL NOT PROVIDE ANY COMPENSATION FOR INJURIES RELATED TO THE RESEARCH, THEN INCLUDE IN THE SOUTH COLLEGE COMPENSATION CLAUSE,

“South College and [name of sponsor] have not provided for any payment….”

* **Reasonably foreseeable risks or discomforts.** FOR RESEARCH IN WHICH YOU WILL PERFORM A TREATMENT OR PROCEDURE ON THE SUBJECTS, ADD A STATEMENT HERE THAT THE PARTICULAR TREATMENT OR PROCEDURE MAY INVOLVE RISKS TO THE SUBJECT (OR THE EMBRYO OR FETUS, IF THE SUBJECT IS OR MAY BECOME PREGNANT) THAT ARE CURRENTLY UNFORESEEABLE.
* **Collection of identifiable private information or identifiable biospecimens.** CHOOSE ONE OF THE TWO STATEMENTS BELOW, WHICHEVER IS APPROPRIATE FOR YOUR RESEARCH, AND DELETE THE OTHER STATEMENT.

Identifiers might be removed from your identifiable private information or identifiable biospecimens. After identifiers have been removed, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

Your identifiable private information or identifiable biospecimens will be collected as part of this research study only. Even if identifiers are removed, your information or biospecimens will not be used for future research studies or distributed to another investigator for future research studies.

* **Anticipated circumstances under which your participation may be terminated.** ADD TEXT HERE DESCRIBING ANY ANTICIPATED CIRCUMSTANCES UNDER WHICH THE SUBJECT’S PARTICIPATION MAY BE TERMINATED BY THE INVESTIGATOR WITHOUT REGARD TO THE SUBJECT’S OR THE LEGALLY AUTHORIZED REPRESENTATIVE’S CONSENT.
* **Costs to you to participate in the research.** ADD TEXT HERE DESCRIBING ANY ADDITIONAL COSTS TO THE SUBJECT THAT MAY RESULT FROM PARTICIPATION IN THE RESEARCH.
* **Consequences of your decision to withdraw from the research.** IF THERE ARE CONSEQUENCES OF A SUBJECT’S DECISION TO WITHDRAW FROM THE RESEARCH, ADD TEXT HERE DESCRIBING THE CONSEQUENCES AND PROCEDURES FOR THE ORDERLY TERMINATION OF PARTICIPATION BY THE SUBJECT.
* **Significant new findings developed during the research will be provided to you.** IF YOUR RESEARCH WILL DEVELOP NEW FINDINGS DURING THE COURSE OF PERFOMING THE RESEARCH THAT MAY IMPACT THE SUBJECT’S WILLINGNESS TO CONTINUE TO PARTICIPATE IN THE RESEACH, THEN ADD THE FOLLOWING STATEMENT HERE: Any significant new findings developed during the course of the research that may relate to your willingness to continue to participate in the research will be provided to you.
* **Your biospecimens may be used for commercial profit.** IF YOU ANTICIPATE USING A SUBJECT’S BIOSPECIMENS FOR COMMERCIAL PROFIT, ADD A STATEMENT HERE 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 THIS COMMERCIAL PROFIT.
* **Disclosure of clinically significant research results.** IF THE RESEARCH WILL PRODUCE CLINICALLY SIGNIFICANT RESULTS, ADD A STATEMENT REGARDING WHETHER CLINICALLY RELEVANT RESEARCH RESULTS, INCLUDING INDIVIDUAL RESEARCH RESULTS, WILL BE DISCLOSED TO SUBJECTS, AND IF SO, UNDER WHAT CONDITIONS.
* **The research on your biospecimens will/might include whole genome sequencing.** FOR RESEARCH INVOLVING BIOSPECIMENS THAT WILL (IF KNOWN) OR MIGHT INCLUDE WHOLE GENOME SEQUENCING (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen), ADD A STATEMENT INDICATING SO HERE.