**Key Information for {Project Title}:**

 *[Before the subject reads the rest of the consent form, they should be given the opportunity to read the study’s key information section. This section should include a brief but concise description of study elements crucial to the subject’s decision to be in the study. There are five key elements that need to be considered: 1. Consent is being sought for research purposes and that participation is voluntary; 2. the purpose of the research, the expected duration of the subject’s participation, and the research procedures; 3. a list of reasonably foreseeable risks and/or discomforts to the prospective subject; 4. Listing direct benefits to the subject (if any) and the scientific/social benefits of the study; and 5. Alternative procedures or courses of treatment, if any, that may be advantageous to the prospective subject.]*

**What Am I Being Asked To Do?**

[*This section is required.* *Briefly state that subjects are being asked to be in a research study and that their participation is voluntary.]*

* [Example Language:] “You are being asked to be a volunteer in a research study. This page will give you key information to help you decide if you would like to participate. Your participation is voluntary. As you read, please feel free to ask any questions you may have about the research.”

**What Is This Study About and What Procedures Will You be Asked to Follow?**

*[This section is required. Briefly describe the purpose and procedures of the study in lay terms.]*

* [Example language:] “The purpose of this study is to see if white blood cell counts change after a dose of Aspirin is given. First, we will intravenously draw 10 ml of blood from your arm. Then we will administer to you one 25 mg dose of aspirin via mouth. 30 minutes afterward, we will draw another 10 ml of blood from your other arm. Your participation in this study is expected to last no more than 1 hour.”

**Are There Any Risks or Discomforts you Might Experience by Being in this Study?**

*[This section is required. Briefly describe any risks or discomforts that subjects may experience, as well as the probability of said risks and/or discomforts, as a result of this study.]*

* [Example language:] “Common risks of drawing blood from your arm include discomfort at the site of puncture, possible bruising, redness, swelling, or feeling light-headed. There is also a chance you might get an infection at the site of puncture, however, this is rare. Aspirin is generally well tolerate, however, in very rare cases in can cause stroke or Gastrointestinal bleeding. If you have an allergy to Aspirin or have a history of adverse effects while taking aspirin, you should not be in this study.”

**What Are the Reasons You Might Want to Volunteer For This Study?**

*[This section is required. Briefly describe any direct personal benefits there may be to the subject, and also how this study might benefit the scientific field/society.]*

* [Example language:] “You are not likely to benefit in any way from joining this study. However, your participation in this study may assist researchers in understanding how over-the-counter pain-relievers, like Aspirin, affect the immune system.

As compensation for your time, we are offering a $5 Amazon gift card. You will be given the gist card even if you decide to leave the study early.”

**Do You Have to Take Part in the This Study?**

*[This section is required. Briefly state that the subject is not required to participate in the study and any alternative procedures or courses of treatment, if applicable.]*

* [Example Language:] “It is fully your decision if you wish to be in this study or not. If you choose not to participate, or choose to participate and later determine you no longer wish to, you will not lose any rights, services, or benefits as a result of your withdrawal. The study is completely voluntary.”

*[This template is designed to help you create a consent document to facilitate obtaining fully informed consent from human research participants. Federal regulations specify the several required elements of consent; those required items, indicated throughout this template, must be included in the consent document before the IRB can issue approval. Regardless, you should edit the template language so that it fits your research needs.*

*Note that the average person reads at the 8th grade level, so prepare this document accordingly. Investigators are encouraged to use computer software applications or other techniques to assess reading level of the finished document; use a large font (at least 12 point); use short, simple sentences and avoid technical language; define all abbreviations and acronyms when they first appear in text; write the document in second person as though you are verbally giving instruction; and follow the format, including headings, given below.*

*Instructions are included in brackets, and examples are bulleted in some sections.]*

**CONSENT DOCUMENT FOR ENROLLING ADULT PARTICIPANTS IN A RESEARCH STUDY**

**Georgia Institute of Technology**

*[In the state of Georgia, persons 18 years and older are legally adults. If enrolling Georgia Tech students who are minors, use this ADULT CONSENT TEMPLATE unless the study poses greater than minimal risk. In those cases, please consult the Office of Research Integrity Assurance for guidance.]*

Georgia Institute of Technology

Project Title:

Investigators: *[List the Principal Investigator (John Doe, Ph.D.)]*

Protocol and Consent Title: *[Include version number and date (Main 00/00/00v1)]*

You are being asked to be a volunteer in a research study.

*[The word* RESEARCH *is required. Protocols proposing experimental medical treatments or that pose greater than minimal risk to participants must include the following two sentences*: “You are encouraged to take your time in making your decision. Discuss this study with your friends and family.” *Do not include these two sentences in minimal risk studies.]*

**Purpose:**

*[This section is required. Give a brief description of the background and purpose of the study. Include an estimate of the number of subjects expected to participate.]*

* *[An example of a Purpose Statement follows:]* “The purpose of this study is to evaluate whether our test prosthetic boot can help persons with an amputated lower limb more safely walk on unlevel surfaces. We expect to enroll 24 people in this study.”

**Exclusion/Inclusion Criteria:**

*[This section is required for studies that, based on a scientific justification, are limited to certain categories of participants.]*

* *[An example of an Exclusion/Inclusion Criteria statement follows:* ] “Participants in this study must have one lower extremity amputation and be currently utilizing a prosthetic device. Those who have severe skin irritation or other problems with their residual limb may not be in this study. Those with bilateral amputations may not be in this study.”

**Procedures:**

*[This section is required and must include a description of all research procedures; the frequency, scheduling and time commitment of each procedure and visit; and the total time commitment. Any audio- or video-taping should be addressed in this section as well.]*

* *[If participants are being randomly assigned to different groups, this should be disclosed with a statement such as* "You will be randomly (by chance, like flipping a coin) assigned to one of…."]
* *[An example of a procedures statement follows:]* “If you decide to be in this study, your part will involve two visits one week apart. In the initial visit, which will take about one hour, you will complete a questionnaire about the problems you have walking with your prosthetic device in public areas that have not been modified for pedestrians. We will then fit you with our test prosthetic boot, and you will walk on a treadmill in the laboratory for three five-minute trials. You will be given a clean sock or stocking to wear. A research assistant will be with you to ensure that you do not fall. With your permission, we will videotape your lower body as you walk. Your face will not be video-taped, and your identity will not be revealed to anyone who sees the video. You may stop at any time and for any reason. After you complete the treadmill walking, we will ask you some questions about how the boot helped or hindered your walking. At the second visit, which will take place the next week, you will be asked to wear the prosthetic test boot again and to step up and down some steps in the laboratory while we videotape you. You will go up four steps and back down five times. A research assistant will be with you to ensure that you do not fall. With your permission, we will videotape your lower body as you use the steps. After you finish the steps, we will ask you some questions about how the boot helped or hindered your going up and down the steps. This visit will take no more than one hour. The total amount of time you will be in the laboratory is no more than 2 hours. Remember, you may stop at any time.”

**Risks or Discomforts:**

*[This section is required and must disclose any reasonably foreseeable risks and discomforts that a participant may experience. Risks and discomforts should be grouped according to probability of occurrence, whether rare or common. If there are special risks to pregnant or nursing women, women of childbearing potential, or to fetuses, these should be disclosed in* ***bold print****, with special instructions regarding need for acceptable birth control. Similar disclosure should be made for studies in which effects on sperm are possible. If there are no known or anticipated risks or discomforts associated with participation, the consent form should include such a statement.]*

* *[An example of a Risks or Discomforts Statement follows:]* “The following risks or discomforts may occur as a result of your participation in this study. Although we will carefully fit the test prosthetic boot, it might rub your residual limb. Please inform the researcher immediately if the boot is uncomfortable or rubs. It is also possible that you could fall, although research assistants will be at your side whenever you are using the boot.”
* *[An example of a Risks or Discomforts Statement when no risks or discomforts are associated with participation follows:*] “The risks involved are no greater than those involved in daily activities such as …..”

**Benefits:**

*[This section is required and must include a description of any benefits expected for the participants or for society. It is okay NOT to expect the participant to benefit; in such a case, you should describe possible eventual benefits of this research to society. Note that compensation is not a benefit of being in the study.]*

* *[An example of a Benefits Statement follows:]* “You are not likely to benefit in any way from joining this study. We hope that what we learn will someday help others with lower extremity amputations to benefit from improvements in walking safety with prosthetic devices.”

**Compensation to You:**

*[This section is required even if there is no compensation. If there is no compensation at all, this fact should simply be disclosed. This section should specify participant compensation and reimbursement, whether monetary, gift card, or class credit.* ***Be sure to review the tax language at the end of this section.*** *Compensation should**be prorated in cases where participants may make several trips or go through a number of sessions. It is generally inappropriate to pay bonuses for completion or to withhold payment until the study is completed. You should disclose that full compensation will not be given to those who withdraw early or do not complete the study, if that is the case. In studies such as this example, the IRB recommends that full compensation be given when participants must stop due to a physical inability to complete the study. For example, if the test boot causes irritation, the participant should be compensated for their time and effort anyway.]*

*[Protocols for Class Credit: Class credit may be offered for participation in some studies which enroll Georgia Tech students. In these cases, students should be given other options for fulfilling the research component that are comparable in terms of time, effort, and educational benefit. To fulfill the research component, students could participate in another research study, write a brief research paper, or attend faculty research colloquia. The paper should not be graded, and students who attend the colloquia should only have to attend. If students do choose to participate in research studies, they should be given several studies from which to choose.]*

* *[An example of a Compensation to You Statement follows:]* “You will be compensated $20 per hour for your time and effort. You will make two visits to the laboratory, for one hour each time, so your total compensation is $40. If you do not come for the second visit, you will be compensated a prorated amount. For example, if you complete the first visit, you will receive $20. If you do not come for the second session, you will receive no additional compensation.”
* *[An example of a Compensation to You Statement when class credit is being offered follows:]* “Instead of monetary compensation, Georgia Tech students will receive 1.0 Sona credits for each hour of participation.”
* *[An example of a Compensation to You Statement when there will be no compensation follows:]* “There is no compensation for participation.”
* *[The statement in quotes below is required when monetary compensation will be provided. Note that if U.S. tax residents receive $600 or more per calendar year, a 1099-misc will be issued. At that point, researchers need to collect tax reporting information from those human subjects. If non-U.S. tax residents receive more than $75, mandatory 30% withholding is required.]*

*“U.S. Tax Law requires that a 1099-misc be issued if U.S. tax residents receive $600 or more per calendar year. If non-U.S. tax residents receive more than $75, mandatory 30% withholding is required. Your address and Tax I.D. may be collected for compensation purposes only. This information will be shared only with the Georgia Tech department that issues compensation, if any, for your participation.”*

**Storing and Sharing your Information:**

*This section is required if researchers wish to retain participants’ images/data for future research use. During the consent process, researchers are**encouraged to consider whether**they should also obtain consent at this time to utilize participants’ information in future, unspecified research. (If you intend to build a repository, please see the separate guidance in the IRB Policies and Procedures Manual). Several suggested statements are provided below; you should include and edit as needed to fit your purposes.]*

* *An example of a consent statement for future, unspecified research use of participants’ information/data follows: “Your participation in this study is gratefully acknowledged. It is possible that your information/data will be enormously valuable for other research purposes. By signing below, you consent for your de-identified information/data to be stored by the researcher and to be shared with other researchers in future studies. If you agree to allow such future sharing and use, your identity will be completely separated from your information/data. Future researchers will not have a way to identify you. Any future research must be approved by an ethics committee before being undertaken.”*

*[Protocols Using, Analyzing, and/or Storing Human Genetic Information: NIH-funded genomic studies are required to obtain consent for participants' genomic and phenotypic data (which may include some clinical information) to be used for future research purposes and to be shared broadly through databases. These expectations for informed consent also include studies using genomic data from de-identified cell lines or clinical specimens that were created or collected after the effective date of the policy (January 25, 2015). See http://gds.nih.gov/ for more information].*

* *[An example of a Human Genetic Storing and Sharing Statement follows:]* “Your samples, genomic data and health information will be stored and shared with other researchers. The samples and information will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, or the study of where different groups of people may have come from.”
* *[Protocols Storing and Sharing Human Biological Samples and/or Data: This section is required for studies that plan on storing and sharing samples and/or data for future research use (e.g., biobank, repository, etc.). See also the IRB Policies & Procedures Manual for additional guidance on storing biological specimens and on establishing a repository). The following section should describe what samples/data are being stored, who will have access to it, how long it will be stored, how it might be used in future research (keep broad if unclear), if subjects will be contacted in the future, what will happen if participation status changes, if subjects’ samples will be used for commercial profit and, if so, if they will or will not share in those commercial profits, and what will happen if the storage protocol closes].*

*[An example of a Human Biological Storing and Sharing Statement follows:*  “Your blood samples will be stored and shared with other researchers. Your blood will be stored in a controlled access biobank. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. (If using a public database: Your blood will be stored in an unrestricted access biobank. This means that the information from this study will be freely available in a public, unrestricted database that anyone can use.) As such, the use of your samples in future research (even of identifier are removed) may be used for commercial profit. However, you will not receive any future profits if the research results in products that are eventually developed and sold for commercial purposes. Your blood will only be used to further research specifics in HIV/AIDS. We may contact you with any new information regarding the sample and its relation to any abnormalities. If you withdraw from this study, we will destroy your sample. Furthermore, if this study closes, your sample will be destroyed.

* *[This section is required for protocols where biospecimens will be collected and will (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. The following section should include a clear statement as to whether the subject’s collected biological samples will undergo genome sequencing. If so, clearly and briefly describe what genome is, and what it will be used for (if known) (e.g. establishing cell lines):*
	+ *[Example language:]* The tissue we collect from you can provide us with a lot of information. One of the ways we may use your tissue is by using your samples for Whole Genome Sequencing. Whole Genomic Sequencing is a process in which researchers can look at, or “read”, each part of your DNA all at one time. By doing this, researchers may use this information to create a living tissue sample (called a “cell line”) that can be grown in the laboratory. This allows researchers to have an unlimited supply of your cells in the future without asking for more samples from you. Your cells [will/may] be mixed with other human cells, mixed with animal cells, or grown in lab animals like mice.

These the cell lines and other samples may be stored in a "cell bank," so that other researchers and companies can apply to use the cell lines in their own research. The cell bank will only release cell lines to researchers and others under certain conditions. [Specify the terms of release established by the repositories, such as IRB approval or approval by a governance committee.]”

**Use of Photographs, Audio, or Video Recordings:**

*[This section is required if you are collecting photographs, audio, or video recordings. Specifically address who has access to these, how they are stored, for what purposes they will be used, and what happens to them once the study ends. Disclose whether recordings are erased after all the necessary information is collected from them and whether they are kept for archival purposes.*

* *[An example of using photographs, audio, or video recordings in public presentations statement follows:]* “We may want to use some of the photographs, audio, or video recordings of you in public presentations related to the research. We will not use any videotapes, photographs, recordings, or other identifiable information about you in any future presentation or publication without your consent.”

**Confidentiality:**

*[This section is required and should describe the extent, if any, to which confidentiality of records identifying the participant will be maintained.]*

* *[This example of a confidentiality statement is offered for your consideration. However, researchers should use language that accurately reflects the extent to which confidentiality can be assured. Be aware that you are required to inform subjects as to whether their collected private information or identifiable bio-specimens will be, or will not be, used for future research.]*

“The following procedures will be followed to keep your personal information confidential in this study: We will comply with any applicable laws and regulations regarding confidentiality. To protect your privacy, your records will be kept under a code number rather than by name. Your records will be kept in locked files and unless you give specific consent otherwise, only study staff will be allowed to look at them. Your name and any other fact that might point to you will not appear when results of this study are presented or published. **(If you want to store and share data and/or bio-specimens for future research:)** However, in the future, we may strip your data and/or bio-specimens of all information that could identify you. If this is done, we will share the de-identified information and/or bio-specimens for purposes of future research without obtaining additional consent from you/**(If you do not want to store and share data and/or bio-specimens for future research:)** Even if all identifiers have been removed from your data and/or bio-specimens, your data will not be used or distributed for the purposes of future research. The Georgia Institute of Technology IRB and the Office of Human Research Protections may look over study records during required reviews. **(If your study is regulated by the FDA, then use this as the last sentence)**The Georgia Institute of Technology IRB, the Office of Human Research Protections and/or the Food and Drug Administration may look over study records during required reviews.”

* *[If applicable, add the following sentence:*  “The sponsor of this study, National Institutes of Health, has the right to review study records as well.”]
* *[Web-based consent documents should include appropriate information like that which follows here:]* “You should be aware that the experiment is not being run from a ‘secure’ https server of the kind typically used to handle credit card transactions, so there is a small possibility that responses could be viewed by unauthorized third parties such as computer hackers. In general, the web page software will log as header lines the IP address of the machine you use to access this page, e.g.,102.403.506.807, but otherwise no other information will be stored unless you explicitly enter it.”]
* *[When confidentiality of participant identity is not proposed, such as when participants will be quoted by name, this section should be very clear regarding where and how the quotes will be used. Participants should also have the opportunity to review the text in which their quotes or identity appear to ensure proper attribution.]*

**Costs to You:**

*[This section is required and must disclose the cost, if any, that participants will bear as a result of being in this study. If there are no costs, this information should be specified.]*

* *[An example of a Costs to You Statement, when there is no cost to the participant, follows:]* “There are no costs to you, other than your time, for being in this study.”
* *[An example of a Costs to You Statement, when there IS cost to the participant, follows:]* “If you participate in this study, you will be responsible for the cost of the doctor’s visit.”

**Alternative Treatments:**

*[This section is only used when the study involves clinical or medical treatment, and is not needed for social and behavioral studies. If applicable, describe other medical treatments or procedures available if the person chooses not to participate or later withdraws from the study.]*

1. *[An example of an Alternative Treatments Statement follows*:] “If you do not participate in this study, the only alternative is to continue with your current program of medical treatment. If you withdraw from the study, you must consult your personal physician regarding ….”

**If this is a Clinical Trial, this section is required:**

*[Per 21 CFR 50.25(c), the following statement must be reproduced word-for-word in informed consent documents for applicable clinical trials:*

*“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.”*

*Additional guidance, including the definition of applicable clinical trials, may be found at* [*https://researchintegrity.gatech.edu/clinical-trials*](https://researchintegrity.gatech.edu/clinical-trials)*, under the link to Informed Consent.]*

**Clinically Relevant Information:**

[*This section is required if the study team is conducting clinical research and is collecting information, biospecimens, genetic data, etc. that could result in findings that may be clinically relevant to the subjects. In this section, please include a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.*

* (Example language for not disclosing clinically relevant information:] “As a part of this study, we will be collecting blood samples from you and running genetic tests. However, it is important for you to know that these result will not be disclosed to you under any circumstances, even if the results prove to be clinically relevant. If you are concerned about your health, we recommend you contact your personal healthcare giver.
* (Example language for disclosing clinically relevant information:] “As a part of this study, we will be collecting blood samples from you and running genetic tests. It is important for you to know that results may uncover something of clinical importance. If we discover something that could be of clinical importance to you, we will invite you in for a meeting and debrief you of what we found. However, after this, the responsibility will be yours to follow-up with your healthcare giver and pursue future medical care.

**Conflict of Interest:**

*[This section is required if the Principal Investigator or anyone else on the research team member’s department, and an approved management plan must be on file with the Office of Conflict of Interest Management (for Georgia Tech researchers) or with the appropriate office at Georgia State University for those researchers.  When COI disclosure is required in consent documents, the Georgia Tech or Georgia State University Office of Conflict of Interest Management will provide such language].*

**Questions about the Study:**

*[This section is required and must provide the name and contact information of the Principal Investigator or other person who can address questions about the study. If the study is taking place in another country, include an email address and telephone number for the PI. An example of a Questions about the Study Statement follows:]* “If you have any questions about the study, you may contact Dr. P. Investigator at telephone (XXX) XXX-XXXX) or Principal.Investigator@dept.gatech.edu.”

**In Case of Injury/Harm:**

*[This section is required for studies posing greater than minimal risk. The Principal Investigator, not a student researcher, must be named as the point of contact. If the study is taking place in another country, include the PI’s email address and telephone number, including international dialing information*

*An example of a Parental Permission In Case of Injury/Harm Statement follows:]*

“If you are injured as a result of being in this study, please contact Principal Investigator, Ph.D., at telephone (XXX) XXX-XXXX. Neither the Principal Investigator nor Georgia Institute of Technology has made provision for payment of costs associated with any injury resulting from participation in this study.”

**Questions about Your Rights as a Research Participant:**

*[This section is required and must include the following language:]*

* Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
* You have the right to change your mind and leave the study at any time without giving any reason and without penalty.
* Any new information that may make you change your mind about being in this study will be given to you.
* You will be given a copy of this consent form to keep.
* You do not waive any of your legal rights by signing this consent form.

If you have any questions about your rights as a research participant, you may contact the Georgia Institute of Technology Office of Research Integrity Assurance at IRB@gatech.edu.

*[Finally, include the following signature language. If this study is clinical, participants must write in the date AND TIME of their signature. If you are using electronic signatures, verbal consent, or electronic consent, please see the instructions at the end of the document.]*

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant Name (printed)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant Signature Date Time

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Consent Date

**Consent to Store and Share your Information:**

*[Insert signature line with clear options for subjects to agree or decline.]*

 *“I agree that my de-identified information/data may be stored and shared for future, unspecified research.*

*SIGNATURE \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*I do not allow my de-identified information/data to be stored and shared for future, unspecified research. These may only be used for this specific study.*

*SIGNATURE \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_”*

*[ELECTRONIC SIGNATURES: If the consent process will take place online and you intend to obtain electronic signatures, then a Waiver of Documentation is not needed. You will need to keep the signature section in this document and state in your IRB Wise submission what software will be used to obtain the electronic signature. Currently, only DocuSign is approved by OIT to obtain electronic signatures. Additionally, please state in the IRB Wise submission which survey software will be used to obtain consent. Please see the* [*OIT website*](https://gatech.service-now.com/continuity?id=kb_article_view&sysparm_article=KB0023604) *for more information about which programs/software are approved.]*

*[CONSENT WITHOUT SIGNATURES: If the consent process will take place online or verbally and the study qualifies for a Waiver of Documentation of Consent; you may simply remove the signature section and replace that language with either “Agree” and “Disagree” buttons or the following statement listed below. Additionally, please state in the IRB Wise submission which survey software or teleconference tool will be used to obtain consent. Please see the* [*OIT website*](https://gatech.service-now.com/continuity?id=kb_article_view&sysparm_article=KB0023604) *for more information about which programs/software are approved.]*

* “By completing the online survey, you indicate your consent to be in the study.”

*[Before uploading the consent document, be sure to delete all of the bracketed instruction language from the document. Consent documents will be returned without review if instruction language is not removed.]*