**Rochester Institute of Technology Consent Form**

**Title of Activity:**

**Investigator Name(s) and contact information:**

**Advisor name and contact information if research is conducted by a student:**

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| Key Information About this Study* We would like to invite you to be in a research study.  This study *(insert research question and purpose of the study in clear, concise language for people who are not familiar with your research)*. Participation in this research is voluntary; you don’t have to take part if you don’t want to.
* If you decide to take part, you will (*briefly describe what the subject will do if they take part; study procedures, tasks they will complete, equipment they will use or which will be applied to them, where they will do this. You will provide more detail in the body of the form.*).
* Participation in the study will be for (*insert amount of time subject will be engaged in the research (hours, days, weeks, months, number of sessions, duration of sessions and estimated time spent performing research activities (this may be the same as duration) and any follow-up time)*.
* Potential risks are (*provide potential risks that would be of most significance to subjects and discomforts as a result of study procedures and include any inconveniences (for example, wearing study equipment, standing/sitting for extended time). If there are no known risks then indicate “We believe there are no known risks connected to participating but there may be some we are not aware of”.*
* The most likely potential benefits *(There may be none for subjects, this can be stated, as can potential future benefits to society if applicable*)
* Appropriate alternative procedures or courses of treatment that might be advantageous to potential subjects if applicable.
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**INTRODUCTION**
You are invited to join a research study to look at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Please take whatever time you need to discuss the study with your family and friends, or anyone else you wish to. The decision to join, or not to join, is up to you.
In this research study, we are investigating/testing/comparing/evaluating \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

*The information here should be a clear and short description of the “bottom line” of the study. Hold details of the study until later in the document. Briefly give the subjects some background information about why this study is being done, this can include information about what is already known and what you hope to learn*.

**WHAT IS INVOLVED IN THE STUDY?**
If you decide to participate this is a basic outline of what will happen over the course of your participation \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. We think this will take you \_\_\_\_\_\_\_\_\_\_\_.

*Refer to the subjects as “you*.” *Tell subjects****exactly****what to expect. Explain in detail what will happen during the study and how the study will work. Include****everything****that subjects will be asked to do step-by-step. Describe all surveys and data collection instruments that subjects will experience. Indicate where the research will take place, how often they will be asked to perform the research tasks, how long each survey or procedure will take and state how long (e.g. minutes, hours, days, months, until a certain event or endpoint) the subjects will be part of the study. If multiple visits will be held provide a timeline and detailed description of each visit. If audio or video-taping will be used the subject must be informed. If taping is required for participation this must be stated. If research takes place during a class it must be clear what is effort is required for the class and graded and what is research.*

The investigators may stop the study or take you out of the study at any time they judge it is in your best interest. They may also remove you from the study for various other reasons. They can do this without your consent.

*If appropriate, list any additional reasons why subjects might be taken off the study.*

You can stop participating at any time. If you stop you will not lose any benefits.

**RISKS**
This study involves the following risks \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. There may also be other risks that we cannot predict.

*List the physical and psycho-social risks of participating in the study above.* *Risks may include side-effects, stress, discomforts, breach of confidentiality, invasion of privacy, social, psychological, or economic harm; risk of criminal or civil liability; or damage to financial standing, employability, or reputation. If there are no known risks then indicate “We believe there are no known risks connected to participating but there may be some we are not aware of”.****DO NOT STATE THAT THERE ARE NO RISKS OR THAT RISKS "SHOULD BE" NORMAL.***

**BENEFITS TO TAKING PART IN THE STUDY?**
It is reasonable to expect the following benefits from this research: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. However, we can’t guarantee that you will personally experience benefits from participating in this study. Others may benefit in the future from the information we find in this study.

*List all the benefits that might****reasonably****be expected from participating in the study.  First describe benefits to subjects, then describe benefits to others. If there are no benefits from participating in the research, state that fact.*

**CONFIDENTIALITY**

We will take the following steps to keep information about you confidential, and to protect it from unauthorized disclosure, tampering, or damage: \_\_\_\_\_\_\_\_\_\_\_. In some cases it may be necessary, for your safety or for the integrity of the study, for individuals from the HSRO or appointed by the HSRO, institution staff, IRB or sponsor to access your data.

*List all individuals and agencies who will have access to the data and records, and how data will be described if published or shared with others. Will you be using direct quotes which could be traced to an individual? Will you be aggregating the data?  State whether data will be linked to identifiers or no links.****Do not use statements to the effect that data will only be accessed by the research team.***

*Describe confidentiality protections here.  Explain how you are protecting the subject’s information. Give details as appropriate: for example, are data files kept in locked cabinets, are the data kept on a computer, is a password required for getting onto the system; who has access to the data, etc.*

**USE OF INFORMATION OR SPECIMENS**

*One of the following statements about any research that involves the collection of identifiable information or identifiable biospecimens. The purpose of this is to increase transparency by letting participants know that it might happen. If potential participants find it objectionable, they may not want to participate in the study. Consent forms will need to say either that information or biospecimens collected for the research might be stripped of identifiers and used in other research in the future, or that this will not happen.****Note that this is only about future research use of information and biospecimens that will be stripped of identifiers.***

*A. If you or others will never use information/specimens from this study for future research insert the following:*

Your information or biospecimens, even if the identifying information is removed, will not be used or distributed for future research studies

*or*

*B. If it is possible that information/specimens from this study will be used for future research, insert the following:*

The information or biospecimens collected from you in this research study might be stripped of identifying infromation and used for other research in the future. If we use the information/specimens in future research studies, or share the information/specimens with other researchers so they can use it, we would first remove anything that would identify you. We would use or share the deidentified information/specimens without getting additional permission (consent) from you.

**ALTERNATIVES TO TAKING PART IN THIS STUDY (if applicable)**

*For studies involving interventions (educational, social, medical, behavioral) include descriptions of alternative procedures or standard care that are available if subject chooses not to be in the study.*

***I*NCENTIVES**
*Indicate if subjects will receive anything for participating. If there are partial incentives or if incentives are pro-rated describe payment schedule and requirements for payment. If you are using a lottery of any sort be advised that New York State gaming law requires you to allow anyone who wishes to put their name in for a chance regardless of whether they participate in the research.  Questions about this policy should be directed to RIT's Office of Legal Affairs.*

**YOUR RIGHTS AS A RESEARCH PARTICIPANT**
Participation in this study is voluntary. You have the right not to participate at all or to leave the study at any time. Deciding not to participate or choosing to leave the study will not result in any penalty or loss of benefits to which you are entitled, and it will not harm your relationship with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

*Describe procedures for withdrawing and any follow-up that you will request for subjects who withdraw early. Follow-up such as questionnaires that are part of the research cannot be forced upon subjects who wish to withdraw.*

**CONTACTS FOR QUESTIONS OR PROBLEMS?**
Call  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  or email\_\_\_\_\_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_\_if you have questions about the study, any problems, unexpected physical or psychological discomforts, any injuries, or think that something unusual or unexpected is happening.

Contact Heather Foti, Associate Director of the HSRO at (585) 475-7673 or hmfsrs@rit.edu(link sends e-mail) if you have any questions or concerns about your rights as a research participant.

*Provide the name of one or more researchers who can be reached for assistance. If you are a student provide your advisor's contact information too.*

**Consent of Subject (or Legally Authorized Representative)**
Signature of Subject or Representative                        Date
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Upon signing, the subject or the legally authorized representative will receive a copy of this form, and the original will be held in the subject’s research record. Unless otherwise required by the HSRO, Exempt research does not require a signature.  For all other research, in some cases it may be in the best interest of the subject not to collect a signature and the HSRO will advise you if that is the situation.*