RESEARCH PARTICIPANTS RIGHTS & RESPONSIBILITIES

Your Rights as a Research Participant

If you are asked to consent to be a subject in a research study, you have the following rights:

- 1. To have enough time to decide whether or not to be in the research study, and to make that decision without any pressure from the people who are conducting the research.
- 2. To refuse to be in the study at all, or to stop participating at any time after you begin the study. If you decide to stop participating in the study, you have a right to continued, necessary medical treatment.
- 3. To be told what the study is trying to find out, what will happen to you, what drug/device will be used in the study, and what you will be asked to do if you are in the study.
- 4. To be told about the reasonably foreseeable risks of being in the study.
- 5. To be told about the possible benefits of being in the study.
- 6. To be told whether there are any costs associated with being in the study and whether you will be compensated for participating in the study.
- 7. To be told who will have access to information collected about you and how your confidentiality will be protected.
- 8. To be told whom to contact with questions about the research, about research-related injury, and about your rights as a research subject.
- 9. If the study involves treatment or therapy:
- 10. To be told about the other non-research treatment choices you have.
- 11.To be told where treatment is available should you have a research-related injury, and who will pay for research-related injury treatment.
- 12. To receive a copy of the consent form that you will sign.
- 13. To ask any questions you may have.

Your Responsibilities as a Research Participant

- 1. Completely read the consent form and ask the Principal Investigator (PI) any questions you may have. You should understand what will happen to you during the study before you agree to participate.
- 2. Know the dates when your study participation starts and ends.
- 3. Carefully weigh the possible benefits (if any) and risks of being in the study.
- Talk to the Principal Investigator (PI; the person in charge of the study) if you want to stop being part of the research study.
- 5. Contact the PI and/or the Hartford HealthCare Institutional Review Board (IRB) with complaints or concerns about your participation in the study.
- 6. Report to the PI immediately any and all problems you may be having with the study drug/procedure/device.
- 7. Fulfill the responsibilities of participation as described on the consent forms unless you are stopping your participation in the study.
- 8. Tell the PI or the person you are working with on the study when you have received the compensation you were promised for participating in the study.
- 9. Ask for the results of the study, if you want them.
- 10.Keep a copy of the consent form for your records.

The Investigator's Responsibilities

The PI is the individual who is responsible for a research study. The PI is required to:

- 1. Follow the Hartford HealthCare IRB-approved research study plan.
- 2. Obtain informed consent from all study participants.
- 3. Maintain the confidentiality of study participants.
- 4. Respect the privacy of study participants.
- 5. Quickly respond to all participant concerns and questions.
- 6. Tell participants about changes to the risks or benefits of the study.
- 7. Get approval from the Hartford HealthCare IRB for any changes to the study.
- Promptly report all unanticipated problems or research-related injuries to the IRB.
- 9. Per policy, keep research records for seven (7) years after the study is over.
- 10. Effectively train/mentor student researchers in ethical conduct of research.
- 11.Comply with all Hartford HealthCare procedures for the ethical conduct of human subject research.