15. Information for Prospective, Current Research Participants and Family Members

Before, during or after participating in a research study, individual participants or their family members may have questions, concerns, or complaints, or may want to know their rights as a participant in research. This section details the information that prospective and current research participants, as well as family members or others who may consent on behalf of a loved one or who may simply be consulted by a family member or friend who is considering participating in research, can expect to be provided by Investigators at HSL.

15.1 Consent Form Requirements

When participating in research, prospective participants must ordinarily sign an informed consent form, unless the ethics board at HSL that oversees research (known as an "Institutional Review Board" or "IRB") permits otherwise. There are certain elements contained in a consent form that are required by federal regulations. The basic required elements are:

- A statement that the study involves research;
- An explanation of the purpose of the study;
- The expected duration of participation;
- A description of the procedures to be followed;
- Identification of any procedures that are experimental;
- A description of any foreseeable risks or discomforts;
- A description of any benefits to the subject or to others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- For research involving more than minimal risk, 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, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject, including:
  - Contact information of the Investigator (or his/her staff) for any questions, concerns or problems the participant may have about the research.
  - Where to go and whom to contact (and contact information) in the event of a research-related injury when medical interventions or treatments are involved in the research.
  - Contact information of the IRB (or other appropriate IRB or ethics committee) for any questions the participant may have about their rights as a participant in research or any complaints or concerns about the research.
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.

There are additional required elements of informed consent, which are included as appropriate and may be found here.

The research participant is ordinarily the one that must sign the consent form; if the participant is not able to consent to his or her own participation, the participant's legally authorized representative must consent to the research.

There are certain circumstances under which an IRB can waive informed consent, or certain elements of informed consent, and those circumstances may be found in Section 4 of the IRB Policies and Procedures, which may be found on the HSL IRB website.

15.2 Research Participant Rights

Consistent with the required elements of informed consent, research participants should be aware of their rights:

- To be treated in a caring and polite way;
- To be told what the study is trying to find out;
- To be informed what will happen and whether any of the procedures, drugs or devices used in the research are different from what would be used in standard medical care;
- To be told about possible side effects or discomforts that may occur during the study;
- To be told if participants can expect any benefit from being in the study and, if so, what the benefit might be;
- To be told of other choices for treatment that they have, and how these alternatives might be better or worse than being in the study;
- To be told what sort of treatment is available if any medical problems arise;
- To be allowed to ask any questions about the study both before agreeing to be involved and during the course of the study;
- To be free from pressure when deciding whether to be in the study;
- To be told about new information learned during the study that might affect participants' safety or willingness to continue to take part in the study;
- To refuse to be in the study, or to change their minds about being in the study after it has started.
- To not have their care (or the care of their family members) received at HSL affected by a decision to refuse participation or discontinue participation in a research study;
- To receive a copy of the consent form that they sign indicating their willingness to participate.

Research participants, legally authorized representatives, and family members are encouraged to ask questions about the research, and to feel comfortable and confident that participating in the research is the right decision.

15.3 Questions, Complaints or Concerns

From time to time, research participants, family members, HSL staff and community members may have questions, concerns or complaints about research (including new, ongoing, or previously conducted research) conducted at HSL or by HSL investigators or staff. The following individuals may be contacted to discuss these issues in a confidential manner:

- IRB Director: 617.971.5367
- IRB Chair: 617.678.7592
- VP for Research Administration: 617.971.5351
- Chief Compliance Officer/General Counsel: 617.971.5219

The above-listed individuals may take down the caller's name and contact information, or if the caller does not wish to be identified, notes will be taken on the incident or issue, and follow-up will occur with the Investigator.

Individuals may also call the Healthcare ValueLine at 1.800.273.8452, which is available 24 hours a day, 365 days a year. When an individual calls the Healthcare ValueLine, a trained Communications Specialist answers the call, makes notes of the concern, and prepares a report that is forwarded to the Compliance Officer for review, investigation, and response. Callers are not required to identify themselves, but may do so if they feel comfortable.

Depending on the nature of the call, the callers may be advised to contact the Investigator or his/her research personnel directly, or the Compliance Officer may act as the liaison between the two parties. If a serious allegation is made against the Investigator or his/her research personnel, the allegation will be treated in the manner outlined in Section 9 of this policy document.

15.4 Research Resources for Prospective, Current Research Participants and Family Members

Research participants and family members are encouraged to use resources to learn more about research. The following resources may be helpful, but there are many more resources available online:

- Harvard Catalyst Regulatory Knowledge and Support Program, Research Subject Advocacy Group: http://catalyst.harvard.edu/programs/regulatory/participantsrsa.html
- Community Connect to Research: http://www.connecttoresearch.org/
- Clinical Trials.gov: http://clinicaltrials.gov/