FASTING IN HUMAN SUBJECTS RESEARCH	SOP 5.1.04

1. Purpose & Policy

The purpose of this SOP is to provide guidance to researchers whose human subjects research studies include fasting. IRB Policy *Section 5.1 – 5.2*.

2. General Information

Fasting includes abstaining from food or limiting food intake. Fasting of participants, whether it is a criterion that must be met before participating in the research, during the research, or both, must be described in the approved protocol.

3. Training Requirements

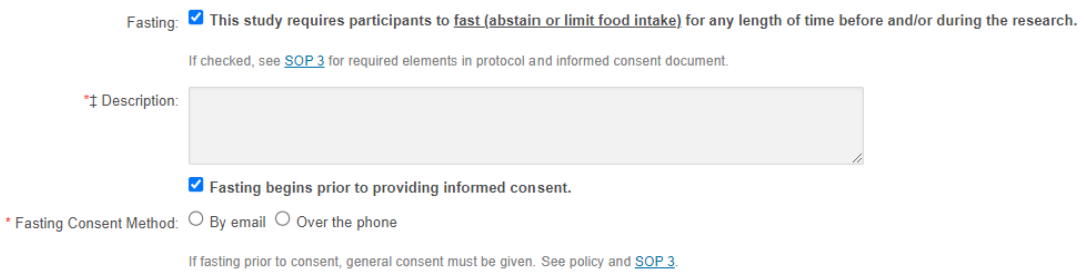
Other than the normally required and study specific training for all human subjects research, there are no additional specific training requirements associated with fasting; however, investigators should carefully read and follow this guidance.

4. Procedure

A. Determine whether your study will require participants to fast before or during the study.

B. The time of day of the fast, and any possible consequences of fasting, must be described in the protocol:

1) Study Participation: Description of Participation – Fasting Description
Include risks, as applicable. For example: Persons with diabetes and/or other metabolic disorders may be at a higher risk.



2) Study Participation: Physical Discomfort

   Include length of fast and other discomforts as applicable.

3) Participant Selection Criteria: Inclusionary and Exclusionary Criteria

   Potential participants that have diabetes and/or other metabolic disorders where fasting is contraindicated should be excluded, unless the inclusionary criteria require the diabetes and/or other metabolic disorders and such inclusionary criteria has been justified and approved by the IRB.

4) Informed Consent Document

   Description of the fasting will carry over from the Study Participation section of the protocol to the Risks & Discomforts Associated with Participant Activities in the Informed Consent document.

C. Fasting Before Enrolling in a Study

If a protocol requires the participant to fast for any length of time prior to arriving for the study, prior to participating in the study, and/or prior to providing formal informed consent, the researcher must receive general consent from the participant before the participant begins to fast. Under these circumstances, the following additional criteria must be met:

1) Recruitment materials must comply with *IRB SOP: Recruitment Materials*. In addition, recruitment materials describing the study must disclose that the study requires fasting. Indicate if fasting is an element of the screening process or if fasting will be part of the study tasks once enrolled. The recruitment materials must also provide the total length of time for the fast, which includes the time from the start of the fast through the experimental procedure time during which food is withheld.

2) During recruitment, participants should consent to fasting and the consent should be documented. This general consent can be obtained over the phone (during a screening interview) or by email.