

<b>FASTING IN HUMAN SUBJECTS RESEARCH</b>	<b>SOP 5.1.04</b>
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## 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

There are no specific training requirements associated with fasting; however, researchers 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.

Fasting:  This study requires participants to fast (abstain or limit food intake) for any length of time before and/or during the research.  
If checked, see [SOP 3](#) for required elements in protocol and informed consent document.

\*† Description:

Fasting begins prior to providing informed consent.

\* Fasting Consent Method:  By email  Over the phone

If fasting prior to consent, general consent must be given. See policy and [SOP 3](#).

- 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 a metabolic disorder where fasting is contraindicated

- should be excluded, unless the inclusionary criteria require the metabolic disorder 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.