Inclusion VS Exclusion Criteria

Inclusion criteria define specific conditions or characteristics that make it appropriate to enroll a person into a study. Exclusion criteria define conditions or characteristics that would make it inappropriate for a person to be enrolled. These criteria are often based on such factors as age, gender, medical history, life experiences, and current needs. Some research studies seek subjects with specific needs or interests, while others seek a broad range of individuals (often referred to as normal volunteers). Exclusion criteria may include pregnant women (unless the research is on pregnancy), severity of disease, mental incompetence, use of other medication concomitantly, or presence of other diseases. Principal Investigators must explain and justify the exclusion of women and/or minority groups and children. A person must qualify for the study before being asked to join as a human subject. It is important to understand that these criteria are not used to reject people personally. Instead, the criteria identify appropriate participants and help minimize the risks those participants face. The criteria also help researchers answer the research questions.

It is important to understand that exclusion criteria are not the opposite of inclusion criteria.

For example: If inclusion criteria are female, over age 18 and having a diagnosis of hypertension, exclusion criteria are not male, under 18 and not having a diagnosis of hypertension. Persons excluded from a study like this might be females who meet inclusion criteria but who are pregnant, nursing, or have a co-morbid diagnosis of diabetes.

Changes to the Common Rule - Researcher Retreats

On January 18, 2017, revisions were published to the Federal Policy for the Protection of Human Subjects, or Common Rule, for the first time since its publication in 1991. The explicit goal of these revisions—the result of collaboration between the US Department of Health and Human Services and 15 other Federal Departments and Agencies—is to reduce administrative burden and better protect subjects in the modern research context.
On January 17, 2018, HHS published an Interim Final Rule that delays both the effective date and the compliance date of the 2018 Common Rule until July 19, 2018. A Notice of Proposed Rulemaking (NPRM), released on April 19, 2018 by HHS and the 16 other departments and agencies that are signatories to the Revised Common Rule, proposes delaying the general compliance date for the 2018 Requirements for an additional six months, for the time period of July 19, 2018 until January 21, 2019. This proposed rule is intended to provide additional time to regulated entities for the preparations necessary to implement the 2018 Requirements. This proposed rule, if finalized, would require regulated entities to continue to comply with the requirements of the current Federal Policy for the Protection of Human until January 21, 2019.

In the event that the NPRM is not finalized such that the compliance date of the Revised Common Rule is July 19, 2018, the USF Institutional Review Board (IRB) is hosting two separate informational sessions for all USF and affiliate Researchers and Research Coordinators. The retreats will include information on the revised Common Rule, which includes:

- New Informed Consent Requirements
- New and revised Exempt categories
- Continuing Reviews and transition of currently approved studies to the revised Rule

Both retreats will be held at the IDR building, Oak View Room, 3720 Spectrum Blvd., USF Tampa Campus. Please register for one of the retreats below.

Thursday, June 28, 2018 from 10:00am until 12:00pm:
https://www.eventbrite.com/e/researcher-retreat-changes-to-the-common-rule-tickets-46402610457

Wednesday, July 18, 2018 from 10:00am until 12:00pm:
https://www.eventbrite.com/e/71818-researcher-retreat-changes-to-the-common-rule-tickets-46403596406

PLEASE NOTE: Contingent on the information regarding the timing of implementation of the New/Revised Rule, these trainings may be canceled. You will be notified of any cancellation via the email you input in your registration.

HRPP Policy Reminders/Updates:

Granting Extensions: A study is approved with contingencies when the study meets the 111 criteria and the IRB requires only minor changes to the IRB application. IRB Staff will communicates the reason(s) for the contingencies to the PI via eIRB. The requested changes must be made within 30 days of the date concerns were communicated. The study team can request an extension, beyond which further extensions will be granted at the discretion of IRB Administration or the IRB Chair. Otherwise, the application will be closed by IRB Staff and a new submission will be required for the research study.
**Reporting UPIRHSOs:** The policy on reporting unanticipated problems involving risk to human subjects or others (UPIRHSOs) has been revised to reflect these events must be reported to the USF IRB within 5 business days, rather than 5 calendar days as previously required.

**Notice of Hold or Closure by the Sponsor or Oversight Body:** When a PI receives notification from an oversight body that the study must be closed or put on a full or partial hold, USF HRPP policy requires the PI to inform the IRB within five (5) business days of receipt of such notification and provide the IRB with a copy of the written notification from the oversight body via a Reportable Event (RE).