



Scope, Objectives, Methodology, and Criteria

The scope of this review included human subject research protocols from September 1, 2017, to July 1, 2019. The human subject research protocols originated in the following departments: LiveStrong Cancer Institute, Surgery and Perioperative Care, Pediatrics, Psychiatry, and Neurology.

Specific audit objectives were to:

- Determine whether PIs are obtaining consent form key elements from human subjects
- Determine whether PIs listed on applicable human subject research protocols completed required training prior to receiving approval to perform research

To achieve these objectives, Internal Audits:

- Reviewed IRB applications and signed informed consent forms
- Reviewed and verified that required training was completed
- Interviewed PIs and related staff concerning policies and procedures specific to sick and acutely ill participants

Internal Audits randomly selected a sample of eight human subject research studies from a listing of greater than minimal risk human subject research protocols provided by the Office of Research Support. Six human subject research protocols originated from UT Austin and two transferred from Seton Medical Center.

The governing policies used as the criteria for this audit are as follows:

- Section 7-1320 of UT Austin's *Handbook of Operating Procedures: Human Subjects Used In Research*³
- *IRB Policies and Procedures Manual, Pre January 21, 2019, Changes*⁴
- *Office of Research Support and Compliance Policies and Procedures Manual Post January 21, 2019*⁵
- UT Austin overview of revised Common Rule changes applying to research supported by Department of Health and Human Services and other federal agencies⁶

³ (<https://policies.utexas.edu/policies/human-subjects-used-research>)

⁴ (<https://research.utexas.edu/ors/human-subjects/policies-and-procedures/>)

⁵ (<https://research.utexas.edu/ors/human-subjects/policies-and-procedures/>)

⁶ (<https://research.utexas.edu/ors/human-subjects/common-rule-and-other-regulatory-changes/>)
