



CTSA Program Common Metrics Operational Guideline: *IRB Duration*

Template Element	Description
1. Operationalized Metric Title	Median IRB Review Duration (Time from IRB submission to IRB approval)
2. Purpose	The purpose of this metric is to measure IRB duration and develop strategic management plans, including collaborations, to shorten the time it takes to receive IRB approval. Long IRB review duration can delay study start, prolonging the time until benefits of clinical and translational science findings can be realized.
3. Operational Specification	The median number of calendar days from the official IRB application receipt date to the official IRB final approval date for fully reviewed protocols submitted to the institutional or “local” IRBs at the CTSA Program primary institution (hub).
4. Technical Description	<p><u>Key Definitions</u></p> <ul style="list-style-type: none"> • The <i>receipt date</i> is the actual date that the IRB office initially received an application for IRB review in their office or in an electronic inbox for review. For submissions to IRBs that perform triage or pre-review, the receipt date is the date the protocol is received back at the IRB office subsequent to such triage or pre-review. • The <i>final approval date</i> is the date that the IRB determined that the protocol was approved with no IRB-related contingencies or stipulations remaining, so that, from the perspective of human subjects, the research can commence. • The <i>median duration</i> is the median across all protocols from the CTSA Program hub institution. • Institutional or “local” IRB is any IRB affiliated with the hub institution.

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	<p><u>Timeframe</u> This metric will be collected annually for all protocols approved during the previous calendar year (2015).</p> <p><u>Data Scope</u> All clinical research protocols reviewed by the IRB at the CTSA Program hub institution serving as the institutional or “local” IRB.</p>
<p>5. Score(s), Metric Type, Numerator and Denominator Statements or Continuous Variable Statement, Inclusion/Exclusion Criteria</p>	<p>This metric results in one score:</p> <p><u>Metric Type:</u> Median</p> <p><u>Continuous Variable Statement:</u> <i>The median number of calendar days from IRB submission to IRB approval. For each individual protocol, the duration is the final approval date minus the receipt date and is expressed in number of calendar days.</i></p> <ul style="list-style-type: none"> • Inclusion Criteria for Continuous Variable: Clinical protocols (including multisite studies) that received IRB approval from a fully convened hub institution IRB during the timeframe for this metric. • Exclusion Criteria for Continuous Variable: Protocols are excluded if they received approval from IRBs not affiliated with the hub institution, are currently under review (including deferred), received exempted/expedited review, are multisite protocols reviewed based on a reliance agreement, are an IRB amendment or renewal application.
<p>6. Data Sources & Methods for Data Collection</p>	<p><u>Data Source</u> May be IRB electronic records, manual records or a hybrid for each submitted protocol.</p> <p><u>Method</u> This metric is a retrospective metric. It can be reported for the most recent timeframe and can also be computed retrospectively for timeframes.</p>

Template Element	Description
7. Frequency of data collection and Reporting	Data are collected on an ongoing basis (at intervals determined by the timeframe) at the protocol level and reported at the timeframe for this metric at the aggregated level for a hub.
8. Unit of Analysis	Data will be collected within each hub at the protocol level and reported aggregated at the institutional level.
9. Notes/Comments	<p>*See NIH definition of clinical research http://grants.nih.gov/grants/glossary.htm#ClinicalResearch</p> <p>Different institutions are likely to have different processes for IRB review. A number of contextual variables are likely to be related to IRB review duration. Two previous CTSA Program studies have investigated, for small samples from multiple hubs, the relationship of these variables to IRB review duration. These contextual variables, which would likely be collected as part of the normal hub internal evaluation, need to be considered in interpreting the data locally.</p>