CTSA Common Metric (CM) Operational Guidelines

Median IRB Duration

Template Element	Description
1. Operationalized Metric Title	Median IRB Duration (Time from IRB submission to IRB approval)
2. Common Function Group	Resources and Services in a Hub
3. Common Sub-function	Regulatory Knowledge and Support
4. Operational Specification	The median number of calendar days from the official IRB application receipt date to the official date of IRB final approval granted for <u>all</u> protocols from the CTSA primary institution (hub).
5. Technical Description (include key definitions, timeframe, data scope)	<u>Definitions</u> • A *protocol* is any human subjects proposal that was reviewed by the hub institution's IRB during the data collection timeframe for the metric. • The *receipt date* is the actual date that the IRB office initially received an application for IRB review in their office or in an electronic in-box for review; this includes the receipt date for submissions to IRBs that perform triage or pre-review. • The *final approval date* is the date that the IRB determined that the protocol was approved with no IRB-related contingencies remaining, so that, from the perspective of human subjects, the research can commence. • The *duration* is the final approval date minus the receipt date and is expressed in number of calendar days. • The *median duration* is the median across all protocols from the CTSA hub institution. <u>Timeframe</u> This metric will be collected annually for all protocols approved during calendar year 2015. <u>Data Scope</u> All IRB reviewed protocols at the CTSA hub institution.

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6. Data Sources, Method of Data Collection, Exclusion Criteria	Data Source May be IRB electronic records, manual records or a hybrid for each submitted protocol. Method This metric is a retrospective one. It can be reported for the most recent timeframe and can also be computed retrospectively for timeframes. Exclusions Protocols currently under review (including deferred) and exempted/expedited reviews are excluded.
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. Scoring	Duration is a continuous metric that ranges from 0 to the maximum number of days required to complete an IRB review. This metric is scored as the median across the durations of all eligible protocols.
10. Notes/Comments	Protocols must include all human subject protocols (including multi-site studies) that received IRB approval from a fully convened IRB during the timeframe for this metric. If the IRB Office serves as a distribution mechanism, forwarding applications to other offices that must first be reviewed by other committees or entities (e.g., scientific review committees) prior to IRB review, and the IRB office takes no other action than forwarding the application to another committee or entity, the receipt date should be when the IRB office receives the application back and begins triage or triage and pre-review. Different institutions are likely to have different processes for IRB review. A number of contextual variables are likely to be related to IRB duration. Two previous CTSA studies have investigated, for small samples from multiple hubs, the relationship of these variables to IRB review duration. These

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	contextual variables, which would likely be collected as part of the normal hub internal evaluation, need to be considered in interpreting the data locally.