CTSA Common Metric (CM) Operational Guidelines

Study Start Up: IRB Approval to First Subject Enrollment

Template Element	Description
1. Operationalized Metric Title	Median Study Start Up Time (Time from IRB Approval to First Subject Enrollment)
2. Common Function Group	Sub-group of Consortium 2.0 and Collective Impact of Hub
3. Common Sub-function	Facilitate clinical research including multi-site studies
4. Operational Specification	The median number of calendar days from the official IRB final approval granted for <u>all</u> protocols from the CTSA primary institution (hub) to the enrollment of the first study subject.
5. Technical Description (include key definitions, timeframe, data scope)	<u>Definitions</u> • A *protocol* is any human subjects' proposal that was approved by a <u>fully convened IRB</u> at the hub institution during the data collection timeframe for the metric. The protocol must include the requirement of written consent from subjects including protocols with minimal risk. • The *IRB 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 *first subject date* (FS) is the date when the first research subject is enrolled in the study and is the date on the consent form of the first subject who was deemed eligible for the study. If the protocol includes multiple sites, the earliest first subject visit at any site should be used as the FS date. If no subjects were enrolled during the timeframe for the metric, enter 00/00/0000 for FS. • The *duration* is the FS date minus the IRB Approval 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 requiring written consent that received initial approval during calendar year 2015. <u>Data Scope</u> All IRB approved protocols requiring written consent at the CTSA hub institution for single and multi-

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	site studies.
6. Data Sources, Method of Data Collection, Exclusion Criteria	Data Source IRB Approval Date and First Subject Date may be found in a clinical trials management system (CTMS), such as Velos or OnCore. IRB Approval Date may be found in IRB electronic records, manual records or another system that tracks approved protocols. First Subject Date should be taken from the study consent form, as entered into CTMS or similar system or as reported by the PI or study coordinator. Method This metric is retrospective. It can be reported for the most recent timeframe and can also be computed retrospectively for timeframes. Exclusions Does not included IRB approved protocols that do not require a written consent form. Includes only protocols receiving initial approval (not renewal) during the timeframe. IRB approvals that meet the criteria but are for student projects should not be included.
7. Frequency of data collection and Reporting	Data are collected per protocol and on an ongoing basis. Data are to be reported annually and aggregated to the level of 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 enroll at least one subject. This metric is scored as the median across the durations of all eligible protocols.
10. Notes/Comments	This metric should be considered as the first of a set of metrics pertaining to clinical research process markers. The definition of IRB Approval Date is consistent with the IRB Duration metric. A number of contextual variables are likely to be related to IRB to FS Duration, e.g., clinical trial vs other clinical research designs; phase I, II, III; studies involving special populations; and rare disease studies. Protocols involving multiple sites will require collecting data on FS from all sites. The metric computed for a specific hub will be most useful if it is restricted to the enrollment targeted for that site.

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	Two previous CTSA studies have investigated, for small samples from multiple hubs, the IRB approval date data element, and one study has investigated FS. In general, updates of enrollment tables requested by the IRB at annual review or renewal were not adequate to obtain the FS data element. In the 2014 pilot of a similar metric by the Evaluation KFC, contacting a study PI or coordinator was necessary to obtain FS at many hubs and this was time consuming and in some cases impossible because the PI or coordinator no longer worked at the hub. On the other hand, most CTMS' typically contained the FS date. It is not known how many hubs have CTMS and for how many or what types of protocols. The feasibility study for the pilot of this metric should include a "flash poll" of hubs to determine the extent to which the FS date is collectable through CTMS vs only by contacting a study PI or coordinator.