

**DANA-FARBER / HARVARD CANCER CENTER
STANDARD OPERATING PROCEDURES FOR CLINICAL RESEARCH**

TITLE: ~~Responsibilities of the~~ Accrual Monitoring ~~Subcommittee~~

SOP #: QA-710

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**Applicable Regulations
& Guidelines:**

~~**Other References:** Clinical Investigations Policy and Oversight Committee (CLINPOC) Policies and Procedures~~

Responsible Personnel: ~~Accrual Monitoring Subcommittee~~ Scientific Progress Review Committee (SPRC), Principal Investigators (PI) or study staff designee, QACT Programmer, QACT Administrative Coordinator, QACT Program Systems Coordinator

Policy Statement: ~~The Accrual Monitoring Subcommittee, a subcommittee of CLINPOC~~ The Scientific Progress Review Committee, with the support of the QACT, is responsible for overseeing the ~~slow and fast~~ accrual monitoring of protocols.

Background: Monitoring of slow accruing protocols maximizes participant contributions by minimizing the likelihood that studies will fail to complete their objectives; promotes efficient use of resources and maximizes the likelihood that studies supported by DF/HCC Institutions will be completed, reported, and published. Monitoring of fast rapidly accruing protocols identifies protocols that ~~will need~~ require close monitoring to ensure adequate resources, prospective data collection and appropriate safety review.

Procedure:

~~1) Members of the Accrual Monitoring Subcommittee are appointed by the Chair of CLINPOC according to their role in the research process.~~

~~2) The Accrual Monitoring Subcommittee meets semi-annually.~~

~~3) 1) Slow Accrual Monitoring Procedures:~~

a. The QACT SPRC programmer-administrative coordinator runs a report ~~monthly semi-annually~~ to identify slow accruing protocols that will be reviewed by the SPRC the following month. Protocols are identified as accruing slowly if the actual accrual rate is less than or equal to 50% of the expected target accrual rate or if the actual accrual is equal to zero. Protocols that are included in the report must have been activated for six months, ~~involve an investigational treatment,~~ and have a valid target accrual ~~and be DF/HCC or NCI sponsored (non-~~

~~cooperative group) or PI-initiated Industry studies. The SPRC will not be responsible for the accrual monitoring of Phase III PI-initiated studies that fall under the purview of the Data and Safety Monitoring Board (DSMB). -will be excluded from slow accrual subcommittee review.~~

- b. The ~~QACT-SPRC~~ administrative coordinator sends memos on behalf of the ~~subcommittee-SPRC~~ to ~~the~~ PIs of therapeutic protocols. ~~Memos are sent to PIs of specific cooperative group, non-therapeutic or banking protocols if deemed necessary by the SPRC chair. The disease program leaders are notified of the slow accrual at the scientific progress review, and disease program leaders of protocols that are accruing slowly.~~ The memos specify which category the protocol(s) fall under:

- Protocols open for 6 to <12 months*:
~~-If accrual is zero, a response is required within 30 days~~
- If accrual is slow but greater than zero, a response is not required, the subcommittee will review the protocol at the next meeting
- Protocols open for 12 to < 18 months*:
~~-If accrual rate is less than or equal to 10% of the target rate, the study will be closed unless extenuating circumstances exist~~
~~-If accrual rate is slow but greater than 10% of the target rate, a response is required within 30 days~~
- Protocols open for 18+ months*:
~~-If accrual rate is less than or equal to 50% of the target rate for the length of the study and the target rate for the last 6 months, the study will be closed unless extenuating circumstances exist~~

* Temporary suspension time periods are taken into consideration.

If the PI requests that the study remain open, the response should include an explanation for the slow accrual rate, a plan for increasing accrual, and a statement for why the protocol should remain open. If the PI closes the study, this should be communicated to the ~~subcommittee~~SPRC.

~~b. The Accrual Monitoring Subcommittee~~The Scientific Progress Review Committee ~~meets to review~~ responses/justifications from PIs ~~at the monthly meeting.~~ If the members agree with the justification, the protocol remains open. ~~The SPRC can request that accrual to specific protocols be reviewed prior to the next annual review. -until the next slow accrual report is run.~~ If the justification is not adequate or the ~~subcommittee-SPRC~~ disagrees with the justification, the protocol ~~can be closed to enrollment. -is brought to the next CLINPOC meeting with a recommendation and the full committee decides the final outcome. CLINPOC also receives a summary report of all of the protocols reviewed and the outcome of the review.~~

c. The QACT-SPRC administrative coordinator sends follow-up memos to the PIs and disease program leaders as needed. If CLINPOC accepts the subcommittee's recommendation for a protocol to close, the PI or designee is asked to complete a closure form and send it to the Office for Protection of Research Subjects (OPRS). If the SPRC agrees to review the accrual prior to the next annual scientific progress review, a memo is sent to the PI. If the SPRC agrees to close a protocol to enrollment, a memo is sent to the PI informing him or her of the closure date. The QACT administrative coordinator completes the closure form and submits it to the Office for Human Research Studies (OHRS). A copy of the form is then sent to the PI.

2) Zero Accrual Monitoring Procedures

a. Semi-annually, the QACT administrative coordinator will run a report identifying protocols meeting the zero accrual criteria:

- Protocols open > 12 months with zero subjects enrolled
- If a disease is rare, this will be considered in discussion with the PI.

b. After a protocol has been identified as zero accruing, the following will occur:

1. A summary of zero accruing protocols will be sent to the SPRC chair.
2. A standardized letter will be sent from the QACT to the PIs informing them that their protocol has been identified as zero accruing and will be closed by the SPRC.
3. Should there be significant extenuating circumstances the PI can request reconsideration to the SPRC Chair with a cc to the Director of the QACT by writing in detail the reasons for this.
4. The QACT administrative coordinator completes the closure form and submits it to the Office for Human Research Studies (OHRS). A copy of the form is then sent to the PI.

4)3) ~~Fast~~ Rapid Accrual Monitoring Procedures

a. Monthly, the QACT ~~Protocol Systems Coordinator~~ administrative coordinator will run a report identifying protocols meeting the ~~fast~~ rapidly accruing protocol criteria:

- An expected duration of less than one year
- An expected duration of greater than one year and having an accrual rate 1.5 times faster than expected

b. ~~Once After~~ a protocol has been identified as a ~~fast~~ rapidly accruing study, the following will occur:

1. The QACT Data Analyst will run a missing forms report (if applicable).
- 1.2. A standardized letter will be sent from the QACT to the ~~study team,~~ including the PI, ~~principal Investigator, Site Investigators, Research Nurses and study coordinators~~ informing ~~them~~ him or her that the protocol has been identified as ~~fast~~ rapidly accruing and reminding them to be closely monitoring the study's progress, including toxicities and data.

~~2.3. The study will be flagged as fast rapidly accruing for the DF/HCC Data and Safety Monitoring Board (DSMB) or Data and Safety Monitoring Committee (DSMC) (if applicable). The DSMC will review fast rapidly accruing trials every three months. The DSMB will determine if more than semi-annual review is necessary on a trial-by-trial basis.~~

~~3. The QACT Data Analyst will run a missing forms report to be sent to the study team (if applicable).~~

~~4. The Accrual Monitoring Committee will be notified via email when a fast accruing trial is identified and a brief study status report (accrual, data if at the QACT and adverse events) will be provided for their review.~~

~~c. After a protocol is initially identified as rapidly accruing, progress will be monitored by the QACT monthly and follow-up letters will be sent to the PI as needed. This process of monitoring (letter, missing forms report etc) will occur every 6
—months if the protocol remains identified as a fast accruing trial.~~

~~d. The list of fast accruing protocols will be presented. The protocols accrual and data statuses will be included for the Accrual Monitoring Committee's review. The Accrual Monitoring Committee will review the protocols and decide if further action or increased monitoring is required.~~

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