DANA-FARBER / HARVARD CANCER CENTER
POLICIES FOR HUMAN SUBJECT RESEARCH

TITLE: New Protocol Submission Requirements		
POLICY #: RCO-104	**Page:** 1 of 4	**Effective Date:** 08/01/2023

1. POLICY STATEMENT:

To ensure timely review and activation of new protocols, investigators must ensure certain requirements are met prior to the submission of a new research project. The Core Site PI, or designee (though with designee, the Core Site PI should remain actively involved throughout the process to ensure timely submission to activation), is responsible for ensuring the submission packet is complete prior to submission, tracking the progress of reviews and approvals, and responding to conditions in a timely manner. Submissions that do not comply with these requirements are subject to withdrawal.

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This is a new DF/HCC policy outlining:

- Requirements that the Core Site PI or designated research team member must meet or ensure are completed prior to new protocol submissions in iRIS
- Guidelines for responding to conditions for new protocol submissions in a timely manner and actions that may be taken when conditions are not responded to in the defined timelines.
- Administrative withdrawal timelines for all pending protocols and actions that study teams may take to avoid such withdrawals.

2. BACKGROUND:

The DF/HCC strives to encourage timely and efficient review, approval, and activation of new research protocols. Researchers are expected to adhere to minimum submission requirements and acceptable time frames for responding to conditions.

3. RESPONSIBLE PERSONNEL:

3.1. Core Site Principal Investigator (Core Site PI)
3.2. Research Manager
3.3. Regulatory Coordinator
3.4. Reviewers and Review Committees
3.5. PRMS Clinical Research Project Manager (CRPM)
3.6. DF/HCC Associate Director of Clinical Trials
3.7. DF/HCC Medical Director
3.8. OHRS Staff

4. DEFINITIONS:

4.1. **Administrative withdrawal**: Removal of a submission from the review process that has not received all necessary approvals. The proposed submission will not proceed to activation and no research activities may occur.

4.2. **Administrative hold:** Completion of a new protocol submission in the review process that is unable to activate. The protocol submission will be completed, but the research will remain on hold and no research activities may occur until a future submission is approved and activated to resolve the reason(s) for the hold.

5. POLICY:

5.1. **Minimum Requirements for New Protocol Submission**

5.1.1. The following are minimum requirements for initiating a new protocol submission. The Core Site PI, or designated research team member, must ensure that all requirements are in place and all required documents have been received from the sponsor prior to making a new protocol submission.

5.1.1.1.A final protocol document, final versions of all mandatory subject-facing materials (e.g., diaries, questionnaires), and final pharmacy manual (if applicable) are required and must be included in the initial submission.

5.1.1.2. The sponsor-approved informed consent document must be included in the initial submission.

5.1.1.3. At least a draft version (preferably a final document) of any other operational documents required to conduct the study (e.g., laboratory manual, imaging manual, sample collection manual) must be included in the initial submission.

5.1.1.4. For studies requiring an IND or IDE, including externally sponsored research, the sponsor must provide the IND number that is assigned upon submission of the IND application to the FDA. DF/HCC investigator-sponsored protocols that are pending FDA review should not be submitted until the FDA approval/study may proceed memo is obtained. However, DF/HCC investigator-sponsored protocols that are expected to receive an IND exemption can be submitted once the exemption is confirmed or at 30 days past the submission to the FDA.

5.1.1.4.1. For CIRB sponsored studies the NCI ensures this requirement is met so they do not need to be submitted locally.

5.1.1.5. DF/HCC strongly encourages the participation of multiple DF/HCC sites on new research protocols, when appropriate. The Core Site is expected to contact other DF/HCC institutions to confirm their interest in participating prior to the submission of a new protocol. If some or all the other DF/HCC sites do not wish to participate, the core site must indicate on the new project application who was contacted at other site, that person's role within research team, and reason for not participating when making the submission.

5.2. **Responding to Conditions**

5.2.1. Research teams must respond to any conditions from feasibility reviewers as well as SRC and IRB to allow for approval in a timely manner. The expectation is response to conditions within 14 calendar days.

5.2.1.1. A new protocol submission pending responses to conditions issued by scientific review committees (SRC) or institutional review boards (IRB) for greater than 90 days is subject to administrative withdrawal by OHRS. A new protocol submission pending responses to any other conditions for greater than 90 days is subject to administrative withdrawal by the PRMS Clinical Research Project Manager (CRPM).

5.3. **Withdrawal of Pending Submissions**

5.3.1. Any new protocol submission that remains pending for 200 days or more from the date of initial submission, or meets other criteria for withdrawal under this policy, is subject to administrative withdrawal by either OHRS or the CRPM.

5.3.1.1. If a new protocol is pending due to study team or internal delays, the CRPM may request a review of the program's current portfolio of active and pending protocols by program leadership, the cancer center clinical trials office, and/or DF/HCC leadership. The DF/HCC Associate Director of Clinical Trials or DF/HCC Medical Director may request the program close out inactive studies, withdraw pending new protocol submissions, or pause submission of new protocols.

5.3.1.2. If a new protocol is pending due to sponsor delays or other factors outside of the research team's control, the CRPM may require that the study either be activated by a certain date, be put on administrative hold or administratively withdrawn.

5.3.1.3.If a new protocol is pending due to a lack of responses to conditions issued by scientific review committees (SRC) or institutional review boards (IRB), OHRS may request that the protocol be withdrawn. Otherwise, protocols pending due to a lack of response may be subject to administrative withdrawal by the PRMS Clinical Research Project Manager (CRPM).

5.3.2. The Core Site PI may appeal any request to withdraw a new protocol submission within 2 weeks. A request to appeal must include a plan and timeline for activation of the protocol. Appeals will be adjudicated by the DF/HCC Associate Director of Clinical Trials and DF/HCC Medical

Director.

5.3.3. Any new protocol submission that remains pending for 250 days or more from the date of initial submission will be administratively withdrawn and is not subject to appeal.

6. APPLICABLE REGULATIONS & GUIDELINES:

OHRS Letter to Sponsors

7. RELATED FORMS & TOOLS:

DF/HCC iRIS Wiki: Responding to a Condition