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GUIDANCE DOCUMENT: INVESTIGATOR REPORTING RESPONSIBILITIES AND CORRESPONDENCE GUIDELINES

RCRC IRB requires that you notify us of the following in writing:

- Any changes to the information or documents provided to the Board at the time of initial review and approval (e.g. PI licensing status, FDA approval status, Conflict of Interest Information)
- Revisions/amendments to the protocol, planned protocol deviations, informed consent document, Investigator's Brochures prior to initiation of changes (except when necessary to eliminate an apparent immediate hazard to research participants).
- Advertisement(s), Recruitment, or study material (i.e. any information provided to participants);
- Changes in the research site address or the addition/deletion of a study site(s);
- Changes in the research laws of the state;
- Changes in significant site personnel such as the Principal Investigator or Research staff responsible for receiving documents or corresponding with RCRC IRB.
- Changes in the Conflict of Interest for the Principal Investigator or the research staff.

Unanticipated Problems and Findings Detected in the Monitoring Process

- Reports of unanticipated problems involving risks to participants or others. RCRC defines unanticipated problems as "any incident, experience, or outcome that is (1) unexpected, (2) related or possibly related to the research, AND (3) suggests that the research places participants or others at a greater risk of harm than was previously known or recognized". RCRC requires reporting of these events within 10 business days of discovery.
- Findings detected in the monitoring process when those findings could affect the safety of the participants or their willingness to continue participation, influence the conduct of the study or alter RCRC's approval to continue the study;

RCRC requires reporting of the above events within 10 business days of discovery. Reporting of these events/information should occur regardless of whether the event/information is discovered during or after study completion, or after participant withdrawal or completion of the research.

RCRC does not require review for the following items;

- Minor protocol deviations - Minor protocol deviations are accidental or unintentional changes from the IRB-approved protocol that do not increase risk to one or more participants, do not adversely affect the rights, safety or welfare of one or more participants, or do not adversely affect the integrity of the study data.
- Safety Reports which do not meet the definition of an unanticipated problem.
- If these events must be reported to satisfy Sponsor or site reporting requirements, please utilize FORM 320 Non-Reportable Event Form.

To request approval of protocol amendments, Investigator Brochures or Product Information:

- Complete and submit FORM 220 "Modifications to Previously Approved Research" Include a detailed summary of the proposed changes, preferably provided by the sponsor, which clearly indicate the previously approved wording and the new wording, and
- Include a clean copy of the revised or amended protocol.

To request the review of planned protocol deviations:

- Complete and submit FORM 220 "Modifications to Previously Approved Research"
- Ensure the applicable questions are answered completely and with enough detail for Board/Reviewer consideration
- Include the sponsor approval for the deviation.

To request the review of informed consent document revisions:

- Complete and submit FORM 220 “Modifications to Previously Approved Research”
- Include a copy of the previously approved RCRC IRB consent document, reflecting the proposed changes. If changes are extensive please use track change mode.
- It is necessary for the reviewer to compare the previously approved information to the proposed revisions. Therefore, please use reference numbers on the sections of the document(s) being compared or write changes legibly on a separate attachment.

To request the review of new or revised advertising materials or study material:

- Complete and submit FORM 220 “Modifications to Previously Approved Research”
- Attach a copy of the previously approved document(s) reflecting the proposed changes.
- Include a clean copy of the revised document.

To report changes to the FDA form 1572:

- Submit a cover letter.
- Submit a copy of the revised 1572.
- If changes affect Box 1 or 3, also submit FORM 150 (PI change) or FORM 140 (site change) as applicable

To request a Continuing Review or to submit an Interim Report of your research:

- Single Site Investigators - Complete and submit FORM 120.SS *Continuing Review Report for Single Site Research*, at least two (2) weeks prior to the expiration date.
- Multi-Site Investigators - Complete and submit FORM 120.I *Interim Report for Investigators in Multi-Site Research*, at least two (2) weeks prior to the expiration date.

To report site additions, deletions or address changes:

- Complete and submit the “Additional Site/Change in Site” FORM 140
- Include a copy of the revised 1572, if applicable.

To report a change of the Principal Investigator:

- Complete and submit the “PI Change” FORM 150

To report Unanticipated Problems involving risks to participants or others:

- Complete and submit FORM 300 “Event Determined to Be an Unanticipated Problem”

To report the completion of your research:

- Complete and submit the Final/Close-out Report: *FORM 130*, two (2) weeks prior to the expiration date.

Additional Information:

- If an Investigator submits an Unanticipated Problem (UP), it will be reported to the FDA, DHHS or other federal agencies, as appropriate.
- All findings of serious or continuing non-compliance will be reported to the FDA, DHHS or other federal agencies, as appropriate.
 - Serious non-compliance defined as: *non-compliance that places the participants at increased risk of harm.*
 - Continuing non-compliance defined as: *a pattern of non-compliance that indicates that further non-compliance may occur without intervention.*

RCRC does not require reporting of the following items (If submitted, an administrative processing fee will be charged);

- Minor deviation (Form 320)
- IND Safety Report or adverse event which has not been determined to be a UP (Form 320)
- 1572 or Statement of Investigator revision, when revisions do not affect Box 1 or Box 3
- Addition/Removal of a Sub-Investigator or update to Sub-Investigator credentials, if not required by RCRC (RCRC does not typically require information on Sub-Investigator credentials unless directed by the Board).