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GUIDANCE DOCUMENT: PROJECT MANAGER REPORTING RESPONSIBILITIES AND CORRESPONDENCE GUIDELINES

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

- Revisions/amendments to the protocol, informed consent document(s), Investigator's Brochures prior to initiation of changes (except when necessary to eliminate an apparent immediate hazard to research participants).
- Template Advertisement(s), Recruitment, or Study Material (i.e. any information provided to participants);
- Changes in significant study management personnel such as the Project Manager and staff responsible for receiving documents or corresponding with RCRC.

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”.
- 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 reporting requirements, please utilize FORM 320 Non-Reportable Event Form.

To request approval of protocol amendments/revisions, Investigator Brochures or Product Information, please use FORM 220 Modifications to Approved Research and:

- Include a detailed summary of the proposed revisions, which clearly indicate the previously approved wording and the new wording, and
- Include a clean copy of the revised or amended protocol.
- If these protocol revisions require modifications to the template Informed Consent Document (ICD), the ICD revisions must be submitted with the protocol amendment/revisions.

To request the review of template informed consent document revisions, please use FORM 220 Modifications to Approved Research and:

- Include a copy of the previously approved RCRC template consent document, reflecting the proposed revisions. If revisions 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 template advertising materials or study material, please use FORM 220 Modifications to Approved Research and:

- Submit a copy of the previously approved document(s) reflecting the proposed changes or new template document(s).
- Include a clean copy of the revised template document, in MSWord format.

To request a Continuing Review of your research, please use form FORM 120.PM Continuing Review Form for Project Managers:

- RCRC should receive a Continuing Review Report within two weeks of study expiration to allow time for processing and avoid a lapse in IRB approval.

To report Unanticipated Problems involving risks to participants or others:

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

To report a change in Project Manager or research contact staff:

- Please complete a Change in Project Manager Form and return for update of our files.
- For a change or an addition to the research management staff, please submit your request to rcrc@rcrc-irb.com and identify the Sponsor and Protocol number for the change.
- For a change in invoicing contact, please submit your request to rcrc@rcrc-irb.com and identify the Sponsor and Protocol number for the change.

To report the completion of your research:

- RCRC will automatically close the research after review of the last Investigator's Final/Closeout report. The Project Manager will be notified, in writing, after the acceptance of the final site closure.

Additional Information:

- The Project Manager, and any identified research management staff, will be copied on all Investigator Correspondence
- If an Unanticipated Problem (UP) is submitted by either the Project Manager or an Investigator participating in the research, it will be copied to the FDA, DHHS or other federal agencies, as appropriate.
- All findings of serious or continuing non-compliance will be copied 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 IRB Administrative Staff aims to foster a consultative relationship with the Principal Investigators, Project Managers and their research staff. Please contact us with any questions or concerns regarding submission documents or reporting requirements. Be sure to include all applicable supporting documents and required attachments.