CPRC Application Information

*Only fully completed CPRC submission packets, including all required signatures, will be reviewed by the committee. Any missing documents will be requested before reviewing.*

**Application Process**

- Obtain required signatures on CPRC application. Required signatures include: PI (all studies) and Biostatistician (where applicable; write “N/A” if not applicable). If application and supporting documents are sent directly from the PI’s x500 then signature is not required.
- Email the CPRC application and required documents listed below to ccprc@umn.edu.
- Required documents:

<table>
<thead>
<tr>
<th>Required for Therapeutic Interventional Studies</th>
<th>Required for Non-Therapeutic Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol</td>
<td>YES</td>
</tr>
<tr>
<td>TRUC Approval Letter</td>
<td>YES</td>
</tr>
<tr>
<td>Investigators Brochure</td>
<td>if applicable</td>
</tr>
<tr>
<td>IRB Application</td>
<td>NO</td>
</tr>
<tr>
<td>Consent</td>
<td>NO</td>
</tr>
<tr>
<td>Data &amp; Safety Monitoring Plan or Charter</td>
<td>if applicable</td>
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</tbody>
</table>

**Submission Deadlines**

Two Fridays prior to the scheduled CPRC meeting. Check the CPRC website for meeting dates.

**Administrative Review**

The following protocols may be eligible for administrative review:

- National Clinical Trials Network (NCTN) studies, formerly Cooperative Group
- Externally peer-reviewed (non-therapeutic only).
  See list of approved organizations.
- Treatment/management guidelines not asking a research question
- Focus group

**Expedited Review**

The following protocols are eligible for expedited review. Please use the CPRC Expedited Application Form found here.

- Chart review
- Repository
- Specimen banking

**Definitions**

- Therapeutic Interventional Trials: Clinical trials using drugs, devices, radiation, surgery, and/or biological agents.
- Non-Therapeutic Interventional Trials: Studies utilizing a behavioral intervention, a non-drug/biologic/device/radiation or surgical agent/technique or having an epidemiologic/observational outcome.
- Principal Investigator: Individual who is in charge of the study; if there is a study team, the leader is the Principal Investigator.
- Co-Investigator: Member of a study team who makes a direct and significant contribution to the management of a trial.
- Subject/Study Coordinator: Research nurse and/or coordinator assigned to the study.
- Regulatory Contact: Person performing the study’s regulatory functions.
- Study Contact: Person who will receive public inquiries regarding the study (required by ClinicalTrials.gov).

**After Submission**

- Subjects may not be enrolled on the study until final approval is granted by the CPRC.
- The Principal Investigator should notify the CPRC via email when the study opens to accrual.
- The CPRC should be added as a correspondent on the initial IRB application. If the IRB application has already been submitted, complete the Add, Remove or Change Personnel form found on the IRB website (http://www.irb.umn.edu/forms.html). Use the exact input as the correspondent name: CCPRC, Committee.
- The CPRC should be copied on any of the following IRB submissions: protocol amendments, consent form revisions, changes in enrollment and changes in Principal Investigator until study is closed to accrual.
- The Principal Investigator or Study Contact should notify the CPRC via email when the study closes to accrual.