

Disease Team Sign off Process

V.3 date 7.24.2020

- Information from disease team form will be available within email template.
- Disease team paper form to be combined with PRMC application.
 - Page 2-Priority Scoring Sheet and additional information, to be transferred to the PRMC application.
- In all cases – lead site will initially send email to internal disease team leader documenting approval of the study via below template:
- All emails are required for PRMC submission, and approval requests and responses must be highlighted

Subject Headers to be used for appropriate situation:

- “PRMC1234: Disease team approval needed”
- “PRMC1234: Disease team notification” for sending Co-ops or non-joint studies to UH.
- “PRMC1234: Disease team approval – URGENT RESPONSE REQUIRED, 2nd, 3rd request etc.” If urgent or after multiple requests

Dear Dr. XXX

Do you support the attached trial?

Please answer Y or N.

Your positive response back documents your support for the trial.

Sincerely,

XXX

After this above process occurs the following steps shall be taken for each of these trial types:

IIT Trials

- Lead site sends protocol to non-lead site via email.
- Lead site will email the respective disease team MD leader and the corresponding research coordinator contact.
- Email responses will count as signatures.
- Non-lead site needs to respond to the email within 5 business days.
- Emails forwarded to PRMC manager with submission.

After email to own/internal disease team lead, the email template below can be used for IIT trials that can be conducted at non-lead site:

Dear Dr. XXX,

Please see attached protocol for disease team sign off. Please respond to the following:

- Does CCF/UH wish to participate?
 - If no, why not?
 - If yes, annual and total target accrual number?
 - If yes, who will be the PI?

Your email response to the above questions indicate your approval for the protocol.

Sincerely,

XXX

Email template for single site IIT trials:

Dear Dr. XXX,

Please see attached protocol for disease team sign off. UH/CCF may not participate because XXX.

As the disease team leader, do you approve this trial?

Sincerely,

XXX

Industry Sponsor Trials That Both Sites Can Participate

- Lead site sends protocol to non-lead site via email.
- Lead site will email the respective disease team MD leader and the corresponding research coordinator contact.
- Email responses will count as signatures.
- Non-lead site needs to respond to the email within 5 business day.
- Emails forwarded to PRMC manager with submission

After email to own/internal disease team lead, below is the industry sponsored email template that can be sent to non-lead site:

Dear Dr. XXX,

Please see attached protocol for disease team signoff. Per sponsor, CCF/UH may participate. Please respond to the following:

- Does CCF/UH wish to participate?
 - If no, why not?
 - If yes, annual and total target accrual number?
 - If yes, who will be the PI?

Your email response to the above questions indicate your approval for the protocol.

Sincerely,

XXX

Single Site Industry Sponsor Trials

- Participating site sends protocol to non-participating site as acknowledgement.
- Lead site will email the respective disease team MD leader and the corresponding research coordinator contact.
- A copy of the below email template sent to the non-participating site must be attached with the PRMC application.

Dear Dr. XXX,

Please see attached protocol being submitted to PRMC. Per sponsor, CCF/UH may not participate.

Sincerely,

XXX

NCTN Trials

- Participating site sends protocol to other site email as acknowledgement – either as lead site or secondary addition
- Lead site will email the respective disease team MD leader and the corresponding research coordinator contact.
- Each site completes the PRMC application at time of activation. (Shortened application for COOP trials)
- After internal email approval is sought, a copy of the below email template sent to the other site must be attached with the PRMC application.
- Requirement for PRMC Application

Dear Dr. XXX,

Please see attached protocol being submitted to PRMC. This is a NCTN trial available on CTSU.org

Sincerely,

XXX