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
CASE CCC CLINICAL TRIALS DISEASE TEAM LEADERS

Breast – ID #1
UH: Alberto Montero, MD - alberto.montero@uhhospitals.org
UH: Nicole McClain - nicole.mcclain@uhhospitals.org
CC: Halle Moore, MD - moorehl@ccf.org
CC: Katie Gardner - GARDNEK5@ccf.org

Gastrointestinal (GI) – ID #2
UH: Anit Mahipal, MD - amit.mahipal@uhhospitals.org
UH: Rachel Carney - Rachel.carney@uhhospitals.org
CC: Smitha Krishnamurthi, MD - krishns3@ccf.org
CC: Natalia Rosas - rosasn@ccf.org

Brain – ID #3
UH: Herbert Newton, MD - Herbert.Newton@UHhospitals.org
UH: Joyce Callahan - joyce.callahan@uhhospitals.org
CC: Gene Barnett, MD - barnetg@ccf.org
CC: Theresa Naska - naskat@ccf.org /
Kathy Robinson - robinsk2@ccf.org

Head & Neck – ID #3
UH: Rod Rezaee, MD - rod.rezaee@uhhospitals.org
UH: Joyce Callahan - joyce.callahan@uhhospitals.org
CC: Jessica Geiger, MD - geigerj@ccf.org
CC: Jennie Laeng - LAENGJ@ccf.org

Thoracic – ID #5
UH: Afshin Dowlati, MD - afshin.dowlati@uhhospitals.org
UH: Carol Tackett - carol.tackett@uhhospitals.org
CC: Nathan Pennell MD, PhD - penneln@ccf.org
CC: Jennie Laeng - LAENGJ@ccf.org

Melanoma – ID #6
UH: Jeremy Bordeaux, MD - Jeremy.Bordeaux@UHhospitals.org
UH: Josephine Chan - Josephine.Chan@UHhospitals.org
CC: James Isaacs, MD - isaacsj3@ccf.org
CC: Natalia Rosas - rosasn@ccf.org

Soft Tissue Sarcoma – ID #7
UH: Ankit Mangla, MD - ankit.mangla@uhhospitals.org
UH: Josephine Chan - Josephine.chan@uhhospitals.org
CC: Dale Shepard, MD, PhD - shepard@ccf.org
CC: Sarah Abdelwahab - abdelws@ccf.org

Pediatric
UH: John Letterio, MD - john.letterio@uhhospitals.org
UH: Kristin Leuchtag - Kristin.leuchtag@uhhospitals.org
CC: Rabi Hanna, MD- hannar2@ccf.org
CC: Tina Ours - ourst@ccf.org

Genitourinary (GU) – ID #8
UH: Pedro Barata, MD - pedro.barata@uhhospitals.org
UH: Rachel Carney - Rachel.carney@uhhospitals.org
CC: Shilpa Gupta, MD - Gustas5@ccf.org
CC: Katie Gardner - GARDNEK5@ccf.org

Gynecologic (GYN) – ID #8
UH: Kristin Zanotti, MD - kristin.zanotti@uhhospitals.org
UH: Leslie Ortega - Leslie.Ortega@UHhospitals.org
CC: Robert Debernardo, MD - debernr@ccf.org
CC: Megan Park – parkm2@ccf.org

Hematologic Malignancy / Stem Cell
Myeloma ID #A, Lymphoma ID #4, Leukemia ID #9
BMT UH: Leland Metheny, MD - leland.metheny@uhhospitals.org
BMT (IIT) UH: Barb Calabro - barbara.calabro@uhhospitals.org
BMT UH: Joyce Callahan - joyce.callahan@uhhospitals.org
BMT CC: Craig Sauter, MD - sauterc@ccf.org
BMT CC: Sarah Abdelwahab - abdelws@ccf.org

Leuk/Lymph/MM
UH: Brenda Cooper, MD - Brenda.cooper@uhhospitals.org
UH: Leslie Ortega - leslie.ortega@uhhospitals.org

Leukemia - CC: Hetty Carraway, MD - carrawh@ccf.org
Leukemia - CC: Natalia Rosas - rosasn@ccf.org

Lymphoma - CC: Brian Hill, MD - hillb2@ccf.org
Lymphoma - CC: Katie Gardner - GARDNEK5@ccf.org

MM - CC: Jason Valent, MD - valentj3@ccf.org
MM - CC: Jennie Laeng - LAENGJ@ccf.org

Phase I – ID #Y
UH: Afshin Dowlati, MD - afshin.dowlati@uhhospitals.org
UH: Kim Thomas - Kimberley.Thomas@UHhospitals.org

CC: Dale Shepard, MD, PhD - shepard@ccf.org
CC: Sarah Abdelwahab - abdelws@ccf.org

Radiation ONLY Studies
CC: Chirag Shah, MD - shahc4@ccf.org
CC: Jennie Laeng - LAENGJ@ccf.org

UH: send to leader of specific disease team

For more info contact: PRMC@case.edu - Revised: 6/12/2023