C›I›R›B
FOR THE NATIONAL CANCER INSTITUTE

Annual Principal Investigator Worksheet

OMB #: 0925-0753 **Expiration Date: 5/31/2027**

STATEMENT OF CONFIDENTIALITY

The purpose of the information collection is to conduct reviews of clinical trial studies. NCI guidelines mandate the participation of institutions in the CIRB for Network group studies. You are being requested to complete this instrument so that we can conduct activities involved with the operations of the NCI CIRB Initiative. Although your participation in Network group research and completion of the forms is voluntary, if you wish to participate in the CIRB, you must complete all questions on the form. The information you provide will be combined for all participants and reported as summaries. It will be kept private to the extent provided by law.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0753). Do not return the completed form to this address.

Please refer to the Quickguide on Completing the Annual Principal Investigator Worksheet for further guidance.

Reason for submission:

- ☐ First Submission of the Annual Principal Investigator Worksheet About Local Context
- ☐ Revised Submission of the Annual Principal Investigator Worksheet About Local Context

Signatory Institution Information

Submitting User Information (auto-populated)

1. Enter Principal Investigator email address.
   If the PI's name does not appear above the email address field, this means there is no active account associated with this email address. Please confirm the email address is correct and that it is the email address associated with the PI in IAM.

   If the email address is correct and the PI name still does not appear, you will need to contact your Signatory Institution's RUMS Update Person and request that this PI be added to the CIRB Roster in RUMS.

2. Name of Signatory Institution (select from auto-populated)
If the name of your Signatory Institution does not populate in this field, you must add the PI to your institution roster in RUMS. For more information on updating the roster, go to Updating Your CIRB Institution Roster.

Research Staff

3. How many sub-investigators do you have supporting you in conducting CIRB-approved research?
   - ☐ 0
   - ☐ 1-2
   - ☐ 3-5
   - ☐ 6-7
   - ☐ 8-10
   - ☐ 11-15
   - ☐ 16-35
   - ☐ 36-50
   - ☐ 51+

4. How many research nurses/CRAs do you have supporting you in conducting CIRB-approved research?
   - ☐ 0
   - ☐ 1-3
   - ☐ 4-5
   - ☐ 6-7
   - ☐ 8-10
   - ☐ 11-22
   - ☐ 23-29
   - ☐ 30+

5. Have you or any of your research staff reported a financial conflict of interest related to any studies on the CIRB menu that resulted in a management plan?
   - ☐ Yes
   - ☐ No

   If Yes, attach the institutionally-approved management plan.

NOTE: Principal Investigator Education, Training, and Experience

No additional information is required. Information pertaining to investigator education, training, and experience is captured annually through the NCI Investigator Registration.

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Principal Investigator Resources

6. CIRB-approved studies by Study ID Number for this PI. (auto-populated)

Protocol Site Output Add Note View Audit

Study-Site	Role	Title	Sponsor
ANZGOG-0902-GOG-0274-The Moses H Cone Memorial Hospital Operating Corpo	Investigator	A Phase III Trial of Adjuvant Chemotherapy Following Chemoradiation as Primary Treatment for Locally Advanced Cervical Cancer Compared to Chemoradiation Alone: THE OUTBACK TRIAL (ANZGOG 0902/GOG-0274/RTOG 1174)	CTEP
E2805-The Moses H Cone Memorial Hospital Operating Corpo	Investigator	ASSURE: Adjuvant Sorafenib or Sunitinib for Unfavorable Renal Carcinoma	CTEP
E5204-The Moses H Cone Memorial Hospital Operating Corpo	Investigator	Intergroup Randomized Phase III Study of Postoperative Oxaliplatin, 5-Fluorouracil, and Leucovorin vs Oxaliplatin, 5-Fluorouracil, Leucovorin and Bevacizumab for Patients with Stage II or III Rectal Cancer Receiving Pre-Operative Chemoradiation	CTEP
GOG-0218-The Moses H Cone Memorial Hospital Operating Corpo	Investigator	A Phase III Trial of Carboplatin and Paclitaxel Plus Placebo Versus Carboplatin and Paclitaxel Plus Concurrent Bevacizumab (NSC #704865, IND #113912) Followed by Placebo, Versus Carboplatin and Paclitaxel Plus Concurrent and Extended Bevacizumab, in Women With Newly Diagnosed, Previously Untreated, Stage III or IV, Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer	CTEP
GOG-0252-The Moses H Cone Memorial Hospital Operating Corpo	Investigator	A Phase III Clinical Trial of Bevacizumab with IV Versus IP Chemotherapy in Ovarian, Fallopian Tube and Primary Peritoneal Carcinoma NCI-Supplied Agent(s): Bevacizumab (NSC #704865, IND #113912)	CTEP
GOG-0262-The Moses H Cone Memorial Hospital Operating Corpo	Investigator	GOG-0262: A Phase III Trial of Every-3-Weeks Paclitaxel Versus Dose Dense Weekly Paclitaxel In Combination With Carboplatin With Or Without Concurrent and Consolidation Bevacizumab (NSC #704865, IND #113912) in the Treatment of Primary Stage II, III OR IV Epithelial Ovarian, Peritoneal or Fallopian Tube Cancer and ACRIN 6695: Perfusion CT Imaging To Evaluate Treatment Response in Patients Participating in GOG-0262	CTEP
N0147-The Moses H Cone Memorial Hospital Operating Corpo	Investigator	A Randomized Phase III Trial of Oxaliplatin (OXAL) plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer	CTEP
NRG-BR003-The Moses H Cone Memorial Hospital Operating Corpo	Investigator	A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer	
NSABP-B-47-The Moses H Cone Memorial Hospital Operating Corpo	Investigator	A Randomized Phase III Trial of Adjuvant Therapy Comparing Chemotherapy Alone (Six Cycles of Docetaxel Plus Cyclophosphamide or Four Cycles of Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel) to Chemotherapy Plus Trastuzumab in Women with Node-Positive or High-Risk Node-Negative HER2-Low Invasive Breast Cancer	CTEP, CTEP
S0819-The Moses H Cone Memorial Hospital Operating Corpo	Investigator	A Randomized, Phase III Study Comparing Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/Bevacizumab with or without Concurrent Cetuximab in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC)	CTEP

7. How many study participants are currently receiving study intervention for CIRB studies for which you are the PI? *This number should **NOT** include study participants who are in long-term follow-up or receiving labs and scans only.
   - ☐ 0-5
   - ☐ 6-10
   - ☐ 11-20
   - ☐ 21-40
   - ☐ 41+

Recruitment

8. Identify recruitment methods usually used:

NOTE: Network-supplied recruitment materials are approved by the CIRB and posted to the CTSU website. Only if there are content changes made to these materials do the sites need to submit via a Study-Specific Worksheet. The addition of contact information is permitted.

NOTE: Locally developed recruitment materials require CIRB approval and should be submitted using the Annual Signatory Institution Worksheet or Study-Specific Worksheet.

- ☐ Network Group/sponsor-supplied materials
- ☐ Locally developed recruitment materials
- ☐ None

Please describe.

9. Indicate how potential study participants are identified for CIRB-approved studies.
   - ☐ Using recruitment materials as indicated in question 8.
   - ☐ Through usual clinical practice.
   - ☐ Referrals from other providers.
   - ☐ Using a separate IRB-approved screening protocol (reviewed and approved by another IRB)

Compensation to Study Participants

10. Does your institution provide any compensation/incentives to study participants enrolled in CIRB-approved studies that is NOT otherwise being offered to non-study participants?
    - ☐ No compensation or reimbursement is offered to patients on studies unless specifically stated in a protocol or provided to all patients receiving treatment.
    - ☐ Yes**,** study participants receive additional compensation/incentives.
      If yes, please describe.

Informed Consent Process

Answer the following questions regarding the process used to introduce a trial to a potential study participant and obtain their informed consent.

11. Where does the consent discussion take place? Check all that apply.
    - ☐ In the physician's office.
    - ☐ In a private clinic area or inpatient hospital room.
    - ☐ Other. Please describe.

12. Who is authorized to obtain consent? Check all that apply.
    - ☐ Principal Investigator
    - ☐ Sub-investigators
    - ☐ Research Coordinator
    - ☐ Research Nurses
    - ☐ Other – Please explain

13. Who is available to answer questions? Check all that apply.
    - ☐ Principal Investigator
    - ☐ Sub-investigators
    - ☐ Research Coordinator
    - ☐ Research Nurses
    - ☐ Other – please explain

14. Does the PI confirm that each potential study participant has as much time as needed to review the consent document before a response is required, including time to take the consent document home to review and discuss with others?
- ☐ Yes
- ☐ No

15a. How do you assess patient's/potential study participant's mental capacity and ability to make an informed decision? Check all that apply.

- ☐ The PI or qualified healthcare provider performs the standard clinical assessment which includes review of medical records and medications with the patient/ potential study participant to evaluate for alertness, distinguishing between the present and past, and awareness of their current condition.
- ☐ The PI or qualified healthcare provider performs a mental status exam which test for orientation, attention, memory, and language and visual-spatial skills (an example of one such test is the Mini-Mental State Exam (MMSE)).
- ☐ Other – please explain

15b. How is the potential study participant's understanding of the consent document and the study assessed? Check all that apply.
- ☐ Teach-back technique
- ☐ Question-and-answer dialogue
- ☐ Open-ended discussion
- ☐ Other – please explain

If applicable, an attachment can be added here.

16. How is the informed consent process conducted with non-English speaking potential study participants? Check all that apply
- ☐ Only English-speaking participants are enrolled by this PI.
- ☐ Non-English-speaking participants are consented using a fully translated, CIRB-approved consent form in their native language.
- ☐ Non-English-speaking participants are consented using a translator and short form consents.
- ☐ Translators or translation services are available for use during the consent process and throughout the study (explain below how this would be documented).
- ☐ Other – please explain.

Select the short forms that may be used at your Institution. Check all that apply.
- ☐ Institutional short forms may be used (CIRB approved).
- ☐ CIRB short forms may be used.
- ☐ No short forms will be used by this PI at this institution.

If short form consent is conducted at your institution, attach a copy of your institution's policy for short form use.

17. Who provides consent? Check all that apply.
- ☐ Potential study participant
- ☐ Parent for potential pediatric study participant
- ☐ Legally Authorized Representative

18. For what languages are fully translated consent forms routinely provided?
- ☐ Arabic
- ☐ Chinese
- ☐ Farsi
- ☐ French
- ☐ Greek
- ☐ Italian
- ☐ Korean
- ☐ Polish
- ☐ Russian
- ☐ Spanish
- ☐ Vietnamese
- ☐ Other
- ☐ None

If translations are routinely provided, what process is currently used to translate the informed consent document?
- ☐ CIRB-approved translated Spanish informed consent documents posted on the CTSU website are used.
- ☐ A translation service is used to translate the informed consent document.

If applicable, an attachment can be added here.

19. Describe or attach your institution's policy regarding assent by children or impaired adults for this Principal Investigator. (select all that apply)
- ☐ This Principal Investigator enrolls impaired adult study participants. Please provide or attach your institution's policy on obtaining assent by impaired adults.
- ☐ This Principal Investigator enrolls pediatric study participants. Please provide or attach your institution's policy on obtaining assent by children.
- ☐ No children or impaired adults will be enrolled by this Principal Investigator.

NOTE: The CIRB makes a determination regarding the requirement for assent and the age determination. Institutions enrolling children must obtain assent from any child in the age range determined by the CIRB. The documentation of the assent is per local policy and should be described here. If a child in the age range determined by the CIRB cannot provide assent, an assent waiver must be requested from the CIRB and obtained prior to enrollment of the child. Consult the Completing the Assent Waiver Worksheet for further instructions

20. Describe your institution's process to receive and address concerns from study participants and others about the conduct of the research by answering each question below.
    a) How do participants know the process for raising a concern?

    b) How would participants make a complaint or raise a concern about a study?

    c) When a complaint or concern is received, who receives the complaint and who is responsible for ensuring that the complaint or concern is resolved?
    Note: Also, include to whom complaints or concerns would be sent and resolved if these issues involve the PI or study/research team.

    Add Attachment (if applicable)

Measures to Protect Confidentiality

Confidentiality is defined as the study participant's understanding of, and agreement to, the ways identifiable information pertaining to them will be stored and shared. Identifiable information can be printed, electronic, or visual (such as photographs).

21. Check all measures that will be used to maintain the confidentiality of identifiable information.
    - ☐ Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.
    - ☐ Computer-based files will be available to study personnel through the use of access privileges and passwords.
    - ☐ Prior to obtaining access to identifiable information, study personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.
    - ☐ Whenever feasible, identifiers will be removed from study-related information.
    - ☐ Other Please describe.

Measures to Protect Privacy

Privacy is defined as the study participant's ability to control how other people see, touch, or obtain information about them. Violations of privacy can involve circumstances such as being seen without clothing or partially clothed, being photographed without consent, being asked personal questions in a public setting, etc.

22. Check all measures that will be used to maintain the study participant's privacy.

    - ☐ Use of drapes or other barriers to vision for subjects who are required to disrobe.
    - ☐ Consent is obtained prior to collecting photographs involving study participants.
    - ☐ Sensitive information is collected and used with respect to maintaining privacy.
    - ☐ Individuals are not identified publicly without their consent.

☐ Other Please describe.

Emergency Resources

23. Check all resources available at the site to treat emergencies resulting from study-related procedures.
☐ ACLS (Advanced Cardiovascular Life Support) trained personnel and crash cart
☐ BCLS (Basic Life Support) trained personnel
☐ PALS (Pediatric Advanced Life Support) trained personnel
☐ Emergency response team within facility
☐ Emergency drugs and supplies to stabilize study participant until emergency personnel arrive
☐ Staff available to call 911
☐ Other Please describe.

Using a Legally Authorized Representative (LAR)

24. Do you plan on enrolling study participants through an LAR?
☐ Yes
☐ No

25. At your institution, describe who may serve as an LAR. Check all that may apply.
Even if you responded 'No' to question 24, please answer this question if there is a possibility that study participants may be enrolled through a LAR or confirm 'No LAR will be used.'
☐ Parents
☐ Legal Guardian
☐ Family member
☐ Individual authorized to make surrogate health care decisions
☐ Spouse/Domestic Partner
☐ Family member/ Adult Child
☐ Other (please describe)
☐ No LAR will be used

If applicable, an attachment can be added here.

Vulnerable Populations

26. For each vulnerable population, indicate safeguards or select "Not Enrolled."

Note about prisoners: The CIRB is not constituted to review research involving prisoners. If an investigator wishes to enroll prisoners in a study, IRB review must be conducted by the local IRB.

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☐ Safeguards for Children

Check all safeguards you use for children.

- ❑ Youth Information Sheets
- ❑ Assent
- ❑ Extra monitoring
- ❑ Researchers credentialed in pediatrics
- ❑ Other health professionals with pediatrics experience
- ❑ Children not enrolled
- ❑ Other

Please describe.

☐ Safeguards for Pregnant Women

Check all safeguards you use for pregnant women.

- ❑ Inclusion is scientifically appropriate based on preclinical studies
- ❑ Information is provided pertaining to how study intervention could impact the woman and the fetus
- ❑ Pregnant women not enrolled
- ❑ Other

Please describe.

☐ Safeguards for Economically disadvantaged

Check all safeguards you use for Economically disadvantaged.

- ❑ Cost burden is fully explained
- ❑ No financial incentives are provided
- ❑ Social services are available to assist study participant
- ❑ Other

Please describe.

☐ Safeguards for Educationally disadvantaged

Check all safeguards you use for Educationally disadvantaged.

- ❑ Verbal explanation of the research is provided in lay language
- ❑ Extra time is available to answer questions
- ❑ At the potential study participant's request, family members/significant others can participate in informed consent process
- ❑ Caregiver to assist with medications and identifying adverse events
- ❑ Translations are available, if needed
- ❑ Other

Please describe.

☐ Safeguards for Physically disadvantaged

Check all safeguards you use for Physically disadvantaged.

- ❑ Treatment facility is accessible
- ❑ Assistance is available, as needed
- ❑ Witness to consent is available, as needed

- ❑ Other
  Please describe.

☐ Safeguards for Employees
  Check all safeguards you use for Employees.
- ❑ Records are confidential
- ❑ Participation is private
- ❑ Supervisor does not request participation and is not informed of those who do participate.
- ❑ Employees not enrolled
- ❑ Other
  Please describe.

☐ Other Vulnerable Populations

Describe all safeguards you use for 'Other' vulnerable populations.

Additional Confirmations When Investigators Enroll Pregnant Women or Women Who May Become Pregnant On Study [45 CFR 46.204 (h), (i), (j)]

27. The PI confirms the following statements are true by choosing 'Yes'.

No inducements will be offered to terminate a pregnancy.
☐ Yes

Research team will have no part in decisions related to the timing, method, or procedures used to terminate the pregnancy.
☐ Yes

Research team will have no part in determining the viability of a neonate.
☐ Yes