NCI CIRB Guidance: Annual PI and Study-Specific Worksheets

The following guidance serves as an aid to completing the Annual PI Worksheet About Local Context and the Study-Specific Worksheet, which are required for CIRB-approved studies. **This guide reflects the content of the Worksheet which expires on 07/31/2021.**

When referencing DF/HCC polices or guidance, provide a summary in addition to the document reference. Policy and Procedure guidelines, as well as additional guidance information, are outlined in the charts below as they pertain to each section of the CIRB forms. The OHRS recommends inclusion of the suggested language where appropriate to ensure that submissions accurately reflect DF/HCC policies and procedures.

Reminder: Effective January 31, 2020, the Dana-Farber/Harvard Cancer Center (DF/HCC) changed its requirements for Study-Specific Worksheets across DF/HCC institutions. For each new DF/HCC protocol or new add site change submitted to the NCI CIRB, there must be a separate Study-Specific Worksheet for the Site PI at each participating institution. **The Worksheet responses need to reflect information true for that Site PI's institution alone (e.g., the Pharmacist for that institution, numbers of research personnel, etc.)** Each Site PI is responsible for the oversight and conduct of research at their institution.

A. Annual PI Worksheet About Local Context

When an investigator wishes to become a Site PI for research approved by the NCI CIRB, the investigator (or designee) must begin by completing an Annual PI Worksheet About Local Context. The worksheet is completed via the NCI CIRB's IRBManager system.

NCI CIRB ANNUAL PI WORKSHEET SECTION	DFCI/DFHCC GUIDANCE OR TEMPLATE LANGUAGE
Signatory Institution Information	
Reason for Submission	Select 'First Submission' if the PI does not have an approved Annual PI Worksheet on file with the NCI CIRB. **Note**: Select 'Revised Submission' when the PI has an approved Annual PI Worksheet on file with the NCI CIRB and you are providing either the annual **renewal** or substantial changes to policies or other significant information.
1. Enter Principal Investigator email address	Use the email address associated with the investigator's CTEP-IAM account. **Note**: If the investigator's name does not auto populate after submitting the email address this means there is no active CTEP-IAM account associated with this email address, or an incorrect email address is being provided (e.g., Partners versus institution type). Email your NCTN, COG or ETCTN contact to confirm the email address associated with the PI's account and the account status.
2. Name of Signatory Institution	Dana-Farber Cancer Institute should auto populate in this field.

Research Staff	
3. How many sub-investigators do you have supporting you in conducting CIRB approved research?	Include the total number of sub-investigators on all CIRB approved studies for which you are the Site PI. Note: Responses should apply to your site alone. Count those who will be enrolling participants in the studies opened with you as the Site PI and any PharmD or RPh staff who will manage the study drug/agent on your behalf.
4. How many research nurses/CRAs do you have supporting you in conducting CIRB approved research?	Include the total number of study staff on all CIRB approved studies for which you are the Site PI. Note: Response should apply to your site alone. Count those Research Nurses, Statisticians, Study and Regulatory Coordinators, and Research Managers who will support studies where you are the Site PI.
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?	Limit this response to individuals' Conflicts of Interest and attach Management Plans as applicable. **Note**: Institutional Conflict of Interest is addressed in the Study-Specific Worksheet. See below in Part B. Include the following information per *IRB Policies and Procedures for the Protection of Human Subjects* and *DFCI IRB Institutional Conflicts of Interest Policy*: "The DFCI IRB requires that protocols be reviewed for Institutional Conflicts of Interest (Institutional COIs) in addition to individual study team member COIs in each circumstance where the Financial Interest could reasonably appear to affect the integrity of the research, or the safety of human subject. The DFCI Committee will review the circumstances of the financial interest and the research and will establish an appropriate plan to manage any resulting conflict of interest."
Principal Investigator Resources	
6. How many actively accruing research studies, for which you are the PI, do you have open, including CIRB approved and those not reviewed by the CIRB?	Include all studies (i.e., CIRB-approved, PI-initiated, pharmaceutically-sponsored, etc.) for which you are the Site PI.
7. How many study participants are currently receiving study intervention for studies for which you are the PI?	Specify the most up-to-date number of study participants actively receiving study intervention. This number should not include participants currently in long-term follow-up only.
Recruitment	
8. Identify recruitment methods usually used	Select the appropriate items and provide additional information as appropriate.

9. Indicate how potential study participants are identified for CIRB-approved studies.	Select the appropriate items. Note: Per the *Partners' Policy on Recruitment of Subjects:* Potential subjects can be identified: I. through private medical information about individuals who are NOT patients of the investigator(s) (e.g., medical records, clinical databases, patient registries or by referring physicians); Recruitment letters must be signed by the patient's physician, or the patient's physician in addition to the investigator. II. from among the patients of the investigator(s); Investigators are required to reinforce with their patients that participation is voluntary, that they do not have to participate, and the decision not to participate will not affect their care, now or in the future. Researchers are asked to establish plans to minimize the possibility that patients will feel obligated to participate, e.g., initially contacting patients about the research in writing and allowing patients to make further inquiries if they are interested, etc. III. by advertisements in various media; and IV. from among the employees/students of the investigator(s).
Compensation To Study Participants	
10. Describe any compensation/incentives provided by the Signatory Institution or others to study participants enrolled in CIRB approved studies other than reimbursements that are part of the study, for example: parking validation, cafeteria voucher, etc.	DFCI/DFHCC does not offer compensation or reimbursement to patients enrolled on CIRB approved studies.
Informed Consent Process	
11. Where does the consent discussion take place?	The consent process will take place in a private setting such as: an exam room with a closed door, a private clinic room, an empty conference room, or otherwise private area.
12. Who is authorized to obtain consent?	Include the following information per section 5.1.2 of *SOP CON-100 Informed Consent Process*: The informed consent document must be presented by an individual who is: (1) trained in human subject protections; (2) trained on the protocol; (3) listed on the Delegation of Authority Log; and (4) for all interventional drug, biologic, or

	device research, must be an attending physician registered with the NCI.
13. How long does the potential study participant have to review the consent document before a response is required, including time to take the consent document home?	Participants are given as much time as necessary for them to consider the risks, ask questions and receive answers, discuss with family members, and make their decision.
14. Who is available to answer questions?	The Site PI or a sub-investigator on the study.
15. How is the potential study participant's understanding of consent assessed?	The Site PI or a sub-investigator considers the person's level of intelligence, maturity, and language and adapts the informed consent presentation to each person's capabilities. Per *IRB Policies and Procedures for the Protection of Human Subjects*: in certain instances, it may be possible for researchers to enhance understanding for potentially vulnerable subjects. Examples include the inclusion of a consent monitor, a subject advocate, interpreter for hearing-impaired subjects, translation of informed consent forms into languages the subjects understand and reading the consent form to subjects slowly to gauge their understanding paragraph by paragraph. The consent process should be ongoing and therefore the study should be explained again after enrollment.
16. How is the informed consent process conducted with non-English speaking potential study participants?	Include the following per *SOP CON-101 Obtaining Informed Consent from Non-English Speakers*: There are two options to obtain informed consent from non-English speaking participants: 1) (preferred) The entire informed consent document is translated into a language understandable to the subject. An interpreter will be present to assist with the oral explanation of the research to the subject. 2) A pre-approved short version of the consent form available on the OHRS website will be used. A witness who speaks English and the language of the subject must be present for the entire consent process. The witness may be an interpreter, other impartial person, or a family member. Note: Attach current versions of DF/HCC policy CON-101 and the OHRS Information Sheet on Instructions for Research Involving Non-English-Speaking Participants where indicated.
17. Who provides consent?	Select the appropriate items.
18. For what languages are translations routinely provided?	Include the following information:

	DF/HCC short forms and addenda in various languages are available on the OHRS website (public access) at: http://www.dfhcc.harvard.edu/index.php?id=973#shortform These forms are pre-approved by the CIRB as they are part of the Annual Signatory Institution Worksheet package, and are provided for the following languages: English, Albanian, Amharic, Arabic, Armenian, Bengali, Bosnian, Brazilian Portuguese, Bulgarian, Cambodian-Khmer, Chinese, European Portuguese, Farsi, French-European, German, Greek, Gujurati, Haitian Creole, Hebrew, Hindi, Italian, Japanese, Korean, Nepali, Polish, Romanian, Russian, Serbo-Croatian, Somali, Spanish, Tagalog, Telugu, Thai, Turkish and Vietnamese. Note: Compare this list of DF/HCC short forms against the OHRS website at the time of Worksheet preparation. Expand this list as appropriate.
18a. If translations are routinely provided, what process is currently used to translate the informed consent document?	Per *Policy: Translation Procedures for Short Form, Long Form and Addendum*: The local IRB takes responsibility for confirmation and posting of appropriate short forms and addenda to the OHRS website. If an informed consent document for a study requires complete translation, it will be submitted to the CIRB for review and approval prior to posting on the local website for use in enrolling participants. Note: No attachment is required.
19. Describe your institution's policy regarding assent by children and/or impaired adults.	Refer to DF/HCC policy CON-100. **If applicable, include the following for pediatric studies** per *IRB Policies and Procedures for the Protection of Human Subjects*: The permission of the child's parent(s) or guardian(s) and the assent of the child will be sought and obtained (or formally waived or altered) in accordance with Subpart D of the HHS and FDA human subject regulations at 45 CFR 46.408 and 21 CFR 50.55, respectively. Any waiver or alteration of these permission or assent requirements must be consistent with applicable Federal and State laws and regulations. In cases where research involving cognitively-impaired individuals is approved, the IRB will consider additional safeguards (e.g., involvement of subject advocates, independent monitoring, formal capacity assessment, waiting periods) as part of the research plan to protect subjects. **Note**: Attach current version of DF/HCC policy CON-100 where indicated.

20. Describe your institution's process to receive and address concerns from study participants and others about the conduct of the research.	Individuals may contact the study physician or study staff. Additionally, they may contact a representative of the Office for Human Research Studies (OHRS). Contact information is provided in the consent document. **Note:** When applicable for pediatric trials, also indicate that the contact number for the Patient Advocate at the Patient/Family Relations Office is provided in the consent document.
Pharmacy Information	
21. Will the drugs/agents used in the study be managed by a pharmacist?	If yes, identify the pharmacist who will be managing drugs/agents at the institution for which you are the Site PI. **Beth Israel Deaconess Medical Center** • Heena Patel, RPh **Brigham and Women's Hospital** • Caroline Harvey, RPh **Cape Cod Hospital** • Brian L'Heureux, RPh **Dana-Farber/Harvard Cancer Center** • Caroline Harvey, RPh **Dana-Farber/Brigham and Women's Cancer Center at Milford Regional** • Caroline Harvey, RPh **Dana-Farber/Brigham and Women's Cancer Center at South Shore** • Caroline Harvey, RPh **Massachusetts General Hospital Cancer Center** • Elke Backman, PharmD **Mass General/North Shore Cancer Center** • Elke Backman, PharmD **Steward Saint Elizabeth Medical Center** • Michael Lee, PharmD **The Dana-Farber Cancer Institute at Londonderry** • Caroline Harvey, RPh
22. How is the pharmacist/responsible person provided with a copy of the protocol at the practice location?	Approved protocols are posted to the Oncology Protocol System (OncPro), an internal portal that gives research personnel direct access to protocols and other relevant documents.
Measures to Protect Confidentiality	
23. Check all measures that will be used to maintain the confidentiality of identifiable information.	Select items as appropriate. **Note**: Consider measures to protect paper-based records and computer-based files, limit access to identifiable information, and when feasible, to remove identifiers from study-related information.

	Per IRB Policies and Procedures for the Protection of Human Subjects: When information linked to individuals will be recorded as part of the research design, the IRB requires that adequate precautions will be taken to safeguard the confidentiality of the information. Among the available methods for safeguarding confidentiality are coding of records, statistical techniques, and physical or computerized methods for maintaining the security of stored data.
Measures to Protect Privacy	
24. Check all measures that will be used to maintain the study participant's privacy.	Select items as appropriate. **Note**: Physical privacy during research procedures should meet standards of care and good clinical practice. All participant records and communications are to be kept confidential to the extent provided by law and in accordance with HIPAA Privacy Rule guidelines.
Emergency Resources	
25. Check all resources available at the site to treat emergencies resulting from study-related procedures.	Select items as appropriate. **Note**: Select and describe only those resources available at the site where your research procedures are conducted.
Using A Legally Authorized Representative (LAR)	
26. Do you plan on enrolling study participants through an LAR?	Provide a yes or no answer that accurately reflects the anticipated study participant population. Note: This response should be marked as "Yes" if question 17 indicates a LAR can provide consent.
27. At your institution, describe who may serve as an LAR.	Indicate the institution will follow local and state requirements. Per *Policy – Legally Authorized Representative*, based on guidance provided to OHRS by the Office of the General Counsel of the Commonwealth of Massachusetts: An individual may make medical decisions on behalf of another individual and thus may serve as a legally authorized representative under Massachusetts law: (1) With respect to adult patients, priority among family members is as follows: i) spouse; ii) adult child; iii) parent; iv) sibling; v) other relative; vi) close friend. Such family decisions are not necessarily legally binding; the authority for such decisions is found in Massachusetts case law. (2) With respect to children, a parent of a minor child or a person with legal custody of a minor.

	(3) An individual who is making decisions based upon court-appointment as a guardian. (4) An individual who is making decisions based upon a signed health-care proxy. (5) An individual who is making decisions based upon a durable power of attorney that includes health care directives. As a general matter, when the subject is a minor (less than 18 years of age), permission (informed consent) must be obtained from the subject's parents(s) or court appointed guardian, both of whom are considered legally authorized representatives. Where research is conducted outside the Commonwealth of Massachusetts, investigators should consult with the Office of the General Counsel for guidance on who may serve as a "legally authorized representative" or "guardian." Investigators should also consult with the Office of the General Counsel for guidance on the definition of "child." **Note**: Attach current version of the OHRS Information Sheet on Legally Authorized Representatives where indicated.
28. Provide a description of how you assess a potential study participant's ability to provide consent.	Per DF/HCC policy *CON-100 Informed Consent Process*: The person's ability to understand is based upon that person's level of intelligence, rationality, maturity, and language. The presentation of the information must be adapted to each person's capabilities. Per *IRB policies and Procedures for the Protection of Human Subjects* and *Guide to human Subjects Research Activities:* In cases where research involving cognitively-impaired individuals is approved, additional safeguards (e.g., involvement of subject advocates, independent monitoring, formal capacity assessment, waiting periods) must be in place as part of the research plan to protect subjects. Useful techniques may include simplified consent documents, supplemental summary sheets, and formal Q&A sessions for the subject and legally authorized representative in addition to "waiting periods" after the initial discussion before the prospective participant enrolls if appropriate. **Note**: Attach current version of DF/HCC policy CON-100 where indicated. **Note:** For pediatric trials, refer to question 19 and DF/HCC policy CON-100.

VULNERABLE POPULATIONS	
29. Check all vulnerable populations from which you intend to enroll.	Select populations as appropriate. **Note**: Select **the applicable** safeguards only for those populations from which you intend to enroll.
Additional Confirmations When Investigator Intends to Enroll Pregnant Women [45 CFR 46.204 (h), (i), (j)]	
30. No inducements will be offered to terminate a pregnancy.	Confirm as appropriate.
31. Research team will have no part in decisions related to the timing, method, or procedures used to terminate the pregnancy	Confirm as appropriate.
32. Research team will have no part in determining the viability of a neonate.	Confirm as appropriate.
33. Is there anything else the CIRB should know about local context considerations?	**If applicable, identify** any items that may apply and attach related DFCI/DFHCC policies or guidance as appropriate. **Note:** Typically, this response will be "No" as the applicable policy and guidance documents are uploaded in prior sections.

B. Study-Specific Worksheet

Once the investigator has an approved Annual PI Worksheet About Local Context on file with the NCI CIRB, the investigator (or designee) must complete a Study-Specific Worksheet to become a Site PI and receive approval to open the CIRB-approved study at his/her institution. The worksheet is completed via the NCI CIRB's IRBManager system.

NCI CIRB STUDY SPECIFIC WORKSHEET SECTION	DFCI/HCC GUIDANCE OR TEMPLATE LANGUAGE
Reason for Submission	Select 'Open New Study' if the Site PI does not have an approved Study Specific Worksheet (SSW) for this study on file with the NCI CIRB. Note: Select 'Revision' only if the Site PI has an approved SSW for this study on file with the NCI CIRB and you are providing updated information **specific to this study**. For example: **providing a new translated document**, adding conflict of interest language to the consent form or clarifying Site PI assignments when a new DF/HCC Site PI plans to open the study at their institution.
Signatory Institution Information	
Enter the Study ID Number	Use the complete CTEP study ID number. For example: '10240' or 'NRG-GY004'
Signatory Institution	Dana-Farber Cancer Institute should auto populate in this field

Calculated Field	As appropriate, use the 'Add Note' function to enter a multiple Site PI statement to accurately reflect Site PI assignments across DF/HCC. For example: This SSW is being filed/updated to establish multiple Site PI assignments within the Dana-Farber Cancer Institute Signatory Institution for protocol 10107. Dr. John Doe will be the Site PI at institutions MA036 & MA037. Dr. Jane Smith will serve as Site PI for institution MA034. Note: Each Site PI must submit an SSW to open the study at their institution.
General Information	
1. Enter the email address of the Principal Investigator who is requesting to join this study	Use the email address associated with the Site PI's CTEP-IAM account. **Note**: If the PI's name does not auto populate after submitting the email address this means there is no active CTEP-IAM account associated with this email address **or an incorrect email address is being provided (e.g., Partners versus institution type)**. Email your NCTN, COG, or ETCTN contact to confirm the email address associated with the PI's account and the account status.
Questions from the Annual PI Worksheet About Local Context	
2. General Information (Questions 1-2 on the Annual PI Worksheet)	Items 2-14 refer to a set of questions from the **Annual PI Worksheet**. Indicate if the information previously approved in that Worksheet still applies to the *specific* study the PI wishes to join. If there are changes to previously approved research processes, select 'Changed' and describe the changes. If any of the 'Changed' items can be supported by an attachment, upload the attachment in item 15 (Additional Information).
3. Research Staff (Questions 3-5 on the Annual PI Worksheet)	
4. Principal Investigator Resources (Questions 6-7 on the Annual PI Worksheet)	
5. Recruitment (Questions 8-9 on the Annual PI Worksheet)	
6. Compensation to Study Participants (Question 10 on the Annual PI Worksheet)	
7. Informed Consent Process (Questions 11-20) on the Annual PI Worksheet)	
8. Pharmacy Information (Questions 21-22 on the Annual PI Worksheet)	

9. Measures to Protect Confidentiality (Question 23 on the Annual PI Worksheet) 10. Measures to Protect Privacy (Question 24 on the Annual PI Worksheet) 11. Emergency Resources (Question 25 on the Annual PI Worksheet) 12. Using a Legally Authorized Representative (LAR) (Questions 26-28 on the Annual PI Worksheet) 13. Vulnerable Populations (Question 29 on the Annual PI Worksheet) 14. Additional Confirmations (Questions 30-32 on the Annual PI Worksheet)	**Note:** Minor changes such as a slight increase or decrease in number of studies or research staff can be submitted when joining a study or may wait until the annual PI worksheet update. Any substantial changes to policies or other significant information require a revision to the Annual PI Worksheet.
15. Additional Information (Question 33 on the Annual PI Worksheet)	If there are any changes to the documents approved by the NCI CIRB, use track changes to clearly identify the requested changes and upload them as an attachment. Any requested changes to the CIRB approved consent form including institutional conflict of interest (ICOI) should be uploaded in this section. If an ICOI is indicated for the study, in addition to uploading the clean and tracked ICF, you must also provide the Investigator Management Plan and the Patient Information Sheet. **Note**: Only track additional changes and not changes that are already part of the Signatory Institution's approved boiler plate language. Any intention to use a local drug diary should be described in this section and the diary uploaded as an attachment.
Additional Study-Specific Materials for Review	
16. Recruitment Material(s)	Describe and provide any study-specific recruitment materials developed locally.
17. Assent form or consent at the age of majority form.	Describe and provide any study-specific assent form or consent at the age of majority form.
18. Translated documents for this study.	Provide any locally translated documents specific to this study. **Note:** These documents ***must*** include 1) the translated document; 2) the CIRB-approved English language document that corresponds to the translation; and 3) a Translator's

	Statement or Certificate of Accuracy (or the equivalent), **AND** there must be a clear link which adjoins these 3 items. At a minimum, this can be accomplished by each including references to matching version or version dates for the documents. The version dates may appear within the filenames.
Site Preference Notice	
Action Required	You **must** inform the CTSU Regulatory Office to confirm which institution aligned with the Site PI will be participating in the study. DF/HCC requests that you do NOT email this information to the CTSU prior to receiving the Study-Specific Worksheet Approval from the NCI CIRB. **Note:** CTSU's Regulatory Office follows the NCI CIRB Approval Letter with an email to confirm which institution within the Signatory Institution roster will participate in the study under this Site PI. To document this stated preference, you should wait until receipt of this email request and respond using the following examples (as applicable): **Single institution:** For CTEP Protocol XXXXX, Dr. Y will serve as Site PI for Massachusetts General Hospital Cancer Center (MA034). **Multiple institution participation**: For CTEP Protocol XXXXX, there will be multiple Site PIs. Dr. Y will be the Site PI at Dana-Farber/Harvard Cancer Center (MA036) and the Brigham and Women's Hospital (MA037). Dr. Z will serve as Site PI at Massachusetts General Hospital (MA034). **To add an additional Site PI to an already-opened trial**: This approval was filed to add Dr. Y as an additional Site PI for CTEP Protocol XXXXX within our Signatory Institution. Dr. Y will serve as Site PI at Massachusetts General Hospital (MA034). Dr. X will continue serve as Site PI at Dana-Farber/Harvard Cancer Center (MA036) & Brigham and Women's Hospital (MA037).
PI Intent to Comply	
PI Signature Required	**Note:** A designee may complete the Study-Specific Worksheet, however the Worksheet must be submitted by the Site PI within the IRBManager system. Once the Worksheet is prepared, the system automatically generates an email to the Site PI to 1) request review of the Worksheet; 2) confirm the Site PI's intent to comply with Federal regulations; and 3) submit the Worksheet. As steps 2 and 3 are separate, the Site PI must click the "submit" button on the final page of the Worksheet form or it will not be submitted for review. The Site PI (and if applicable,

	the designee who prepared the Worksheet) will receive automated reminder emails for PI "sign-off." For direct access to the Worksheet in IRBManager, the Site PI should use the link contained within these emails. **Note:** The Site PI will receive reminder emails to sign off at intervals of 2 days, 1 week, and 2 weeks. The study team may send reminder's independent of the CIRB's automatic emails. Investigators should check their Junk mail as the system generated reminders may not appear in their Inbox. **Note:** Protocol-specific requirements (e.g., site initiation visit, protocol training, etc.) must be met before site registration is finalized within CTEP systems and enrollment can begin via OPEN. **Note:** NCI CIRB studies must be submitted to DF/HCC via the iRIS system and activated locally before any study activities may occur at the Site PI's institution.