

Guidance on Completing Protocol Front Sheets

The Protocol Front Sheet is a summary of key information related to the research study that assists both OHRS and the various reviewers to determine the appropriate path for review. Please make sure that the Front Sheet is completely filled out and consistent with all submitted materials. The following information is intended to assist study teams in completing the form accurately.

If you have any questions, please contact OHRS at (617) 632-3029.

1. PROTOCOL TITLE AND VERSION

Title: Please make sure the title matches the title on the protocol document. If there is a cooperative group number that you would like referenced in all correspondence, please consider adding the cooperative group number at the end of the title in parentheses. For example, *"A Phase III Study of Adjuvant Postoperative Irradiation with or without Cisplatin/Taxol Chemotherapy Following TAH/BSO for Patients with Endometrial Cancer (RTOG 99-05)."*

Protocol Version No./Date: Please make sure that this information is consistent with the protocol document. All protocols should include a version number or date.

Sponsor Study Number: This is an optional field which can be used to reference the sponsor protocol number which is different from the DFCI IRB protocol number.

2. DF/HCC STUDY CONTACT INFORMATION

Please only include individuals who are associated with institutions who have designated the DFCI IRB as the IRB of record for the study (i.e., individuals associated with the institutions checked off in Section 6 of the Front Sheet). Please note that a Site PI should be designated for each affiliate checked off in Section 6 of the Front Sheet and should be listed in the title box of the associated informed consent document. A Site PI is not required for each satellite checked off in Section 6.

Only people listed on the front sheet will receive email communications from OHRS.

Please do not use nicknames. Please provide the full first and last name. Where there is more than one person with the same first and last name, please use a middle initial.

The **Study Contact for Questions** must be within the DF/HCC. This is a required field.

All **PIs, Site Responsible PIs and Sub-Investigators** significantly involved with the conduct of the research should be listed on the front sheet. For example, staff listed on the study specific 1572 should be listed on the protocol front sheet. For non-FDA regulated research, non-MD staff may be added to minimal risk research studies on a case by case basis. OHRS will evaluate whether these staff may be added.

Additional Study Staff/Contacts are optional. Please do not include more than one person per non-lead institution checked off in section 6. Please note that the study staff for the lead institution is already provided under "Study Contact for Questions." It is recommended that for protocols that are actively enrolling, or where research interventions continue, a study staff contact for each participating site (excluding the lead site) be identified in the "additional study staff/contacts" section.

Additionally, please add any "mail only" offices to the "Additional Study Staff/Contact" list as follows:

- CALGB sponsored studies, please include DFCICALGB@partners.org.
- Studies involving MGH, please include CCPO@partners.org
- Studies involving BIDMC, please include **BIDMC CTO Mailbox**
- DFCI led clinical trials, please include DFCIClinicalTrials@partners.org
- Studies conducted at DF/PCC affiliates, please include DFPCCAffiliates@partners.org
- Other disease program mailboxes.

3. DRUG/DEVICE INFORMATION

If this is not an FDA regulated study, please select the N/A checkbox in the Section 3 heading. Otherwise, please complete as directed.

IND/IDE Held By: This information should match the information provided in the application form. If the DF/HCC investigator is the IND/IDE holder, please provide the first and last name of the investigator; please do not use nicknames.

Investigational Brochure (IB): If you have previously submitted the IB associated with the drugs being evaluated in the study, please so indicate by checking the box. IBs that have been previously submitted to OHRS need not be resubmitted. If you are submitting more than one IDB, please list both the drug and the version date. For example: "MLX-495 Oct 2008; sirolimus Nov 2007".

Drugs, Biologics, Devices Provided by: Please indicate who is providing any drug, biologic or device for the study. If drug will be obtained through commercial supply, please indicate.

4. SPONSOR & PROTOCOL INFORMATION

Protocol Coordinated By: Please indicate who will be responsible for the protocol. For example, for FDA-regulated research, this would be the IND/IDE holder. For other research, it could be the investigator/entity who controls and will be ultimately responsible for the conduct of the research.

Funding/Support: Please indicate all sources of funding or support for the protocol. If the protocol is funded by a federal grant, please include the grant number; the grant number is required for activation. The study will not be activated until funding has been confirmed by Research Administration.

Cancer Related: Please indicate whether the protocol is cancer related. If the study involves no cancer patients (e.g., non-malignant hematology research such as hemophilia studies, or non-malignant transplant studies for Fanconi anemia patients), the research is not cancer related. If cancer related, please also select the appropriate disease or discipline based program.

Phase: Please select as appropriate. If none apply, please select "N/A" If the protocol a treatment IND or single patient IND as described in 21 CFR 312.34, please select "expanded access". If you are reporting an emergency use of a test article without prospective IRB, please select "emergency use".

Multi-Center: For all studies, please indicate if the research project is a multi-center study. If DF/HCC institutions are the only participating institutions, please select "no."

Protocol Type: For all studies, please identify the type of trial or clinical research study as follows:

- **Therapeutic Trial:** Clinical trials with therapeutic intent using drugs, radiation, surgery, other biological agents or behavioral or other interventions.

DF/HCC Interpretation:

- Trials in which an agent or other intervention is used with the intention to cure cancer or to prolong the life of the patient.

Studies where an objective of the trial is to measure long-term survival or disease-free survival will be included as Therapeutic Trials.

Examples: Treatment for Graft vs Host Disease following Curative Transplant.

- Studies using an agent or other intervention for Secondary Prevention following curative therapy may be defined as Therapeutic. Determination is at the discretion of the Principal Investigator.

Examples: Tamoxifen for Prevention of Breast Cancer Recurrence in subjects following Adjuvant Therapy.

- **Prevention Trial:** Clinical trials for the modulation of cancer risk and inhibition of cancer progression using chemo prevention drugs, nutritional, dietary, behavioral, or other interventions.

DF/HCC Interpretation:

- Trials in which an agent or other intervention is used for the Primary Prevention of cancer. Healthy subjects as well as high-risk subjects are included.
- Trials in which an agent or other intervention is used for Secondary prevention in cancer patients following curative therapy. These trials may be considered Therapeutic Trials; determination is at the discretion of the Principal Investigator.

- **Supportive Care:** Clinical trials intended to improve the comfort and quality of life for the patient using drugs, nutritional, dietary, behavioral or other interventions.

DF/HCC Interpretation:

- Trials using an agent or other intervention to improve the Quality of Life of the Subject.

- **Screening, Early Detection, or Diagnostic Trials:** Clinical Trials directly testing the efficacy of devices, techniques, procedures, or tests for earlier or more accurate detection or diagnosis of disease.

DF/HCC Interpretation:

- **Screening:** Clinical Trials using the *full population* to directly test the efficacy of devices, techniques, procedures or tests for earlier or more accurate detection of disease.

Example: Use of computerized tomographic colongraphy in a screening population for the detection of colorectal cancer.

- **Early Detection:** Clinical Trials using a *select population* (a group that for some reason “stands-out” or is at risk for disease) to directly test the efficacy of devices, techniques, procedures or tests for earlier or more accurate detection of disease.

Example: Preliminary Characterization of Colorectal Flat Polyps

- **Diagnostic:** Clinical Trial testing the efficacy of devices, techniques, procedures or tests to diagnose disease usually leading to a treatment decision.

* DF/HCC category to be included with Diagnostic at this point, but which are distinguished as follows.

Imaging:

- Use of imaging techniques (such as X-ray, CT, or MRI) to evaluate response.
- Use of imaging techniques (such as probes, ligands, or contrast agents) to evaluate diagnostic imaging capabilities and safety.

Imaging studies may be considered Therapeutic when the objective of the trial is to improve the delivery of an agent/drug with the intent to prolong life. The decision is at the discretion of the Principal Investigator.

- **Epidemiologic, Observational, or Outcome:** Studies among cancer patients and healthy populations that involve no intervention or alteration in the status of the participants, e.g., surveillance risk assessment, outcome, environmental, and behavioral studies.

DF/HCC Interpretations

- **Epidemiologic:** Studies among cancer patients and/or healthy populations to determine the patterns, causes, and/or control of disease in groups of people leading to improved understanding of screening and detection, diagnosis, and treatment of cancer.

Example: Prevalence and Correlates of Smoking Behaviors Among Adults with Cancer

- **Observational:** Prospective Studies targeting a defined population to assess changes or alterations in the status of the participants. No interventions are used.

Example: The Evaluation of Lymphedema and Arm Symptoms in Rowers with and without Breast Cancer

- **Outcomes:** Studies of a defined population to assess the outcome of some kind of treatment or behavioral intervention NOT part of the study. No intervention is used.

Example: The National Lymphocare Study: An Observation Study of Treatment Outcomes, and Prognosis in Patients with Follicular Non-Hodgkin's Lymphoma

- **Correlative:** Laboratory based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc. Only studies that can be linked to individual patient or participant data should be reported.
- **Ancillary:** Auxiliary studies that are stimulated by, but not a required part of, a main clinical trial/study, and that utilize patient or other resources of the main trial to generate information relevant to it. Ancillary studies included *must be linked to an active trial* or

epidemiologic or other study and should include only patients accrued to that trial or study. Only studies that can be linked to individual patients or participant data should be reported.

Protocol Involves: Please select all that apply as listed in the protocol document, even if not part of the research, but is mandated by the protocol document.

5. SUBJECT POPULATION

Total Study-Wide Enrollment Goals: Please do not use ranges but rather use a whole number. For protocols that involve two phases, please indicate the enrollment goal for each phase, for example: "Phase 1: 12; Phase 2: 30". Please note that once the IRB has approved the research, any changes to the total study-wide enrollment goal should be submitted for IRB review as an amendment. Depending on the change, a review by biostatistics may also be necessary.

For studies involving *only specimen collection or medical record review*, please indicate the number of individuals from whom specimens or data from medical records will be collected.

Total DF/HCC Estimated Enrollment Goals: For multi-center studies, please note that changes to this number need not be submitted for IRB review unless the change involves increasing DF/HCC enrollment beyond the previously stated total study-wide enrollment goal. For studies conducted only at DF/HCC, the number should equal the total study-wide enrollment goal.

6. INSTITUTIONAL PARTICIPANTS UNDER DFCI IRB

Please select all that apply. Please note that for each site selected, a Site Responsible PI must be designated in Section 2.

7. INSTITUTIONAL PARTICIPANTS UNDER OTHER IRB

DF/HCC Multi-Center Protocols: This section only applies to DF/HCC led studies being conducted at other centers. The other centers should only be listed on the front sheet once their local IRB and the DFCI IRB have approved that center's participation in the research.

DF/PCC Network Affiliates: Please list only those DF/PCC Network Affiliates that rely on their own IRB rather than the DFCI IRB.