Requirements for DF/HCC Collaborations with External Parties

This document defines how DF/HCC investigators may choose to collaborate in the conduct of a research study when the study has an external collaborator that is industry or another academic center or consortium. Any transfer of sponsor obligations to/from the DF/HCC investigator must follow these requirements and be documented in a written Transfer of Obligations. Please see DF/HCC policy RCO-100 on Investigator-Sponsored Research.

The following are examples of such collaborations:

- DF/HCC PI-Initiated trial where DFHCC is the regulatory sponsor and industry has requested a Collaborative Agreement
- DF/HCC PI -Initiated trial where industry is the regulatory sponsor
- Non-DF/HCC initiated/ sponsored trial where the DFHCC is being asked to act as a coordinating center

What we can do

DF/HCC can usually agree to perform the following activities when collaborating with an external collaborator. However, each individual research study is unique. Specific terms must be agreed upon by the PI and their institutional Clinical Trials Office, and appropriate costs must be included in the budget.

1. Provide scientific consultation and input on study design.
2. Develop the protocol document, consent form and amendments for collaborator review and approval.
3. Develop a list of potential DFHCC assessed and approved participating sites.
4. Maintain DF/HCC site-level regulatory files.
5. Provide regular status/progress reports.
6. Provide biostatistical consultation.
7. Act as a central lab. (Requires a separate agreement with the collaborator at full indirect costs.)

What places strain on our infrastructure and resources

DF/HCC may be able to agree to some of the following in specific situations. These items require additional discussion of volume, potential liability, risk and benefit to the institution, resource allocation, and requires approval from cancer center leadership for institution to undertake these responsibilities.

1. Contract directly with a large number of outside sites or distribute payment to outside sites (i.e. greater than 5 subsites).
    a. DFHCC cannot contract directly or distribute payment on behalf of another party.
2. Hire and oversee vendors (e.g., drug distribution, contract research organization).
3. Act as a central IRB for outside sites or provide outside sites access to internal PRMS system

What we can do as the sponsor

DF/HCC can only accept these responsibilities when a DF/HCC investigator is the regulatory sponsor (i.e., IND/IDE holder):

1. Review and approval of outside site consent forms.
2. Creation or management of the CRF database.
3. Maintenance of sponsor TMF.
4. Regulatory submissions to FDA, EMA, etc.
5. Monitoring of non-DF/HCC subsites.
6. Clinicaltrials.gov registration or reporting.
7. Primary responsibility for biostatistical analysis.
8. Study-wide DSMC/DSMB.

What we cannot do

DF/HCC is unable to accept responsibility or oversight for any of the following:

1. Hold an IND/IDE, or act as regulatory sponsor, for any trial where the intention is to generate data to support FDA registration or other regulatory authority marketing approval.
2. Function as a coordinating site and/or accept delegation of responsibilities from another party for a research protocol that is not a DF/HCC-sponsored study. Please note that DF/HCC does not function as an ACRO.
3. 100% source data verification
4. Providing sponsor, CRO, or non-DF/HCC site access to our CTMS.
5. Distribution of investigational product to subsites
6. Study-wide pharmacovigilance monitoring, safety reconciliation or safety reporting beyond DFHCC policies and procedures.
7. Medical review and/or coding of CRF data.
8. Formal medical writing services.
9. Sharing of DF/HCC internal audit reports, audit outcomes or provisioning of auditing services.