Clinical Research Operations Committee (CLINOPS) Procedures

1. BACKGROUND:

The Clinical Research Operations Committee (CLINOPS) was formed in 1997 to review the infrastructure and operational systems required to ensure the conduct of high quality clinical trials across the Dana-Farber/Partners Cancer Care (DF/PCC) institutions. Members of this committee represented institutions, pharmacy, nursing, information services, data management and other research departments. Additional members were added in 1999 and 2001 to represent Dana Farber/Harvard Cancer Center (DF/HCC) institutions. In the fall of 2008, CLINOPS became an independent committee and was granted authority for independent decision making and actions relating to clinical research operations.

This committee's charge is to: 1) address operational issues in the conduct of clinical trials; and, 2) develop and maintain inter-institutional policies for human subject research conducted under DF/HCC.

2. ASSOCIATED DF/HCC POLICIES:

2.1. COM-100

3. PROCEDURE:

3.1. General Procedures

3.1.1. The DF/HCC Medical Director for Clinical Trials Operations is the chair of the committee. The ODQ Director is the co-chair of the committee. The chair appoints members of the committee according to their role in the research process. Membership consists of multi-disciplinary representation from the DF/HCC medical institutions, including but not limited to the institutional clinical trials offices, pharmacy, nursing, the Office for Human Research Studies (OHRS) and ODQ.

3.1.2. The CLINOPS meets at least once a month to review DF/HCC clinical trials processes, facilitate inter-institutional communication, and resolve CLINOPS-identified DF/HCC research issues.

3.1.2.1. The chair and co-chair determine when further considerations from the Clinical Investigations Leadership Committee (CLC) and/or the research community are needed to ensure standardization in the research conducted at DF/HCC.

3.1.3. CLINOPS oversees the creation and maintenance of DF/HCC-wide Policies for human subject research.

3.1.4. CLINOPS meetings are confidential, per COM-100. The committee is administratively managed by the Office of Data Quality (ODQ).

3.1. **Membership**

3.1.1. The committee membership will be determined by the DF/HC Medical Director for Clinical Trials Operations and the DF/HCC Associate Director for Administration.

3.1.2. Members will include representatives with key clinical research responsibilities from DF/HCC member institutions and will include, but not be limited to:

- DF/HCC Medical Director of Clinical Trials Operations (co-chair)
- Director, Office of Data Quality (ODQ) (co-chair)
- DF/HCC Associate Director for Administration
- Director, Office for Human Research Studies (OHRS)
- Director, Research Informatics for Operations (CTRIO)
- Administrative Director of MGH Cancer Center Protocol Office
- Director of DFCI Clinical Trials Office
- Director of BIDMC Cancer Clinical Trials Office
- Clinical Trials Network Manager
- Representative(s) from DF/HCC Research Pharmacy
- Representative(s) from Clinical Trials Nursing

3.1.3. Other individuals may be invited on an ad hoc basis to assist with issues related to their areas of expertise