NCI Clinical Trials Reporting Program (CTRP) Compliance

1. BACKGROUND:

DF/HCC clinical trials must meet the requirements of the National Cancer Institute (NCI) Clinical Trials Reporting Program (CTRP). The purpose of the CTRP is to establish a comprehensive database containing regularly updated information on all cancer clinical trials. Sites will enter specific information about each clinical trial into the database. NCI will internally transfer to CTRP information on Cancer Therapy Evaluation Program (CTEP), Division of Cancer Prevention (DCP) and Center for Cancer Research (CCR) trials, eliminating the need for awardees to enter information on these trials. NCI will use this information to coordinate research efforts to optimize the investment in cancer research.

The DF/HCC Office of Data Quality (ODQ) provides support to DF/HCC investigator-sponsored clinical trials to fulfill the NCI CTRP requirements. These requirements (e.g. when a trial must be registered, accrual reporting, etc) may be reviewed on the NCI CTRP website.

2. ASSOCIATED DF/HCC POLICIES:

2.1. None

3. PROCEDURE:

3.1. The ODQ CTRP Registration Coordinator will obtain a weekly list of newly activated trials and register those trials with CTRP. Documentation of registration will be maintained by the ODQ CTRP Registration Coordinator.

3.2. The ODQ CTRP Registration Coordinator will ensure that updates to trials registered with CTRP meet NCI requirements.

3.3. The ODQ CTRP Registration Coordinator will work in conjunction with Information Services to ensure accrual information is submitted per NCI requirements.

3.4. If awardees receive communications from NCI in regards to CTRP requirements, forward the communications to the ODQ at ODQCTRP@partners.org

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