

**DANA-FARBER / HARVARD CANCER CENTER
Operations for Human Research**

TITLE: How/When to Register a Protocol on ClinicalTrials.gov		
Maintained by: Office of Data Quality (ODQ)	Page: 1 of 3	Effective Date: 08/08/2017

1. BACKGROUND:

DF/HCC main member institutions are registered on ClinicalTrials.gov using distinct “Organization” names DFCI and MassGH. The Office of Data Quality (ODQ), as well as each member institution, has appointed Clinicaltrials.gov administrators (see **DF/HCC Contacts for ClinicalTrials.gov Accounts and Initial Registration** to assist investigators in establishing their personal Protocol Registration System (PRS) accounts for registration and management of protocols for which they are the designated “Responsible Party”.

2. ASSOCIATED DF/HCC POLICIES:

2.1. REGIST-200

3. PROCEDURE:

3.1. Initial Registration

3.1.1. ODQ will facilitate the initial protocol registration for DF/HCC Investigator-sponsored protocols. ODQ will create the initial clinicaltrials.gov registration after IRB approval and before activation.

3.2. Clinicaltrials.gov Registration Transfer, Review Process, Approval and Release to Clinicaltrial.gov

3.2.1. Once, ODQ has finished the initial protocol registration, a transfer notification email will be sent to the “Responsible Party”, to review approve, and release the registration for Clinicaltrial.gov QA review.

3.2.1.1. The transfer notification letter will outline the sections of the record that require review and possible update. Clinicaltrials.gov Registration Criteria:

<https://prsinfo.clinicaltrials.gov/ProtocolDetailedReviewItems.pdf>

3.2.1.2. Once the review process is complete, the registration should be “**Approved**” and “**Released**” to Clinicaltrials.gov for internal quality assurance review (PRS Review).

3.3. Clinicaltrials.gov PRS Review Process

3.3.1. The Clinicaltrials.gov record review process can take between 2 to 5 business days and it will either be assigned a NCT number or will be reset

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without a NCT number.

3.3.2. Records Assigned a NCT Number

3.3.2.1. The Clinicaltrials.gov QA department will notify the Responsible Party of a successful Clinicaltrials.gov registration. This email notification will contain the NCT number for this Clinicaltrials.gov record. Please retain for future reference.

3.3.3. Record Reset without a NCT Number

3.3.3.1. A Clinicaltrials.gov record will be reset without the required NCT number if the Clinicaltrials.gov PRS team has determined the record does not meet pre-determined requirements. These Clinicaltrials.gov QA comments can be found in the “QA Comments” section of the record (see below).

3.3.3.2. Clinicaltrials.gov records that have not been assigned a NCT number are not considered successful registrations and will not be able to activate for accrual.

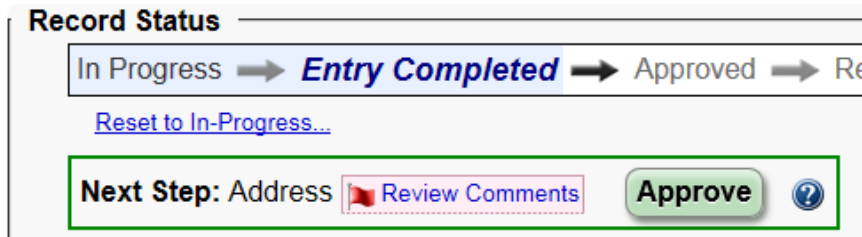
3.3.3.3. All QA Reset Comments for Registrations and Updates, must be addressed within 15 days of reset date.

3.3.3.4. Once all comments have been addressed, the record needs to be approved and re-released by the Responsible Party to Clinicaltrials.gov for QA review.

3.4. How to resolve QA Comments

3.4.1. Locate the “**Next Step: Address Review Comments**” field, found at the top of the Clinicaltrials.gov record.

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- 3.4.2. Click on the “Review Comments”, which will bring you to a “read-only” version of the Clinicaltrials.gov record. Scroll through the record, to locate a “Comments” text box with a description of the “issue” found in the record.
- 3.4.3. To update the record, select [Edit] field by the protocol section that requires an update.
- 3.4.4. Update the section, per the guidelines specified by the Clinicaltrials.gov QA Comments.
- 3.4.5. Once the updates have been made Click on “Save” at bottom of page. To release the updates the Responsible Party needs to “approve” and “release” the record for QA review.

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