ClinicalTrials.gov

In January 2017, active management of user access, registration, updating, editing, and results reporting for both the BMC and the BUMC ClinicalTrials.gov databases was integrated under a single OHRA/CTSI supported ClinicalTrials.gov (CTgov) Administrator. Previously these activities were done by a part time BMC research administrator and several lawyers in OSP at the BU CRC.

A ClinicalTrials.gov plan was developed and implemented to enhance compliance, scientific integrity and transparency which included these tasks:

- Resolve all major problems in the BMC and BUMC databases, prioritizing those applicable clinical trials (ACT) that were in arrears and subject to noncompliance consequences.
- Standardize the registration process to facilitate timely NCT identifier assignment including active support in completing the registration record.
- Establish a dashboard and weekly meetings with OHRA leadership to review progress, problems, and weekly metrics.
- Create materials to assist investigators register, update and report results (eg information on the CRRO website, CTSI/CRRO seminars, presentations to BMC and BUMC research administrators).
- Educate investigators about the expanded NIH and ICMJE definitions of clinical trials and the need for registration prior to participant enrollment for subsequent manuscript submission to any of the ICMJE journals.
- Request and obtain a CRRO review for clinical trials prior to IRB submission.
- Submit the NCT identifier to the IRB prior to IRB approval.
- Initiate trainings of PIs and their research staff of ACT and NIH funded clinical trials.
- Email PI and CRC weekly reminders for needed updates, correcting errors, and impending results reporting.
- Facilitate PI/research team linkage to other CTSI services needed for clinical/human subjects research such as recruiting/retention and biostatistical support.
- Participate in the national ClinicalTrials.gov Task Force and workgroups to improve features of the national database.

Resolving all major problems in the BMC and BUMC databases required time-intensive efforts by the CT.gov Administrator between January and June 2017 to locate investigators, abstract results from published papers and archived study records, and add or edit information. Thirty ACT studies with late results per FDAAA were prioritized and by July 2017 each was made public and all major problems were resolved. Since then, proactive measures have insured there are few if any late results per FDAAA.

To prevent and manage any other problems, weekly, the CTgov Administrator downloads the BMC and BUMC ClinicalTrials.gov databases, with 208 and 157 respective studies, and contacts by email and/or phone the PI/responsible party (RP) and CRC about any needed updates or errors to correct. The average number of monthly contacts is 60. The CTgov Administrator also adds new users and resets passwords of RPs, record owners and research team members with access and transfers records as needed.

Beginning in 2017, education and training about ClinicaTrials.gov was provided through educational venues and integrated into clinical research related trainings. In 2017, about 230 researchers and research administrators attended an event with a projected 175 attendees during the first quarter of 2018 (see table).

Date	Description	Title	Presented by	Learners
Jan. 2017	Clinical Research Seminar	ClinicalTrials.gov Compliance Issues	BMC Research Compliance Officer and CTgov Administrator	43
Jan. 2017	BMC Research Administrators Meetings	ClinicalTrials.gov Compliance	BMC Research Compliance Officer and CTgov Administrator	35
Jan. 2017	Research in Progress Family Medicine	Final Rule, NIH Policy, and ClinicalTrials.gov	CTgov Administrator	13
Aug. 2017	Research Seminar Geriatrics Fellows	Research Basics and the IRB	CRRO educators	7
Nov. 2017	Pharmacy Research Seminar	Navigating the IRB	CRRO educators	23
Feb., June, Oct. 2017; Feb 2018	Fundamentals of Clinical Research Trainings	ClinicalTrials.gov registration, updating and results reporting in GCP	CRRO educators	43
Jan., March June, Dec. 2017	Principal Investigator Trainings	ClinicalTrials.gov registration, updating and results reporting in GCP	CRRO educators	53
June 2017	ACT & NIH funded new CTs PIs/CRCs Individual Training	CTgov registration, updating and results reporting	CTgov Administrator	11
Jan. 2018	BMC/BU Research Administrators	NIH Clinical Trials Requirements	CRC IRB Director and CTgov Administrator	25
Feb. 2018	BU OSP Admin & Leadership	NIH Clinical Trials Requirements	CRC IRB Director and CTgov Administrator	31
March 2018	BMC/BU Research Administrators	NIH Clinical Trials Requirements	CRC IRB Director and CTgov Administrator	~25
March 2018	Clinical Trials Boot Camp	ClinicalTrials.gov Compliance	CTgov Administrator	~55
March 2018	Clinical Research Seminar	New Requirements for ClinicalTrials.gov	CTgov Administrator	~ 50

With expanding ClinicalTrials.gov requirements, use, and integration into other research related functions (eg in the human subjects form E for NIH grant applications, registration and results reporting for all PCORI awardees, IPD-individual participant date sharing plans) ongoing education and training of all involved PIs and research team members are needed.

Additional modalities for the educational materials including videos, webinars, presentations at research staff and research administrators meetings, and check lists have been and are being developed. Overall ClinicalTrials.gov provides both a catalyst, opportunities, and a platform to support and link investigators with other CTSI research resources and services.