



CLINICALTRIALS.GOV PROGRAM

ROLE OF OFFICE

The ClinicalTrials.gov Program was created in 2016 to support research teams with registration and reporting requirements for clinical trials to avoid penalties. These could include manuscript rejections for late registration of studies and monetary penalty of \$11,805 per study per day, for late submission of results.

Our Program manages two different ClinicalTrials.gov Protocol Registration and Results System (PRS) accounts; one for the School of Medicine (SOM) and School of Nursing (SON) and the other for the Sidney Kimmel Comprehensive Cancer Center (SKCCC). Administrators monitor all studies to identify current or pending noncompliance. We reach out to multiple PIs every day. **If our Program contacts you, we urge you to respond fully and in a timely manner.** Due to the importance of compliance, the strict timelines and the potential penalties, inadequate response triggers escalation through Division Directors and up to Dr. Daniel Ford, Vice Dean of Clinical Investigations.

Assistance is free to all JHU faculty. Direct services (i.e., entering results) are available for \$50/hour.

JHU SOM ClinicalTrials.gov Program office is based in the Johns Hopkins ICTR and led by Anthony Keyes, MBA, PMP, Program Manager, Clinical Research Projects with three Clinical Research Compliance Specialists:

- Prince Nuamah – SOM/SON
- Aliya Lalji – SKCCC
- Oswald Tetteh – SOM/SON

CURRENT PERFORMANCE

The SOM/SON account currently has over 1100 records on ClinicalTrials.gov and over 1000 individual users with 5-10 new users added every month. In the last year Program staff have reduced the number of Problem Records from 118/1057 (11%) to 42/1156 (3.6%) and have resolved over 400 records with problems. Metrics for these problems are monitored daily to work towards their resolution. Every record modified by users is carefully reviewed by our Program using a Checklist tool we developed to reduce the number of comments received from ClinicalTrials.gov staff.

JHU SOM/SON	August 2018	July 2019
Total Number of records	1057	1156

Problem Records	118	42
Late Results	1	2

The SKCCC account currently has 472 records. In April 2018 we hired a new Administrator to reduce noncompliance and establish infrastructure. In the past year, she has infused much standardization and made substantial improvements in compliance to late results and other problem records. Our goal is to reach full compliance for the SKCCC records.

SKCCC	August 2018	July 2019
Total Number of records	453	472
Problem Records	169	25
Late Results	48	7

We collaborate with other Johns Hopkins entities through monthly catch up calls and other periodic communications. These entities include All Children’s Hospital (ACH), Johns Hopkins School of Public Health (JHSPH) and the Kennedy Krieger Institute (KKI). We also continue to collaborate with the [Clinical Trial Registration and Results Reporting Taskforce](#).

Three most common mistakes research teams are still making

1. Investigators not abiding by statutory time frames (i.e 25 day limit for response to reviewer comments on results and 15 day limit on registration).
2. Misunderstanding of primary completion date being date for final data collection for primary outcome not date of analysis completion or other chosen date by the study team.
3. Listing a study completion date later than the primary completion when both primary and secondary outcomes are based on same time frame.

Research teams have had manuscripts rejected because of late registration.

Presentations

For an example of a recent presentation, click here to view the June 2019 ICTR Third Thursday:

[Meeting the Demands of Clinical Trials Transparency through ClinicalTrials.gov Compliance](#)

- We are available to conduct in-person presentations to various Schools, Departments and groups.
- Presentations can range from 5-150 attendees and 15-60 minutes. Presentations will greatly enhance the understanding by research teams and improve compliance.
- Please contact us so we can custom tailor a presentation during rounds, a faculty meeting, or specially called meeting for your group.

CHANGES IN THE PAST YEAR

Staffing:

[Oswald Tetteh](#) started with our Program in August 2018 and recently completed the [Executive Certificate in Health Care Leadership and Management](#) at the Carey Business School.

Aliya Lalji formally left the program in June 2019 but is partially available for consultation on SKCCC records.

NEW DEVELOPMENTS

Our Program now runs monthly reports in the IRB to identify studies with changes in Principal Investigators (PIs), studies that have been terminated in the IRB and studies without national clinical trial (NCT) registration numbers even though they are clinical trials. This helps to work with PIs and study teams to get these changes reflected on the ClinicalTrials.gov records to ensure they are accurate and up to date as we work on maintaining our institutional compliance.

In addition, we also run a monthly report we call the “Error calculator” using data from the PRS to track metrics. Another report from the PRS known as the Planning Report is used in identifying studies with results due in about three to four months. This helps us reach out to PIs and study teams to begin working on results entry early enough to avoid having late results.

Our team has also worked with the IRB to revise and update the IRB policy and guidelines for registration of clinical trials which was last updated in 2016. These revisions provides guidance on compliance with the new Common Rule requirement for informed consent posting.

INCORPORATION OF SERVICES INTO GRANT APPLICATION

There are allowances in the NIH companion policy to include direct costs for ClinicalTrials.gov registration and results reporting at the time of grant submission. We are working with ORA in hopes of beginning to do so in the coming year.

BEST WAY TO WORK WITH PROGRAM

- Preferable method of contact is email at registerclinicaltrials@jhmi.edu
- Reach us by phone at 410-550-4145/410-550-6484
- Request a new account via an [ICTR Connection Request](#).