**ClinicalTrials.gov Program 2020 Annual Update**

**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 $12,316 per study per day, for failure to submit required information or submitting false or misleading information.

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 two Clinical Research Compliance Specialists:

* Prince Nuamah – SOM/SON and SKCCC
* Oswald Tetteh – SOM/SON and SKCCC

**CURRENT PERFORMANCE**

The SOM/SON account currently has over 1300 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 59/1172 (5%) to 57/1305 (4%) and have resolved over 400 records with problems. Metrics for these problems are monitored daily to work towards their resolution. Every new record submitted 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.

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| --- | --- | --- |
| **JHU SOM/SON** | **August 2019** | **July 2020** |
| Total Number of records | 1172 | 1305 |
| Problem Records | 59 | 57 |
| Late Results | 3 | 0 |

The SKCCC account currently has 495 records. In September 2019 the PRS Administrators for SOM/SON took over SKCCC. Our goal is to reach full compliance for the SKCCC records.

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| --- | --- | --- |
| **SKCCC** | **August 2019** | **July 2020** |
| Total Number of records | 472 | 495 |
| Problem Records | 26 | 14 |
| Late Results | 7 | 5 |

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](https://ctrrtaskforce.org/).

Three most common mistakes research teams are still making

1. Investigators not abiding by statutory time frames (i.e., annual verification, anticipated start and/or completion dates, reviewer comments).
2. Investigators moving the primary completion date based on when they are ready to enter results and not when the statute requires (final date of data collection for primary outcome measures).
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 presentations, click here to view the June 2020- ICTR Third Thursday: [ClinicalTrials.gov: Research in the Times of COVID-19](https://ictr.johnshopkins.edu/study_team/training-education/third-thursdays-with-the-ictr-lecture-series/)

[*Slides*](https://ictr.johnshopkins.edu/wp-content/uploads/CT.gov-Slides-6-18-20.pptx)

[*Checklist*](https://ictr.johnshopkins.edu/wp-content/uploads/CTgov-QCChecklist.docx)

* 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:*

Prince Nuamah completed the [Executive Certificate in Business Communication](https://carey.jhu.edu/programs/executive-education/programs-individuals/executive-certificates/business-communication) at the Carey Business School.

Oswald Tetteh is working toward completion of the [Executive Certificate in Business Communication](https://carey.jhu.edu/programs/executive-education/programs-individuals/executive-certificates/business-communication) at the Carey Business School.

**NEW DEVELOPMENTS**

Our Program began reaching out to remind PIs and study teams to prospectively perform annual verifications and update anticipated dates to prevent them from becoming problem records. This helps us to update records early enough to avoid having problem records.

Our team has also worked with the IRB to identify studies with NIH grant funding by entering either the grant funding number or the Institute Proposal Number into the IRB application.

**BEST WAY TO WORK WITH PROGRAM**

* Preferable method of contact is email at [registerclinicaltrials@jhmi.edu](mailto:registerclinicaltrials@jhmi.edu)
* You can also reach us by phone at 410-550-4145/410-550-6484
* Website: <https://ictr.johnshopkins.edu/clinicaltrials-gov>. Here, you can also find some educational materials including tutorial videos on trial registration and results entry.
* You can request a new account via an [ICTR Connection Request](https://ictrweb.johnshopkins.edu/ictr/connection/).