



## ClinicalTrials.gov Program

### ROLE OF OFFICE

The Office was created in 2016 to support research teams with ClinicalTrials.gov registration and reporting requirements. An Administrator monitors all studies to identify current or pending noncompliance. We reach out to multiple PIs every day. **If our Office contacts you, we urge you to respond fully and timely.** Due to the importance of compliance, the strict timelines and the potential penalties, inadequate response triggers escalation through Division Directors and up to Dr. Ford.

Initially focused on non-SKCCC records we have recently expanded to provide assistance to SKCCC.

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

Johns Hopkins University (JHU), School of Medicine (SOM) ClinicalTrials.gov Office is based in the Johns Hopkins ICTR and led by Anthony Keyes, MBA, PMP, Program Manager, Clinical Research Projects.

### PERFORMANCE IN THE PAST YEAR

JHU, SOM recently passed 1,000 records (1,041) registered on ClinicalTrials.gov. We conducted a review of all users to require an active, JHU-affiliated e-mail address and phone number and disable non-active users. We currently service over 930 individual users with 3-5 new users added every month. Every record that is modified is carefully reviewed by our Office using a Checklist tool we developed to reduce the number of comments received from ClinicalTrials.gov staff.

Sidney Kimmel Comprehensive Cancer Center (SKCCC) has 450 separate records. In April 2018 we hired a new Administrator to reduce noncompliance and establish infrastructure. In a few short months, she has infused much standardization and made substantial improvements in compliance to late results and other problem records. Our goal is to raise the level of compliance for the SKCCC records to match those of the rest of the SOM.

#### *Publications*

Mayo-Wilson E, Heyward J, Keyes A, Reynolds J, White S, Atri N, Alexander C, Omar A, Ford DE, on behalf of the National Clinical Trials Registration and Results Reporting Taskforce *Clinical trial registration and reporting: A survey of academic organizations in the United States*. BMC Medicine. 2018;16:60. <https://bmcmmedicine.biomedcentral.com/articles/10.1186/s12916-018-1042-6>.

### Presentations

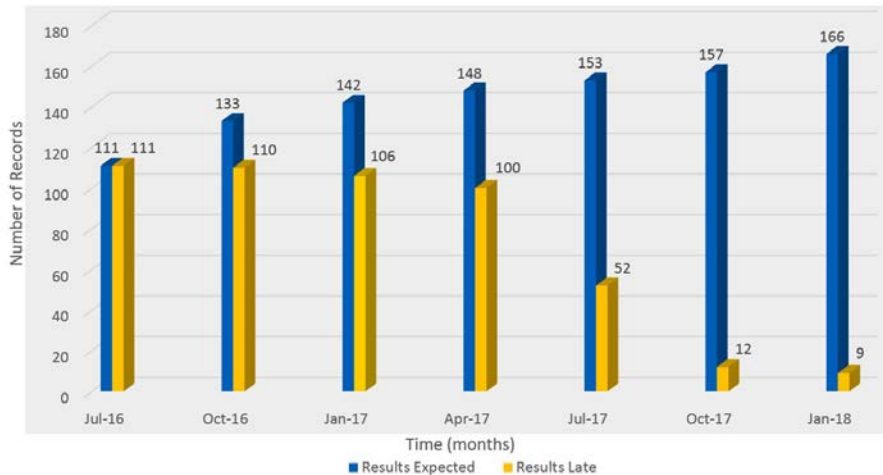
- We conduct 1-3 in-person presentations per month to various Schools, Departments and groups. Presentations range from 5-150 attendees and 15-60 minutes.
- Please contact us so we can custom tailor a presentation during rounds, a faculty meeting, or specially called meeting for your group.
- National highlights include an [Advarra Webinar](#) (700 attendees) and an invited presentation at the [CTSA Spring Meeting](#) in Washington, DC.

### Posters

*Johns Hopkins, School of Medicine ClinicalTrials.gov Program – First Year Successes*  
12th Annual Bayview Research Symposium – Baltimore, MD  
Association of Clinical and Translational Sciences (ACTS) – Washington, DC

### Results

From July 2016 to January 2018 we reduced the number of SOM (non-SKCCC) late studies from 111 to 9. As of June 2018 we had 2 late studies (99% overall compliance). Each late result record carries a potential of criminal proceedings, loss of grant funding and a monetary penalty of \$11,569/day along with substantial reputational risks.



### CHANGES IN THE PAST YEAR

#### Staffing:

Nidhi Atri, MD departed in April 2018 to begin medical residency. We are currently hiring a successor.

Aliya Lalji, MD started with our Office in April 2018 focused 100% on records in SKCCC.

Prince Nuamah, MD/MPH and Aliya recently completed the [Executive Certificate in Health Care Leadership and Management](#) at the Carey Business School.

Anthony was named Co-Chair of the [Clinical Trials Registration and Results Reporting Taskforce](#) in January 2018. The Taskforce is a national consortium of 120 institutions and 350 members.

### *Standard Operating Procedures*

After conferring with administrators in the Sidney Kimmel Comprehensive Cancer Center (SKCCC), All Children's Hospital (ACH), Johns Hopkins School of Public Health (JHSPH) and the Kennedy Krieger Institute (KKI) a series of standard operating procedures (SOPs) were developed and finalized. The entire Johns Hopkins enterprise now follows consistent practices.

## NEW DEVELOPMENTS FOR THE UPCOMING YEAR

Tom Mitchell (30% effort) is reviewing IRB reports looking at 1.) Change in research applications to modify the PI and 2.) Applications that are terminated or expired, to ensure this information is accurately and timely reflected in ClinicalTrials.gov.

Evan Mayo-Wilson, DPhil (20% effort) has obtained funding from FDA to perform qualitative interviews with several academic centers to identify and disseminate best practices of successful Offices.

In collaboration with CRMS and the IRB we have created a report to identify studies that have begun enrollment but do not have a valid ClinicalTrials.gov number. Timely registration is a requirement of Journal editors (prior to enrollment) and FDA (within 21 days).

We completed a review of all results released in 2017 and are identifying ways to reduce the number of review cycles with ClinicalTrials.gov. In 2017, only 12% of records were approved without comments. We aim to increase this percentage to 25% in 2018.

We submitted a letter of support for a Harvard University CTSA Administrative Supplement to expand the Taskforce and create deliverables to support transparency and compliance with reporting of results and adverse events.

We are currently conducting a follow-up to last years' successful survey. Much work has been done to streamline the Qualtrics tool to make data analysis faster and more reliable. We plan to publish the results of this survey with an emphasis on establishing trends.

## 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](mailto:registerclinicaltrials@jhmi.edu)

Website: <https://ictr.johnshopkins.edu/clinicaltrials-gov>

*Helping Research Teams Address New NIH Application Requirements Around Clinical Trials.* You may download the slides, or view the video.

ICTR Third Thursday information session. You may download the slides, or view the video. You can also use [ICTR Connection Request](#).