

## Role of the Office:

The Johns Hopkins ClinicalTrials.gov Program was developed in June 2016 by Dr. Daniel Ford and Anthony Keyes. This Program was designed to address the needs of our investigators and study team members.

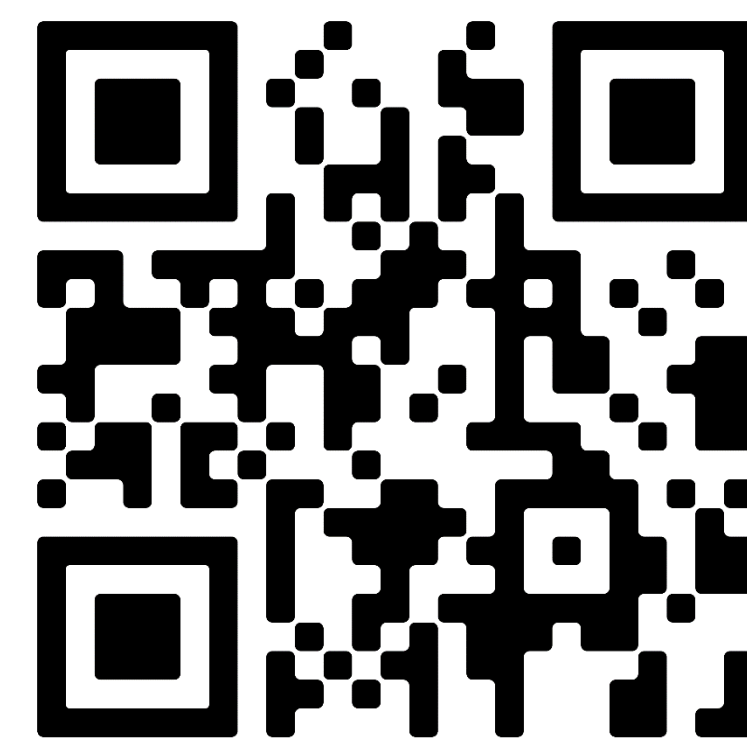
Johns Hopkins is committed to honoring our commitment to research participants by ensuring transparency through the accurate and timely registration, updating and results reporting of clinical research.

Our mission is to increase our institutional compliance to all applicable regulations, such as the FDA Final Rule, the NIH Companion Policy and the Common Rule.



# ClinicalTrials.gov Program

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- Assist PIs/Study teams with trial registration and results reporting
- Collaborate with other ICTR programs to drive institutional compliance to clinical trial regulations
- Contribute to local and national best practices through presentations, YouTube videos and publications

## Services Provided:

The Program provides the following services to JHU investigators:

- Create and maintain individual accounts
- Assist with registration and updating of records
  - Required for Applicable Clinical Trials
  - Required for any clinical trial receiving full or partial NIH funding
- Assist with responding to registration comments (time limited to 15 calendar days)
- Assist with reporting of results (one year after study has reached the indicated "Primary Completion Date")
- Assist with responding to results comments (time limited to 25 calendar days)
- Train PIs/Study teams (1:1 and invited presentations to groups)
- Monitor all studies for missing updates, late results and other errors
- Transfer records when PIs join/leave Johns Hopkins
- Direct services for results reporting (fee applies)