A DIVE INTO ASPECTS OF CLINICALTRIALS.GOV PART I

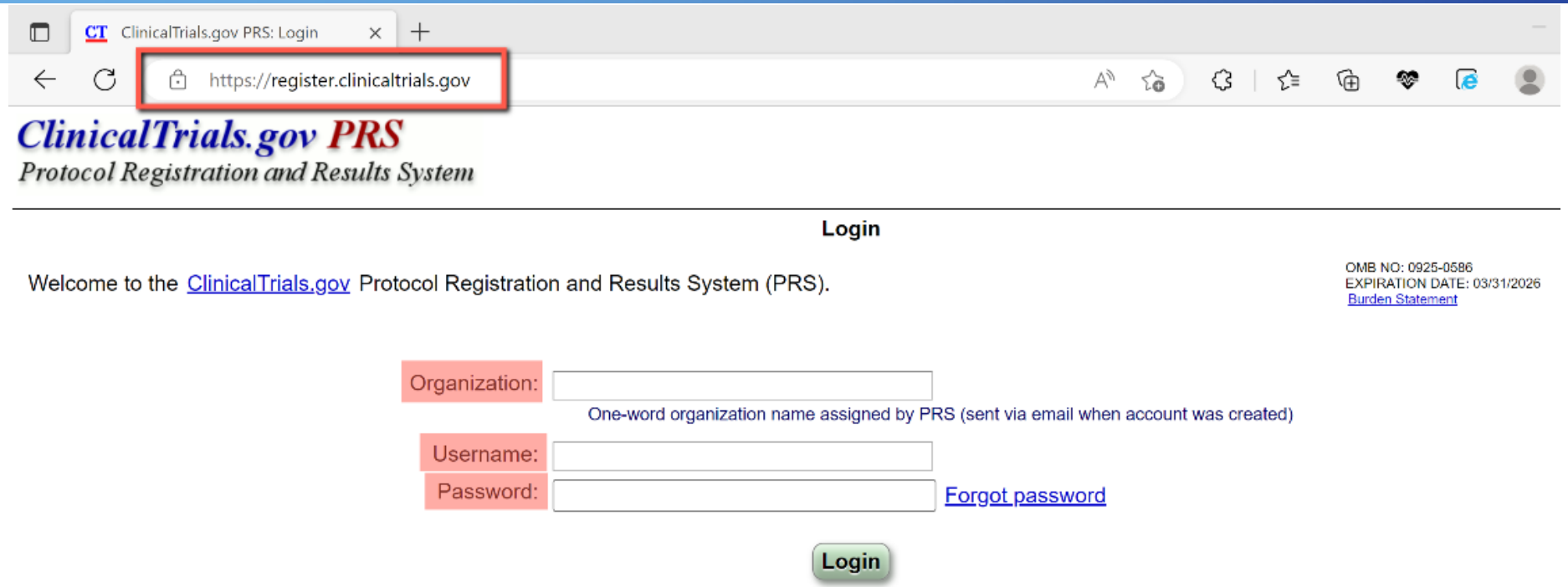
Presented by: Oswald Tetteh, Clinical Research Compliance Specialist

JOHNS HOPKINS
INSTITUTE for CLINICAL & TRANSLATIONAL RESEARCH

Outline

- **Live demonstration of information entry**
  - Tips and tricks
- **The Responsible Party Role**
  - Addressing issues
  - Updating records
  - Releasing Records
  - Checklist before leaving institution

Live demo



JOHNS HOPKINS
INSTITUTE for CLINICAL & TRANSLATIONAL RESEARCH

Support materials

- **Protocol Registration and Results System (PRS) Information**
  - Data Element Definitions, Templates, and Checklists
  - PRS Guided Tutorials
  - PRS User's Guide, Review Criteria, and Major Comments List

https://clinicaltrials.gov/ct2/manage-recs/resources

The Responsible Party (RP)

- ***"Responsible party means, with respect to a clinical trial, the sponsor of the clinical trial, as defined in 21 CFR 50.3; or the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under this part for the submission of clinical trial information."***
- **For clinical trials conducted under an investigational new drug application (IND) or investigational device exemption (IDE), the IND or IDE holder is considered the sponsor.**

https://www.govinfo.gov/content/pkg/CFR-2017-title42-vol1/xml/CFR-2017-title42-vol1-part11.xml
https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission#h-51

RP in ClinicalTrials.gov…

3. Sponsor/Collaborators

Responsible Party, by Official Title *

Definition: An indication of whether the responsible party is the sponsor, the sponsor-investigator, or a principal investigator designated by the sponsor to be the responsible party. Select one.

- Sponsor: The entity (for example, corporation or agency) that initiates the study
- Principal Investigator: The individual designated as responsible party by the sponsor (see Note)
- Sponsor-Investigator: The individual who both initiates and conducts the study

Note: The sponsor may designate a principal investigator as the responsible party if such principal investigator meets all of the following requirements: is responsible for conducting the study; has access to and control over the data from the study; has the right to publish the results of the study; and has the ability to meet all of the requirements for submitting and updating clinical study information.

https://register.clinicaltrials.gov/prs/html/definitions.html?popup=true#Sponsors

RP Duties

- **Addressing issues**
  - Problem records
  - PRS review comments
- **Updating records**
  - Annual Verification
  - Anticipated dates
  - Registration or results entry
- **Releasing records**
- **Departure from institution checklist**

Questions?

Please visit our website for tutorials and more detailed information:
https://ictr.johnshopkins.edu/clinicaltrials-gov

See us on YouTube at "JohnsHopkinsCTgov"

Email us with any questions at
registerclinicaltrials@jhmi.edu

JOHNS HOPKINS
INSTITUTE *for* CLINICAL & TRANSLATIONAL RESEARCH