RUTGERS HEALTH

RUTGERS HEALTH QUICK START GUIDE

MULTI-CENTER INDUSTRY CLINICAL TRIALS

NJacts

Confidential Disclosure Agreement

1 Submit a Document Review record within **RAPSS** to allow the sponsor to share confidential study documents.

Sponsor Feasibility

2 Request assistance if needed from the **CTO** to complete the sponsor's questionnaire or to request a **Deep6 query**.

Site Selection

3 Once officially site selected, submit the protocol, draft consent, budget, draft contract from the sponsor to the CTO via **OnCore** ePRMS.

CTO Feasibility & Intake

4 Participate on the **CTO Feasibility & Intake meeting** with the CTO team to review the study implementation plan and initiate budget/contract negotiations.

Partner Hospitals

5 To obtain permission from UH-Newark or RWJBH to recruit from, utilize clinical services, & collect Epic data, see the IRB's **Performance Site guidance**.

IRB

6 Complete the **Rutgers eIRB** and Central/Commercial IRB submissions and complete regulatory documents and other start-up tasks as directed by the sponsor/CRO.

CTO Progress

7 Coordinate with the **CTO** on start-up progress, track contract and budget status in OnCore, upload approvals, and monitor for study activation in OnCore.

Site Initiation Visit

8 Participate in the Site Initiation Visit (SIV) and obtain the sponsor/CROs activation letter or email before beginning to recruit.