CTA 101 – Covered Today

• General Contract Info
• Types of Agreements
• Common provisions
• How study teams can help CTO
• Investigator Initiated Trial Agreements + SubContracts
General Contract Info

• Who does the contract go to?
  – Who is funding/supporting?
    – Contract-triage@ohsu.edu

• Who can sign?

• When does signing happen?

Types of Agreements

• CDA/NDAs
• CTAs
• Amendments
• IITAs & SubContracts
Clinical Trial Agreements (CTAs)

- Why do we have CTAs?
- PI/Study Team Responsibilities

CTA Provisions

- Confidential Information
- Publication
- Ownership & Use of Data
- Intellectual Property
- Subject Injury & Indemnification
CTA Provisions (cont)

• Term & Termination
• Amendments
  – Budget Change
  – PI Change

How can Study Teams help CTO?

• Make sure info in eIRB is accurate and complete
  – Funding sources
  – Liability language in ICF
• Provide CTO with the information we need
Investigator Initiated Trial Agreements

What Studies need them?

1st thing needed – IIT CDA?

2nd thing needed – IIT Questionaire

3rd thing needed – IITA

4th thing needed – SubContract?

Who needs IITAs

• Who is the SPONSOR of the study?

• Are you receiving funding or other support (drugs, equipment, reduced prices, etc.) from an industry supporter?
IIT CDAs

• Does the protocol or other information you are sending out need protection?

• CDAs for Subsites: MANDATORY

IIT Questionnaire

• Complete ASAP – needed for the IITA

• What is being provided & how?

• Ownership/use of Data

• Intellectual Property

• Possibility for more supporters in the future?
  – Industry or fed grant

• Be as detailed as possible!
IITAs + Subcontracting

• Will there be subsites?
  – Who are you subbing to?

• Who is funding the subsites?

QUESTIONS?
CRSO Page: https://o2.ohsu.edu/clinical-research-services/index.cfm

Clinical Trials Office – Contract (CTO): https://o2.ohsu.edu/clinical-research-services/cto-contracting/index.cfm

Contract Triage: contract-triage@ohsu.edu

Thank You