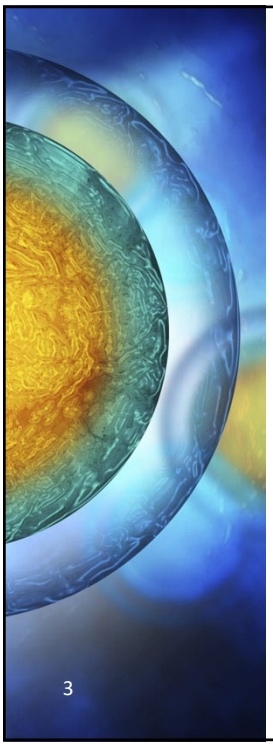
# OCTRI Research Forum
# Clinical Trial Agreements 101

DATE: December 15, 2022 PRESENTED BY: Kristen Baptiste, JD, CTO – Manager & Hannah Shangraw, JD, CTO – Contract Officer

## CTA 101 – Covered Today

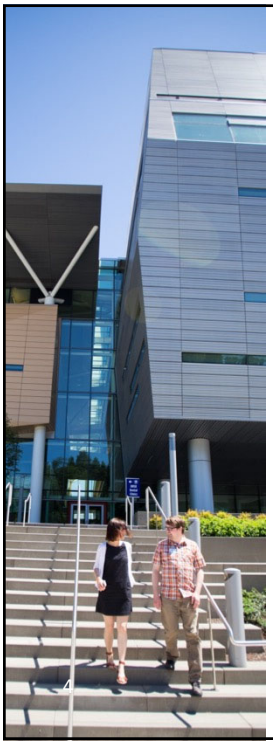
- General Contract Info
- Types of Agreements
- Common provisions
- How study teams can help CTO
- Investigator Initiated Trial Agreements + SubContracts

2



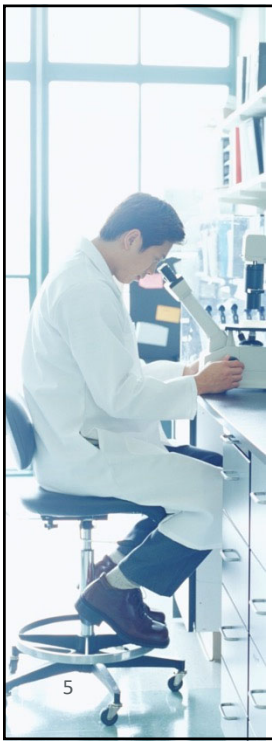

# General Contract Info

- 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

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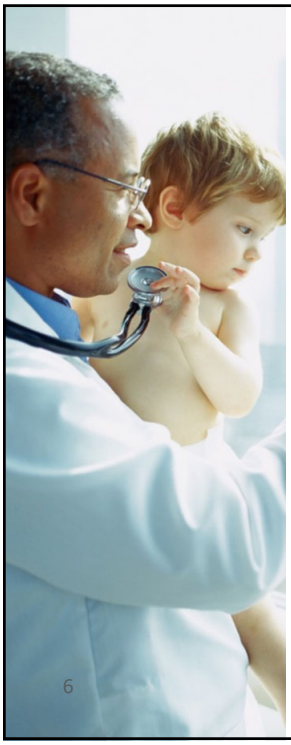

# CTA Provisions

- Confidential Information
- Publication
- Ownership & Use of Data
- Intellectual Property
- Subject Injury & Indemnification

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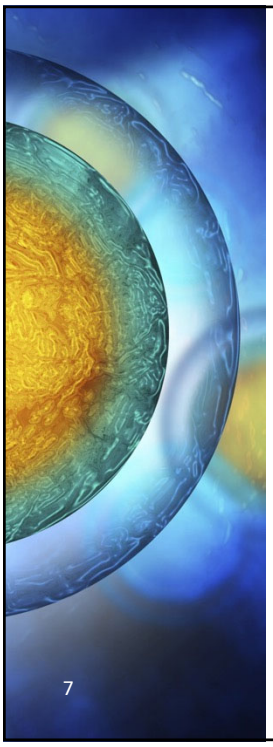

# CTA Provisions (cont)

- Term & Termination
- Amendments
  - Budget Change
  - PI Change

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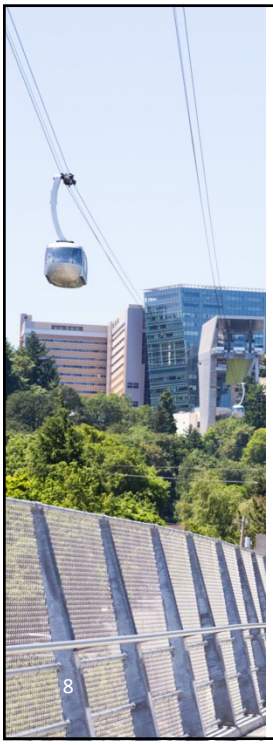
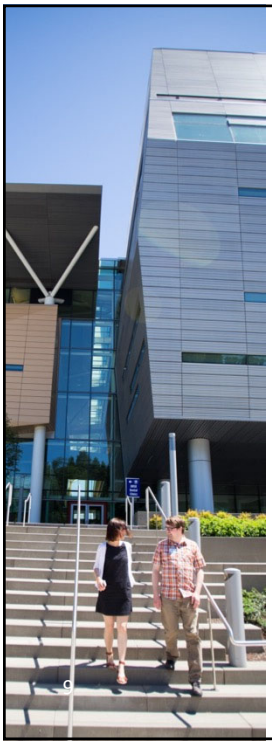


# How can Study Teams help CTO?

- Make sure info in eIRB is accurate and complete
  - Funding sources
  - Liability language in ICF
- Provide CTO with the information we need

8



# Investigator Initiated Trial Agreements

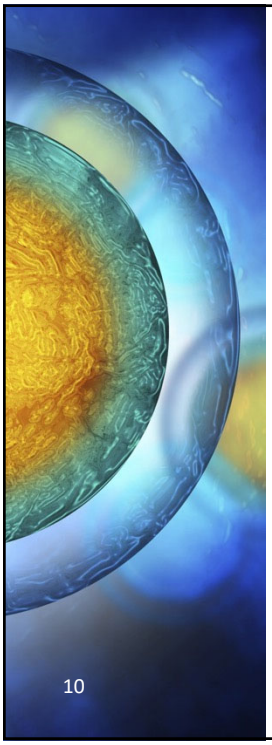
What Studies need them?

1st thing needed – IIT CDA?

2nd thing needed – IIT Questionaire

3rd thing needed – IITA

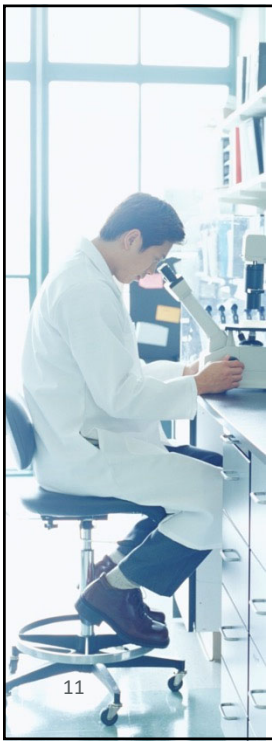
4th thing needed – SubContract?



# 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?

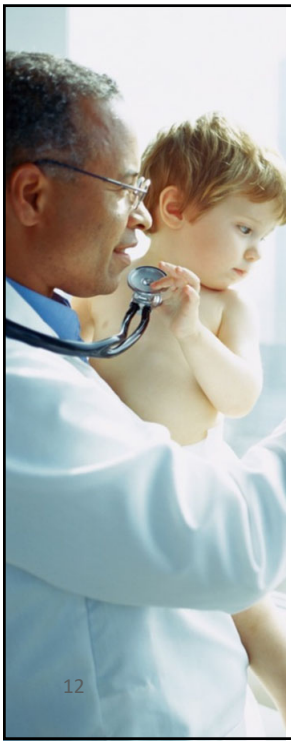
10



# IIT CDAs

- Does the protocol or other information you are sending out need protection?
- CDAs for Subsites: MANDATORY

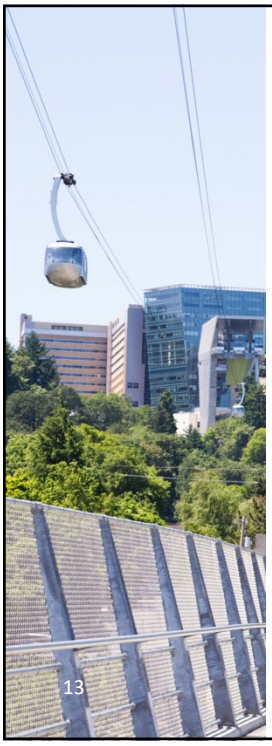
11



# 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!

12




# IITAs + Subcontracting

- Will there be subsites?
  - Who are you subbing to?
- Who is funding the subsites?

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# QUESTIONS?

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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

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# Thank You