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Research Institute

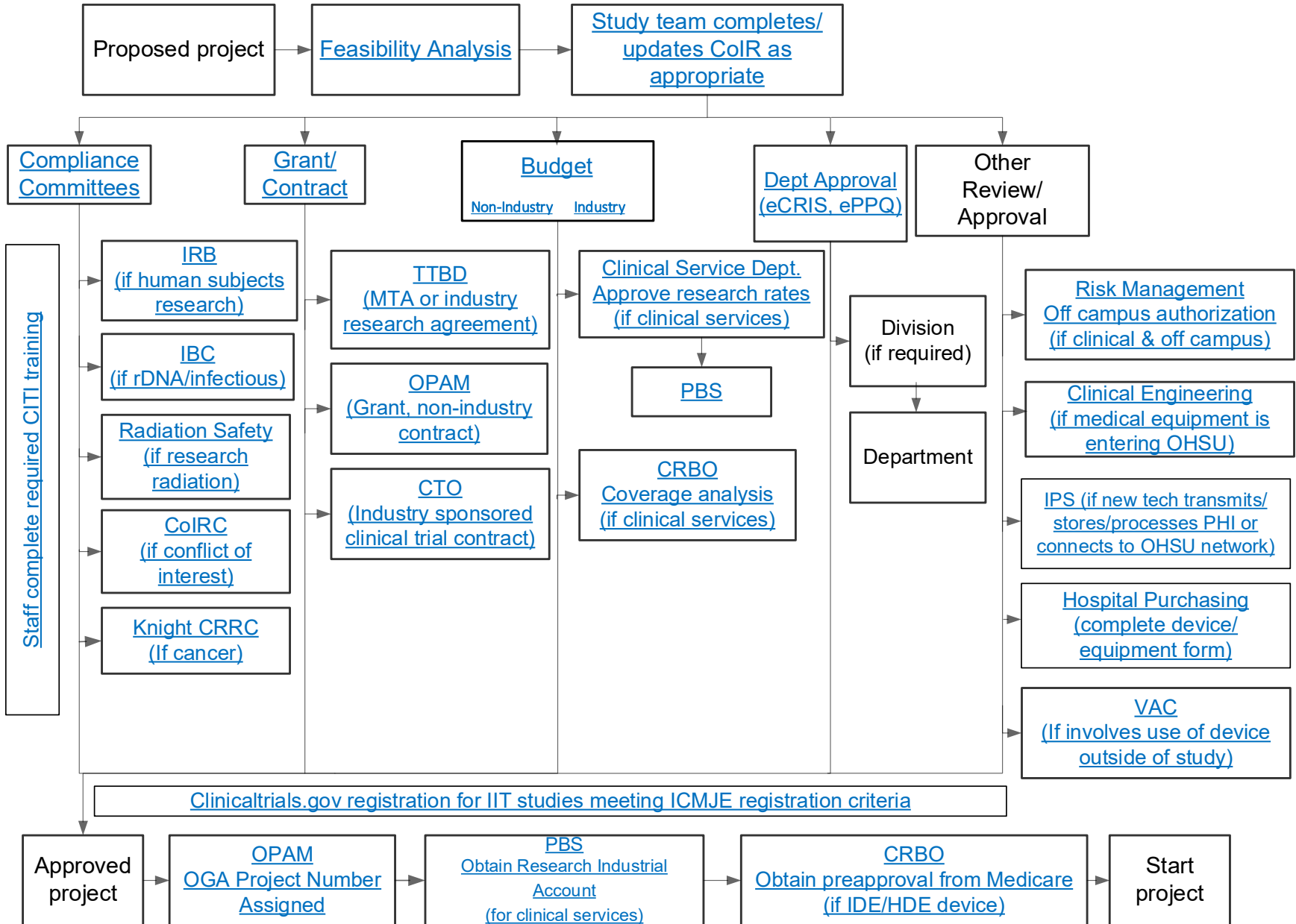
OHSU Study Start-up Process

DATE: September 23, 2021 PRESENTED BY: Bridget Adams, MSHS, CCRA, Manager Regulatory Knowledge and Support,
Oregon Clinical and Translational Research Institute

Objectives

- Cover the study start-up process for a typical OHSU human subjects research project
- Direct study teams to policies, tools, and resources
- Discuss dependencies between systems/approvals and tips to help you plan for a smooth start-up

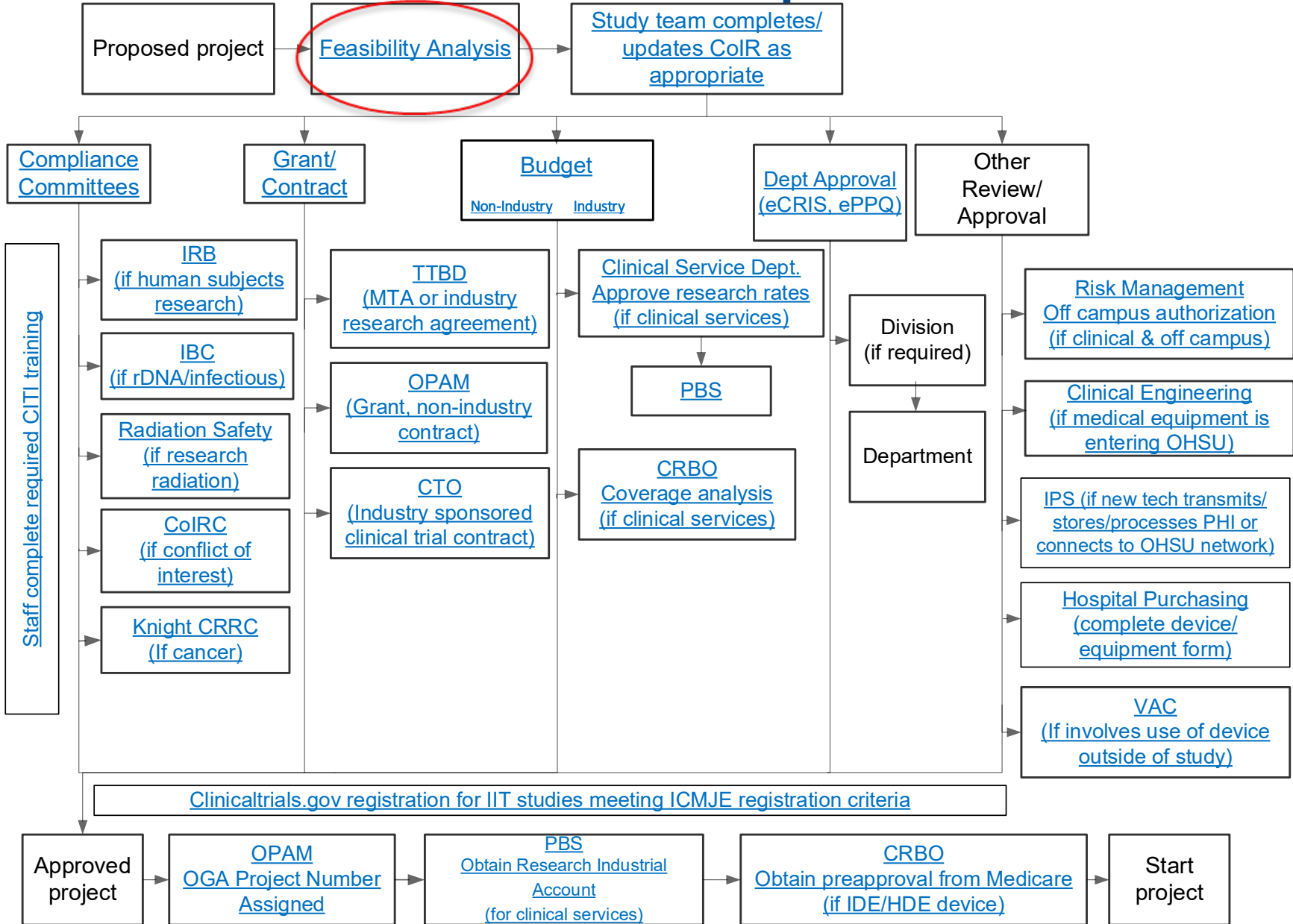
Pre-award Process Map



Proposed Human Subjects Research Project

- The federal regulations for the protection of human subjects, known as the [Common Rule](#), define Research and Human Subject as follows:
 - **Research** is "a systematic investigation designed to develop or contribute to generalizable knowledge." [45 CFR 46.102(d)]
 - A **Human Subject** is "a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information." [45 CFR 46.102(f)(1-2)]
- Can be federally funded, industry sponsored or unfunded research
- The research protocol can be written by the OHSU Investigator or company, collaborator, federal agency

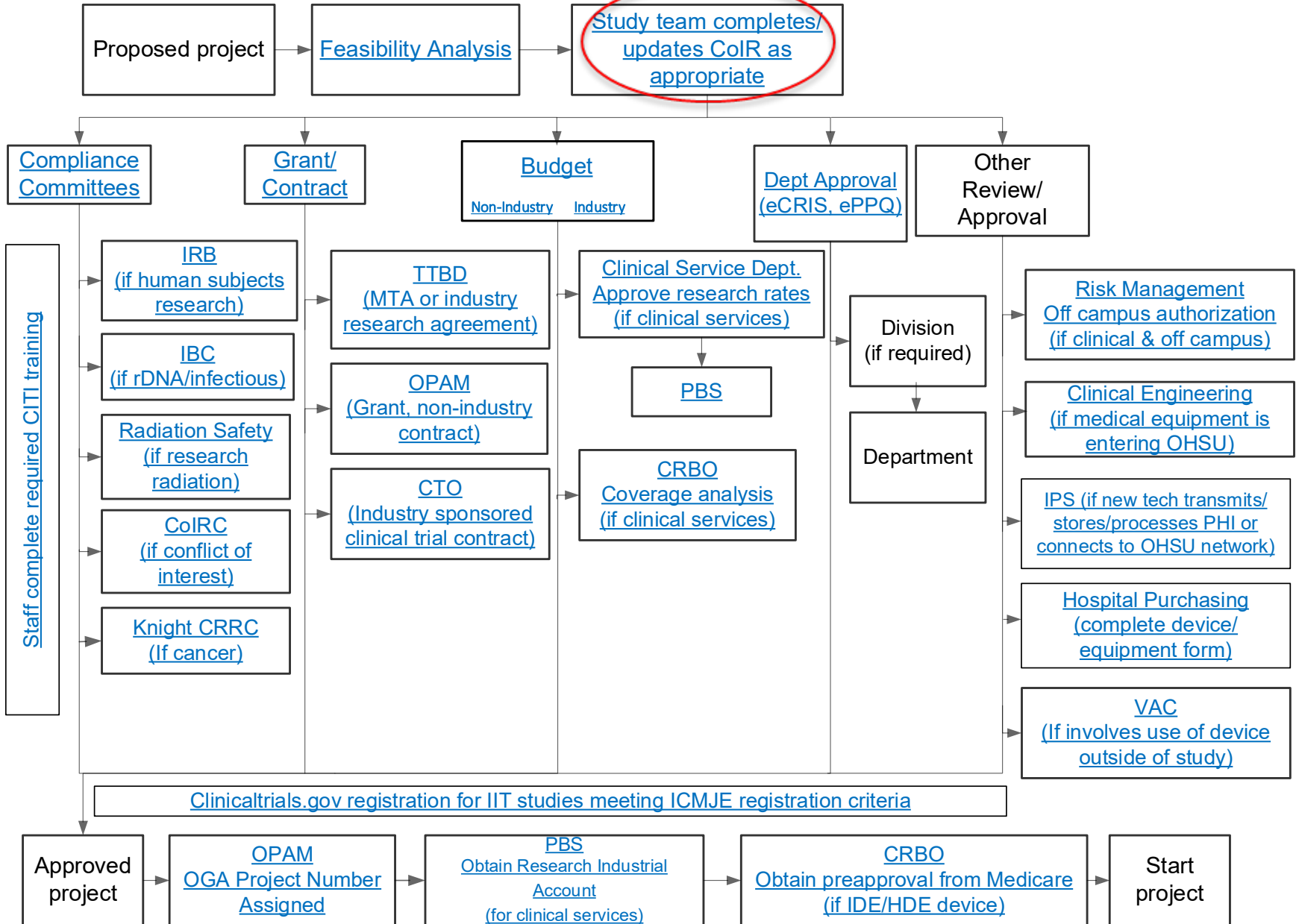
Pre-award Process Map



Feasibility Analysis

- Important because delays in research have significant time and cost implications for study teams and OHSU.
 - Approximately 31% of studies at OHSU enroll 0 or 1 research participants (Kitterman, D.R., Cheng, S.K., Dilts, D.M., & Orwoll, E.S (2011) *The Prevalence and Economic Impact of Low-Enrolling Clinical Studies at an Academic Medical Center. Academic Medicine, Vol. 86(11), pp.1-7*)
- Considerations:
 - Budget, time, experience/expertise, facilities/resources, patients, competing studies
- Resources:
 - Protocol Feasibility Checklist [OCTRI Tools, Templates, Resources](#)
 - [OCTRI Research Forum](#) “Assessing Study Feasibility” (see past seminars)
 - Recruitment consultations available by contacting octrirecruitment@ohsu.edu
 - Epic Recruitment tools, Cohort Discovery, RDW, etc. To find the right tool for you contact the Lindsey Zimmerman, Research Data Concierge zimmerli@ohsu.edu

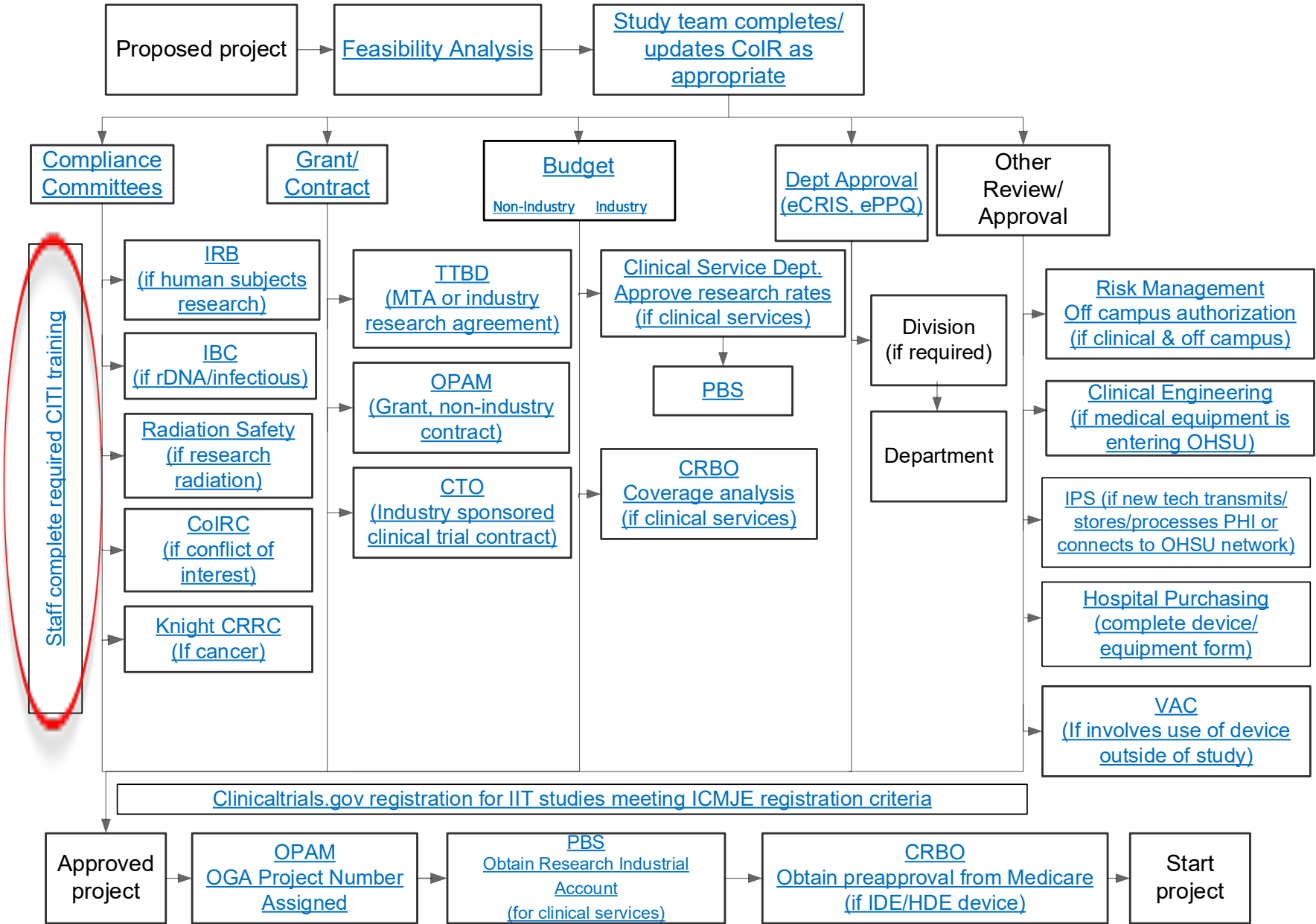
Pre-award Process Map



Conflict of Interest Disclosure

- Conflict of interest disclosures must be up to date **before** IRB approval for any study team member who:
 - Conducts research, with respect to a research protocol, designing research, directing research or serving as the principal investigator, enrolling research subjects (including obtaining subjects' informed consent) or making decisions related to eligibility to participate in research, analyzing or reporting research data, or submitting manuscripts concerning the research for publication
 - Disclosure is required at least annually but are also reviewed on a study by study basis
- TIPS:
 - Best to update outside activities and financial disclosures **before** you “submit” the study in the eIRB so the conflict of interest committee has up to date information for their review (more on this later)
 - Can check status of trainings/disclosures in the eIRB or in Researcher Snapshot in Cognos

Pre-award Process Map

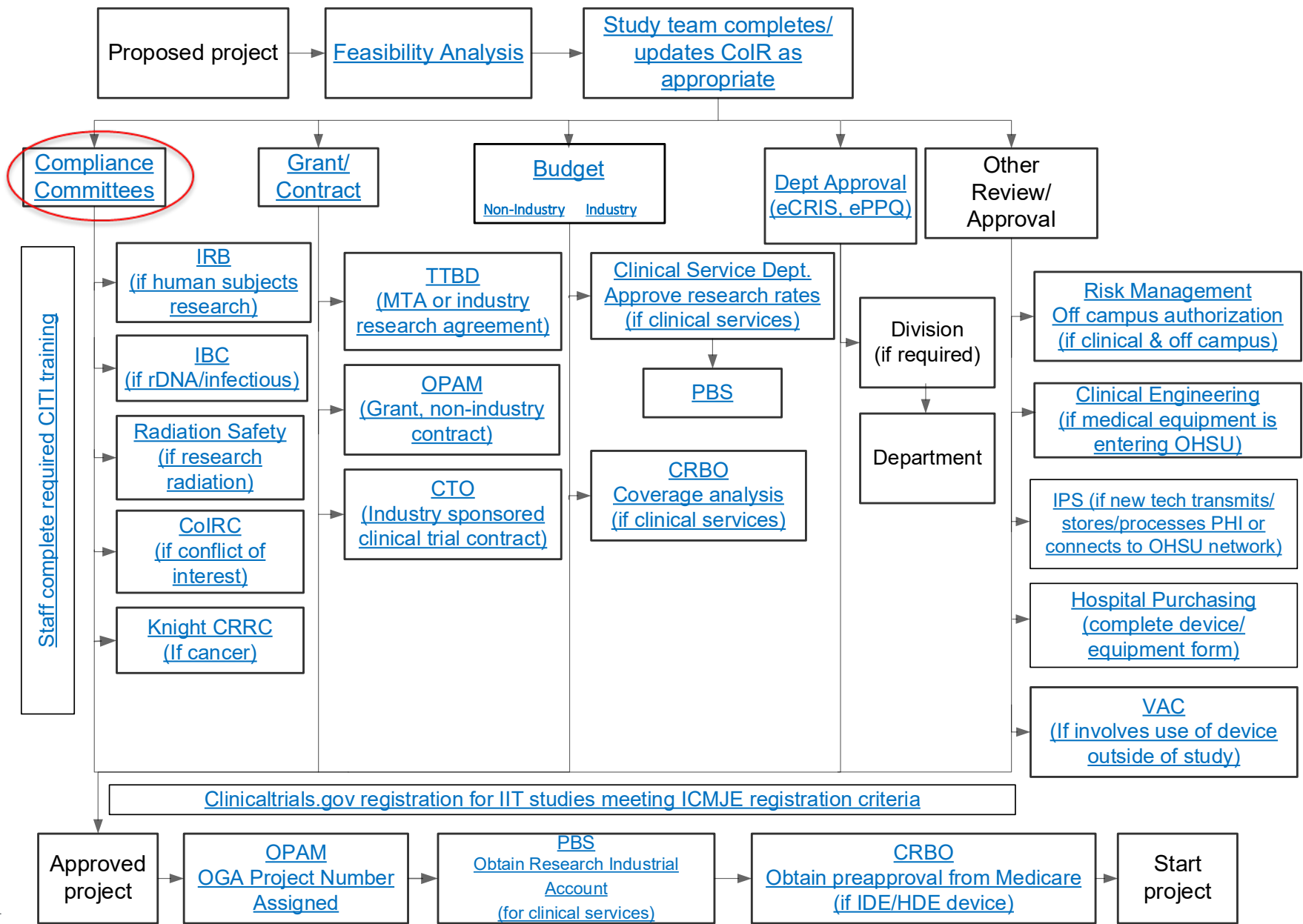


CITI Trainings



- [CITI Trainings](#) must be completed for study staff **before** the IRB will grant final approval of your study
 - Required **before** you can submit follow-on submissions
- Tips:
 - IRQ questions trigger the training requirements so make sure your IRQ is complete/accurate
 - Best to check the training status of study staff early to avoid delays
 - Can check training status in eIRB as you add them to the Initial Review Questionnaire

Pre-award Process Map

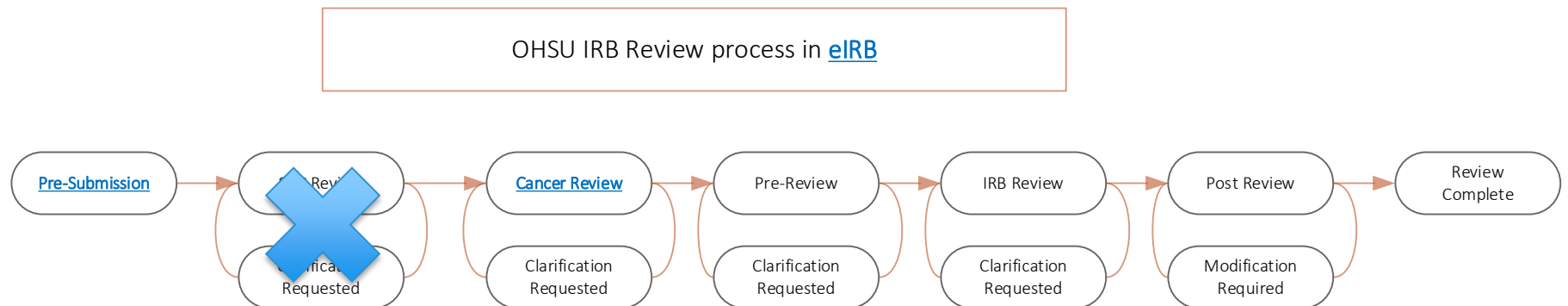


IRB



eIRB

- The OHSU IRB reviews all human subjects research at OHSU
- A complete, consistent, and accurate submission that aligns with institutional policies will minimize clarifications and shorten overall time to final approval
- Use templates and IRB boilerplate language whenever possible
- Address all IRB clarifications when you respond



For policies, guidance and to locate required forms/templates visit the [OHSU IRB Policies and Forms](#) webpage

New users: [eIRB registration](#)

[Using Central or External IRBs](#)

Knight Clinical Research Review Committee (CRRC)

- Reviews all cancer related studies at OHSU
 - Including studies that enroll patients with cancer
- CRRC can require protocol/submission changes **before** IRB review
- Information on CRRC requirements visit the [CRRC Bridge Site](#)
- Tips:
 - Use the Knight consent, protocol templates
 - Complete required forms and follow all instructions
 - Consider CRRC review schedule in your start-up review time

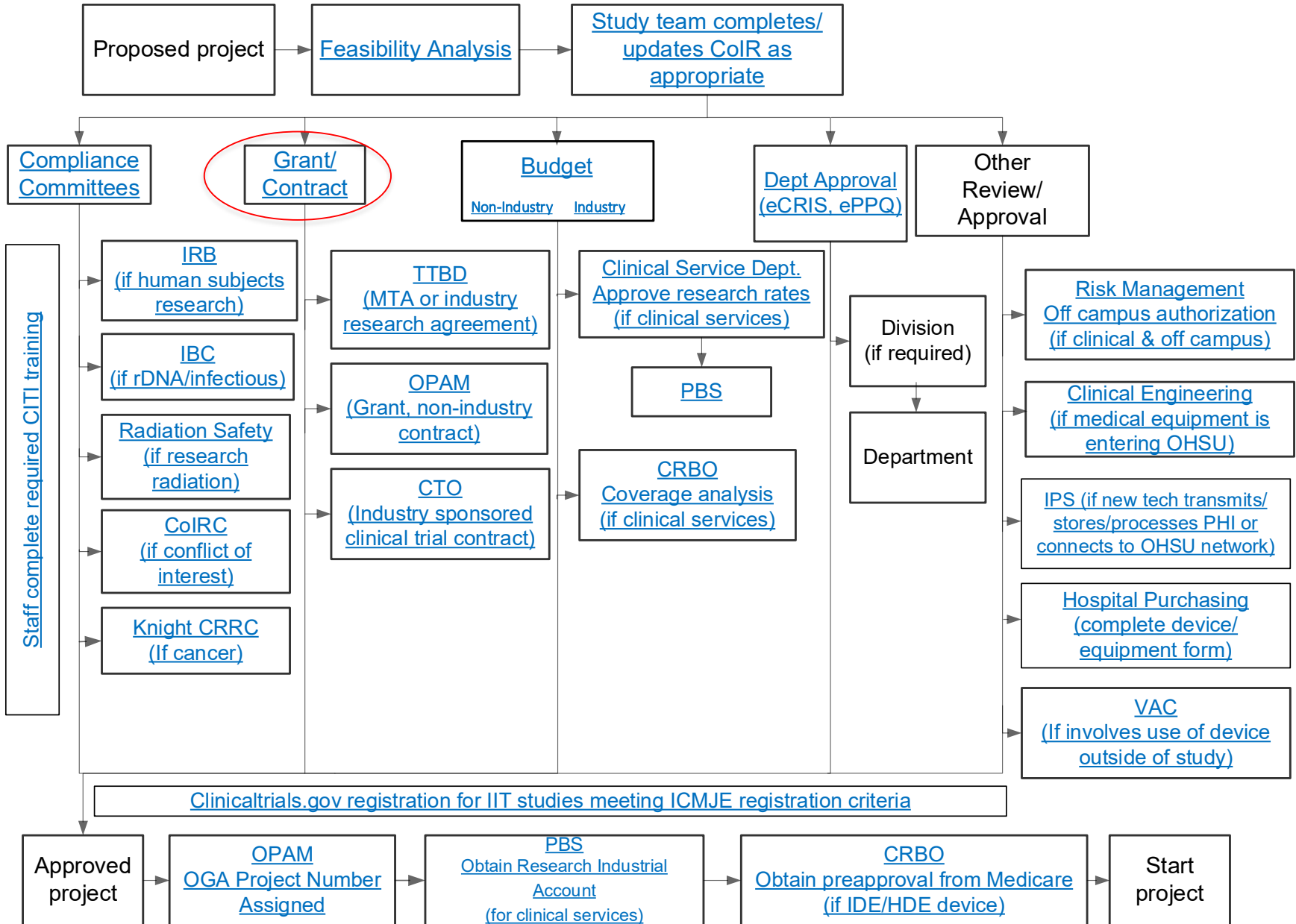
Other Compliance Committees

The following committees conduct their review in parallel with IRB review but their approval is required **before** IRB final approval.

- Radiation Safety
 - Reviews all studies with radiation procedures done for research purposes
 - IRQ questions and form required in the eIRB
- Conflict of Interest in Research –COIR
 - Reviews studies when a potential conflict has been identified
 - There is an IRQ question for OHSU conflicts in the eIRB
 - TIP: Include all funding and support for the study in your eIRB application
- Institutional Biosafety Committee - IBC
 - Reviews studies involving recombinant DNA, infectious agents, or biologically derived toxins
 - [eIBC system](#)
 - Add the eIRB # in the eIBC system and complete an abbreviated submission
 - [IBC Policies and Forms](#) for submission requirements



Pre-award Process Map



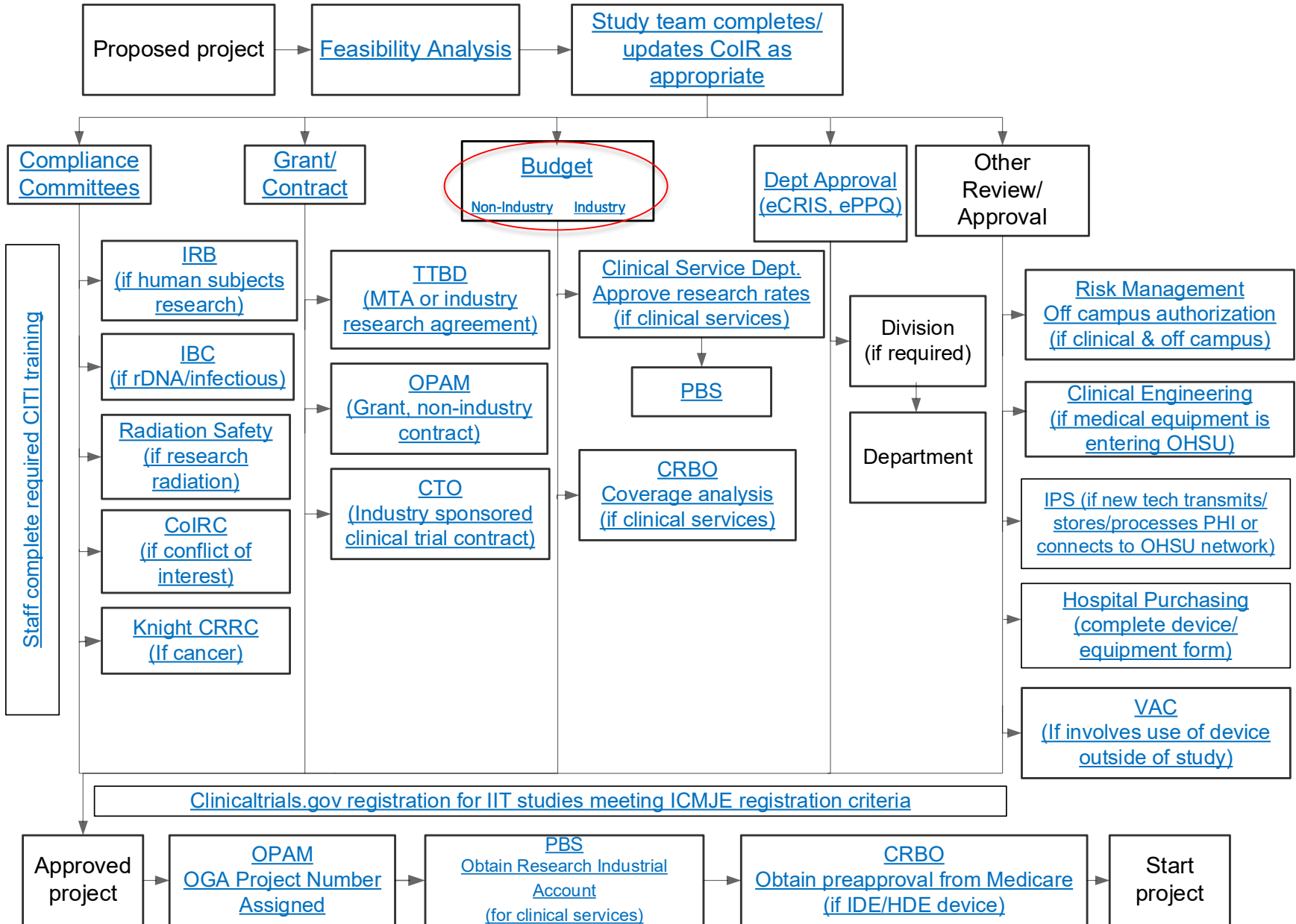
Grant/Contracts

- If you don't know which contract office to contact contract-triage@ohsu.edu will help you
- All contracts/agreements must be signed by an institutional official!!!
- [Technology Transfer](#) (TT)
 - Material transfer agreements
 - Industry funded research/ service agreements
- [Office of Proposal and Award Management](#) (OPAM)
 - Federal Grants and Foundation funding
 - Grant submissions and departmental approvals are done in InfoEd
 - Data use agreements (duainbox@ohsu.edu)
 - Departmental Award Checklist (DAC) to the PI and Departmental contact that includes [compliance requirements](#)
 - IRB/IACUC/IBC approvals needed
 - Trainings
 - COIR
 - VA Memorandum if appropriate
 - Sub-award requirements (if applicable)

Grant/Contracts (cont.)

- [Clinical Trials Office Contracting](#) (CTO)
 - Industry sponsored clinical trial agreements (CTAs) and Confidential Disclosure Agreements (CDAs)
 - CTO contracting is automatically notified when you submit the study in eIRB with industry funding/support
 - Add industry funding/support in the eIRB **before** you submit study to the IRB or the study won't route to CTO contracting
 - Contract completed in eCRIS
 - IRB, clinical services and departmental approvals are required **before** to contract execution
 - TIPS:
 - Contract terms must be consistent with consent/protocol requirements so use OHSU boilerplate subject injury language
 - Complete Investigator Initiated Trial Contract Questionnaire

Pre-award Process Map



Budgeting Resources

- [Non-industry Budgets](#) information available on OPAM website
- [Industry Sponsored Clinical Trials](#)
 - Build industry budgets in [eCRIS](#)
 - [Industry Funded Clinical Trial Budget and Payment Guidelines and Information](#)
- [RATE](#) Clinical Trials 1: Budgeting, Coverage Analysis and Account Set-up
 - Formerly Clinical Trials 1: Pre-Award Administration
 - Slides and course materials available
 - Registration for live trainings in [Compass](#)

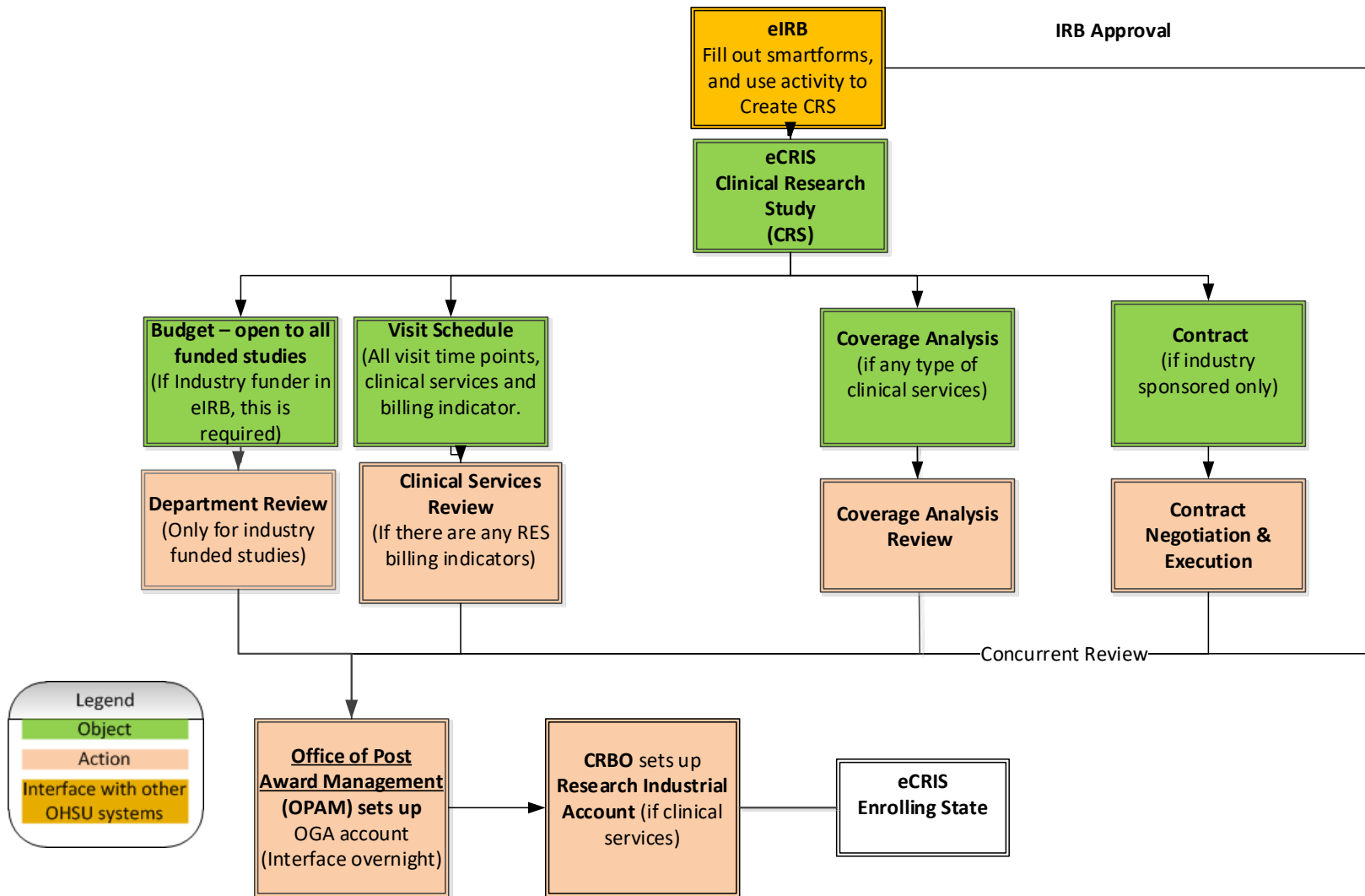
Electronic Clinical Research Information System (eCRIS)

- An institution-wide computer application for the budgeting, financial management, contracting, and study management, including subject tracking, regulatory reporting and document management, of OHSU clinical research studies
- eCRIS interfaces: eIRB, Oracle, and Epic
- Is **Mandatory** for all studies with prospective consent at OHSU
- Budgets for industry sponsored trials are required to be put in eCRIS

eCRIS Resources/Tips

- [eCRIS](#) Resources:
 - eCRIS user Manual – this is a really good resource
 - ecrissupport@ohsu.edu
 - Training available by contacting Kristin Stiller
hackneyk@ohsu.edu
- Tips
 - You can push a study to eCRIS once you complete the eIRB IRQ Smart Forms
 - Verify funding is correct in eIRB prior to submitting study
 - eCRIS study forms need to be completed for CTO contracting for their review

eCRIS Pre-award



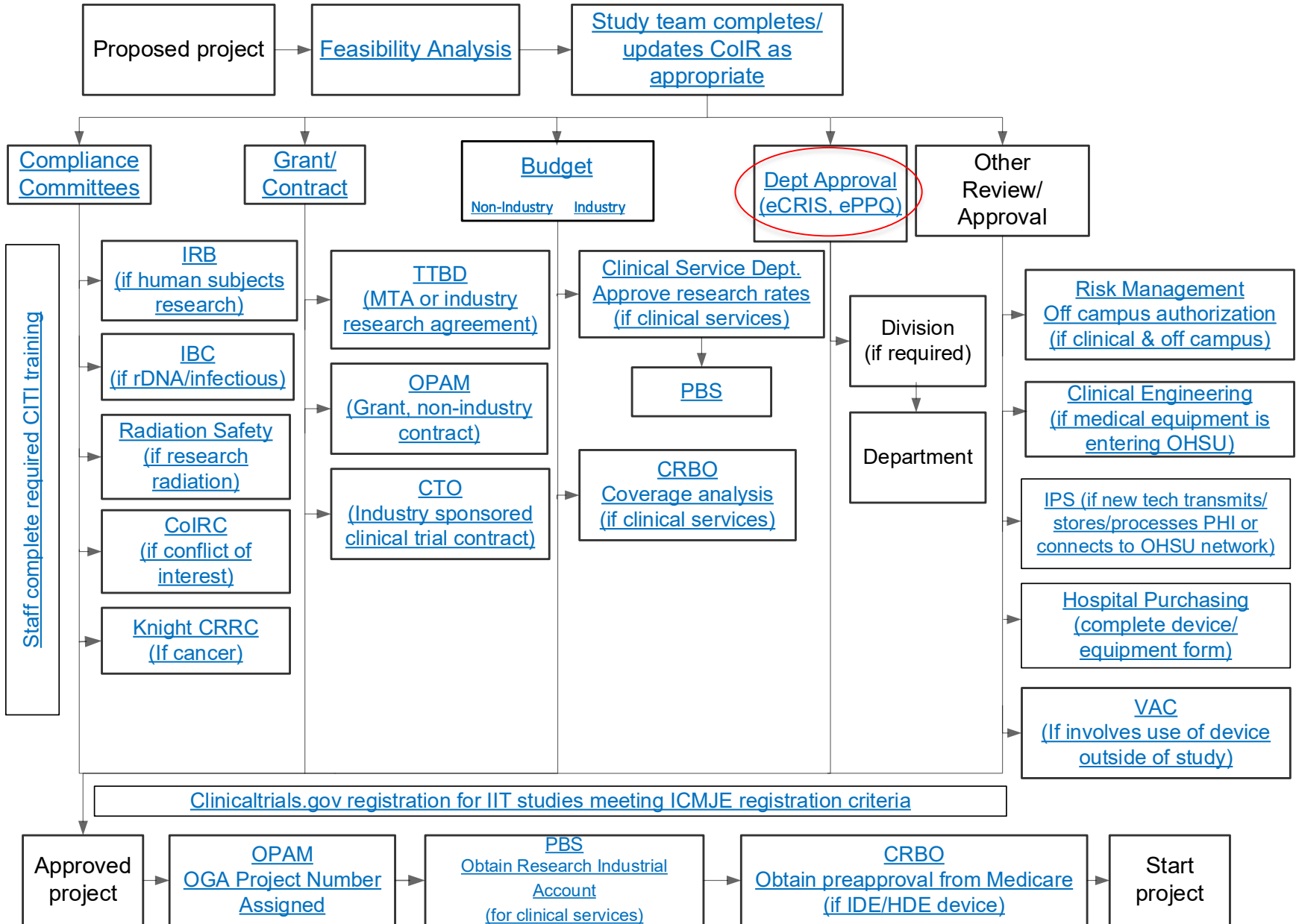
Clinical Services Review

- Any clinical services (labs, pharmacy, imaging, etc.) to be done during the study must be entered in eCRIS
- Research requests are reviewed by cost centers providing clinical services
 - Can the cost center can provide the service?
 - Is the clinical service listed in the visit schedule the appropriate service
 - Cost Centers can request changes
- All Clinical Services need to be approved **prior** to account set up
- Tip:
 - Clinical Services Review can be submitted as soon as study procedures are entered into eCRIS (don't have to have finished sponsor budget negotiation if industry)

Coverage Analysis

- Clinical Research Billing Office (CRBO) completes the coverage analysis
 - [Coverage Analysis: What is it and when is it required?](#)
- Verifies that all clinical services are listed in eCRIS and that the study team has indicated how that service will be billed (research/insurance)
- Verifies cost language in the consent matches the visit schedule/budget
- Verifies that the payment terms in the contract and budget comply with OHSU policy and match the billing indicators
- If items don't match across documents you may need to revise eCRIS, your IRB application and/or your contract payment terms

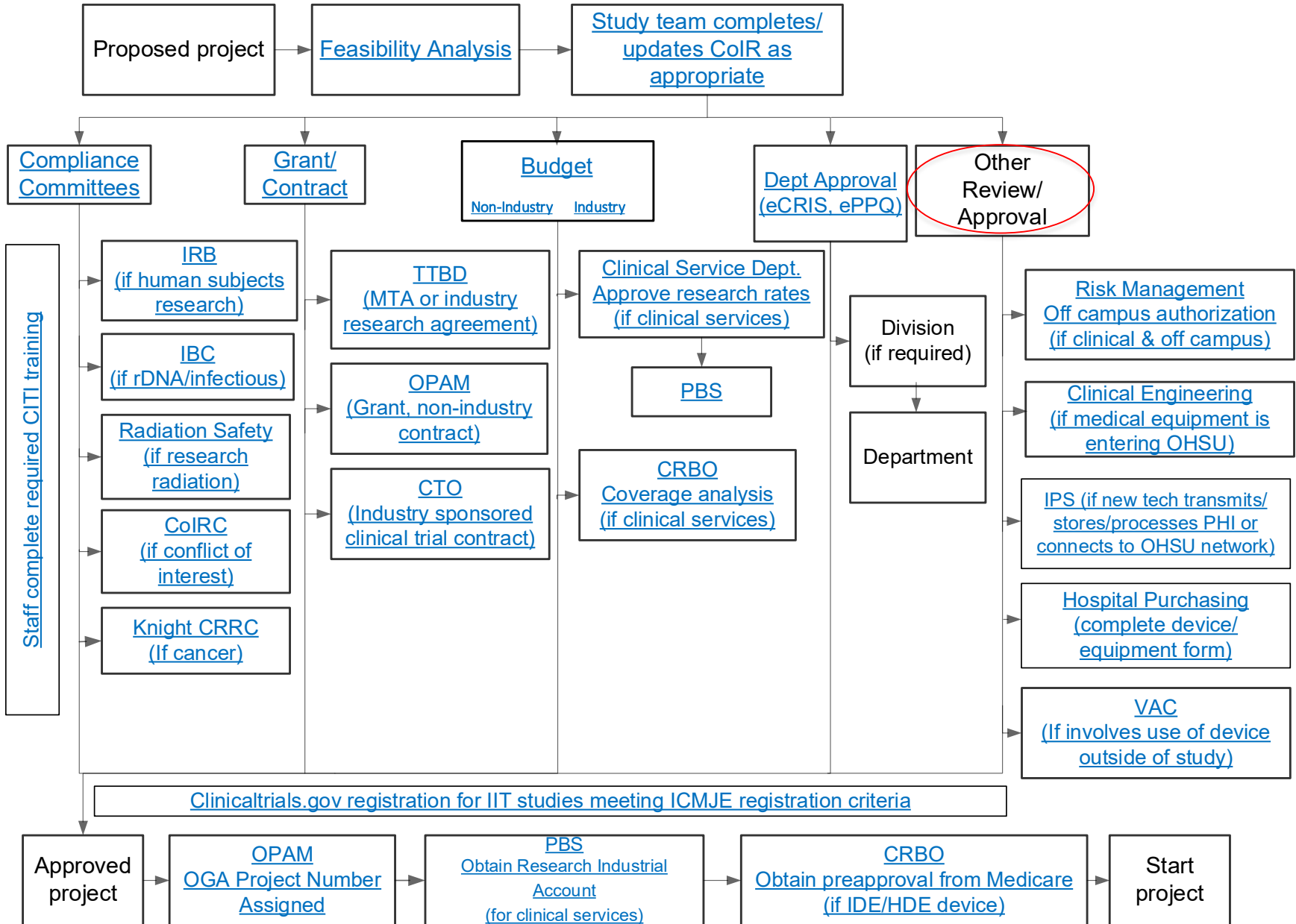
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Departmental Approval

- Departmental Review for industry sponsored study budgets in eCRIS
- Departmental approval is granted in InfoEd for other funded studies
 - Need your ePPQ (project #) for your IRB submission
- Changes to the budget can be requested by the department

Pre-award Process Map



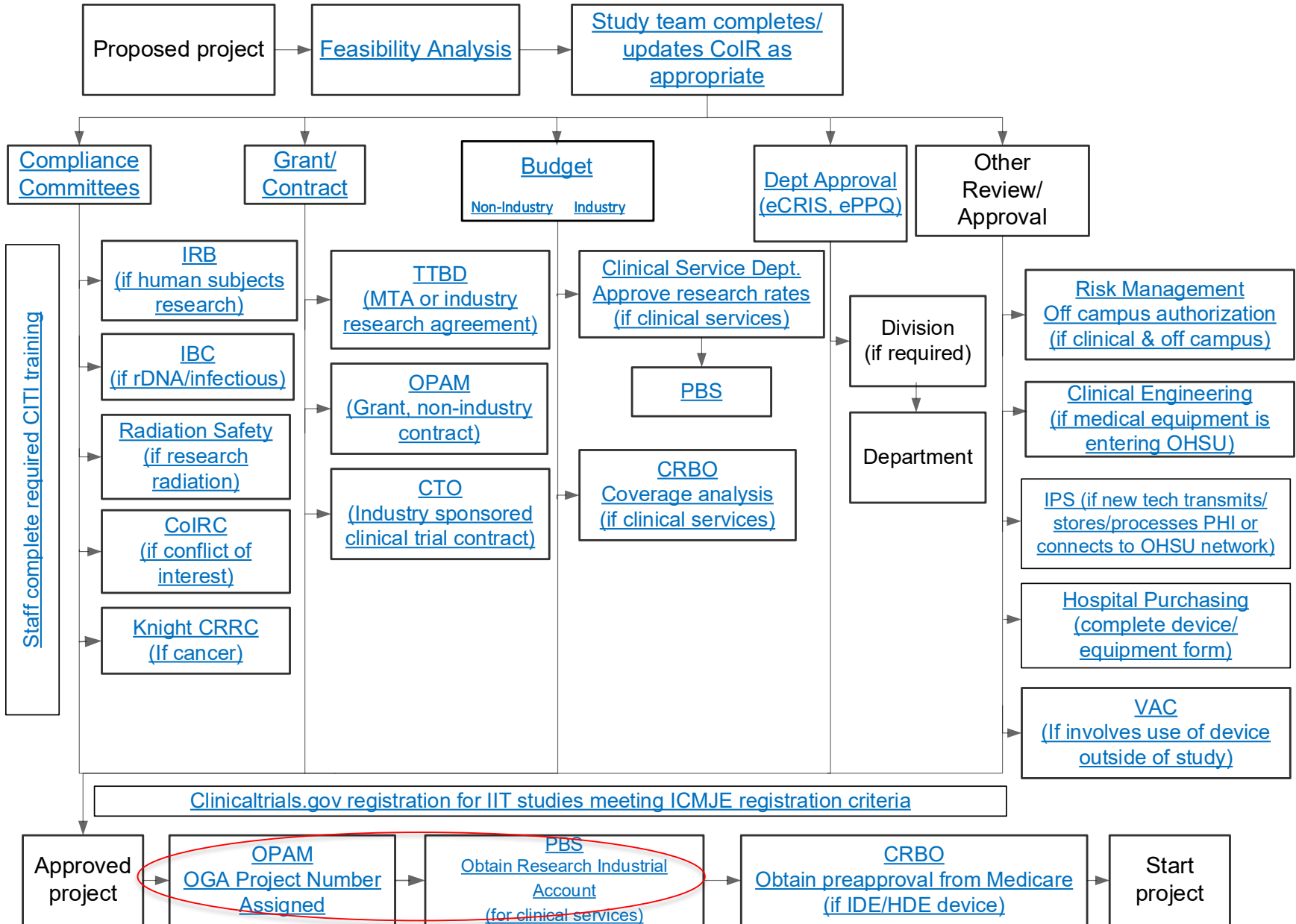
Other Reviews/Approvals

- Risk Management – reviews all research activities to be conducted at facilities that are not owned/leased by OHSU **before** activities occur
 - Need to complete and submit the Off Campus Authorization application link in eCRIS
- Clinical Engineering – reviews all equipment that will be brought into the institution to make sure they comply with safety standards and hospital policies **before** they are used
 - Need to complete and submit the Equipment Screening Questionnaire in the eCRIS
- [Information Technology Group \(ITG\)/ Information Privacy and Security \(IPS\)](#)- Vets whether new technologies (applications/systems, services) comply with our information privacy and security policies, state/federal regulations including HIPAA, FISMA, and FERPA
 - Review required **before** purchasing/using a new technology that store, process, or transmit restricted information, connect to the OHSU network, and/or impact the security of other network technologies
 - Reviews done in [ProcessBolt](#)
 - [Request Device Approval](#) form for [exceptions](#)

Other Reviews -medical devices

- Hospital Purchasing
 - Research Device/Equipment Form must be completed for clinical research studies involving the use of a medical device
 - Link to form can be found in eIRB and on the CRBO webpage
 - Also reviewed by CRBO and hospital finance
 - All form approvals required **before** the contract can be signed
- Value Analysis Committee (VAC) – reviews the use of devices outside of a clinical trial
 - Uses evidence based decision making for new product introduction at OHSU (e.g. post marketing registry studies for new devices)

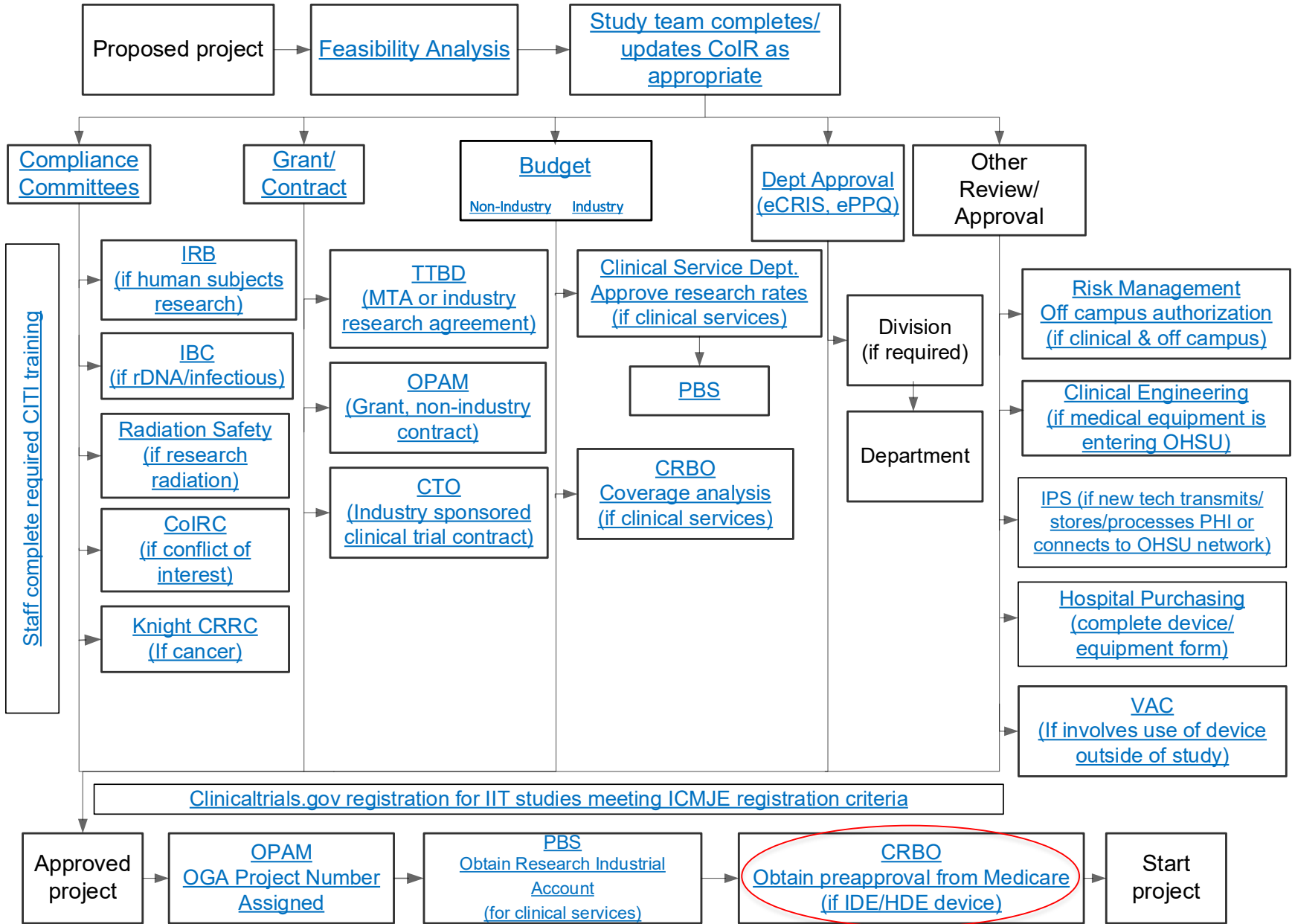
Pre-award Process Map



Obtain Accounts

- Receive Oracle Grants Accounting (OGA) alias number after IRB approval obtained and contract executed or grant received
- Hospital/clinical services conducted for research it must be charged to research/industrial account:
 - Requested automatically from CRBO when OGA account is set-up
 - Use this account to order clinical services

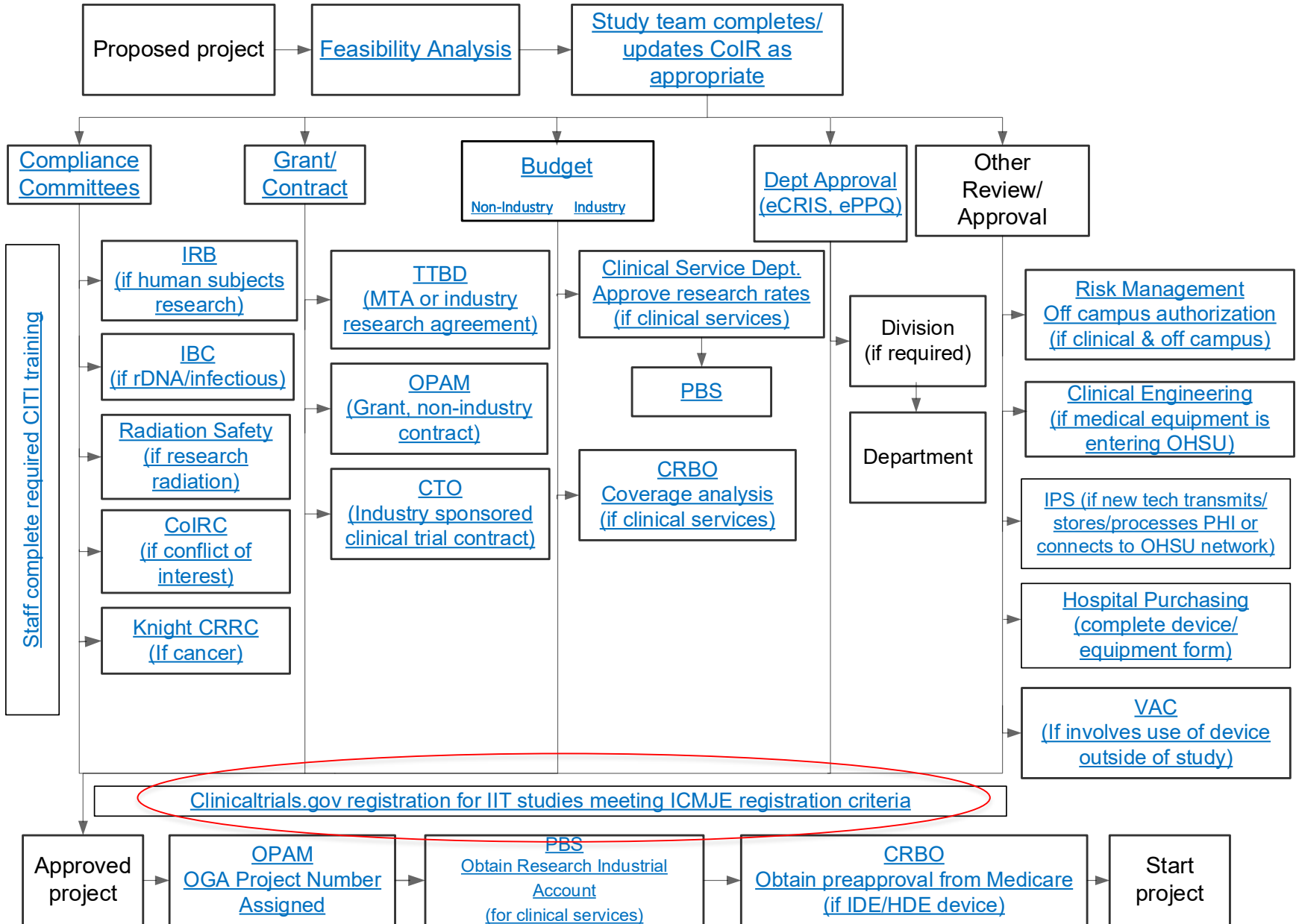
Pre-award Process Map



Medicare Start-up Issues

- Some devices require prior approval from Medicare **before** enrolling Medicare beneficiaries
 - Category A devices for “life-threatening conditions”
 - Category B devices
 - Humanitarian Use Devices (HUD/HDE)
- If sponsor has not obtained approval for all sites through CMS, obtain local CMS approval after IRB approval and contract execution
- Contact: Clinical Research Billing Compliance Office (CRBO)

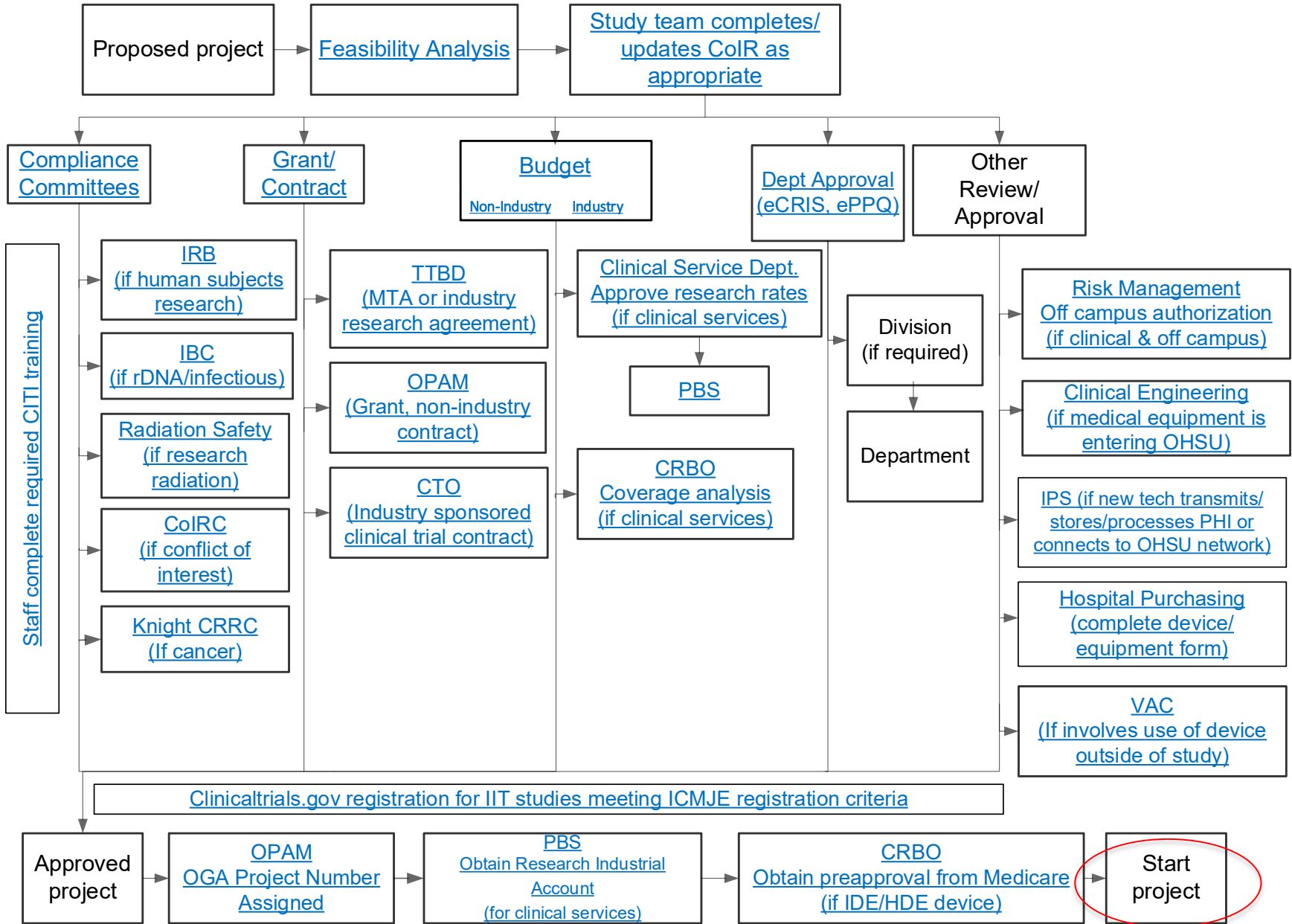
Pre-award Process Map



ClinicalTrials.gov

- Clinical Trial Registration required when:
 - Study meets [ICMJE definition](#) of a clinical trial
 - OHSU Investigator is the “responsible party”
 - **Before** the first participant is consented
- Tip:
 - You will need final IRB approval **before** Clinicaltrials.gov will release your record but start your registration early so you just need to add your approval to the submission
- Resources Available:
 - Knight Clinical Trials Registration Team (CTRP)
 - [Clinicaltrials.gov](#)
 - Clinical Research Support Office (CRSO), contact John Hicks, Clinical Research Compliance Specialist hickjo@ohsu.edu
 - [OCTRI Research Forum](#) 3 past presentations covering registration, maintenance, reporting and common challenges and a help sheet

Pre-award Process Map





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Thank You