Initial Review of External IRB Studies

Start

Industry Studies:
- Submits EGC1 to UW OSP
- Submits to other compliance offices (e.g., CRBB, Radiation Safety) as necessary
- Sends Zipline Application; requests review by External IRB

Non-Industry:
- Receives NOA or invitation to participate as site

UW RESEARCHER

Eligible for External IRB Review?

Yes
- Works with External IRB as needed to establish reliance agreement and communicate local context.
- Sends UW Researcher letter acknowledging reliance

No
- Application sent back to UW Researcher via Zipline

Works with sponsor, CRO, coordinating center, or lead site to submit application describing UW activities to External IRB

IRB is not WCG IRB or Advarra:
- Churches documentation of external IRB approval to hsdrely@uw.edu

IRB is WCG IRB or Advarra:
- Edits consent forms and resubmits to External IRB

Audits consent forms for compliance with MSP and CTA

Compliant with MSP and CTA?

Yes
- Zipline Status: Active
- End

No
- Syltens approval letter to Zipline
- Re-reviews and approves consent forms

Edits consent forms and resubmits to External IRB

Reviews Application

Sends approval letter to UW Researcher (WCG IRB and Advarra also send letter to HSD)

Acronyms:
- CRBB: Clinical Research Budget and Billing
- HSD: Human Subjects Division
- OSP: Office of Sponsored Programs
- UW: University of Washington
- MSP: Medicare Secondary Payer
- CTA: Clinical Trial Agreement
- NOA: Notice of Award
- CRO: Contract Research Organization