Initial Review of External IRB Studies

Start

Industry Studies:
- Submits EGC1 to UW OSP

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

Submits Zipline Application; requests review by External IRB

Eligible for External IRB Review?

Yes

Works with External IRB as needed to establish reliance agreement and communicate local context.

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:
- Sends UW Researcher letter acknowledging reliance
- Zipline Status: Pending sIRB Review

Edits consent forms and resubmits to External IRB

Compliant with MSP and CTA?

Yes

Uploads approval letter to Zipline

No

Audits consent forms for compliance with MSP and CTA

Industry Study?

Yes

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

Review Application

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

Re-reviews and approves consent forms

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