NEW STUDY
HU Is The Reviewing IRB

- HU PI contacts ORRC to initiate a Reliance Agreement process
- PI completes request for non-HU sites to rely on HU IRB

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- HU IRB reviews, and accepts or declines request to serve as reviewing IRB (i.e. another IRB rely on HU IRB)

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- Is relying (outside IRB) a member of SMART IRB?

——YES——   ——NO——

YES branch:
- HU PI submits request for access to SMART IRB
- HU PI then submits study through SMART IRB for reliance determination

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- Reliance is determined
- Reliance is executed
- HU PI receives a letter designating HU IRB as the reviewing IRB

NO branch:
- ORRC works with external sites to negotiate/execute reliance agreement

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- Reliance is determined
- Reliance is executed
- HU PI receives a signed copy designating HU IRB as the reviewing IRB

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- HU PI submits study to HU IRB for review and approval (Include protocol (recommended), and template ICF with local context information, relevant training certifications and other supporting documents)

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- ORRC reviews the application and either process it or return it to PI for clarifications/changes as needed

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- HU IRB review and approves the protocol and ICF

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- HU PI sends approved document to the PI at non-HU site(s)

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- ORRC send letter to PI documenting the HU IRB approval
- PI submits letter to relying IRB