Single IRB (sIRB) Requirement Determination Workflow

Is the research non-exempt human subjects research?  

Yes → Is there more than one U.S institution engaged in the human subjects research?  

Yes → No → Study is not subject to the revised Common Rule Cooperative Research sIRB requirement. It does not require an sIRB.  

No → Is the initial IRB approval date on or after January 20, 2020?  

Yes → Is there more than one U.S. site conducting the same research protocol?  

Yes → Is the award other than an Other Transaction (OT), Career development (K), fellowship (F), or Training (T) Award?  

Yes → Was the competing grant application due date on or after January 25, 2018, or the R&D contract solicitation issued on or after January 25, 2018?  

Yes → STOP  

No → Research study is subject to the NIH sIRB policy requirement unless excepted from these requirements.  

No → All U.S. sites conducting the same NIH-funded research protocol that are subject to the NIH sIRB policy must use a sIRB as required by the terms and conditions of award.

No → No → STOP  

No → Study is not subject to the NIH single IRB Policy. No sIRB is required.

Research study is subject to the revised Common Rule Cooperative Research sIRB requirement unless excepted from these requirements.

All U.S. institutions engaged in the NIH-funded nonexempt human subjects research that is subject to the Revised Common Rule Cooperative Research sIRB requirement (45 CFR 46.114(b)) must use a sIRB as required by the terms and conditions of award.