SMART IRB

Grant Submission and Review:
A Comparison of the Process Before and After the NIH Single IRB (sIRB) Policy

PROCESS	BEFORE THE SINGLE IRB POLICY	AFTER THE SINGLE IRB POLICY
		Process differences due to the sIRB Policy are indicated in **BLUE**.
1	Research team obtains input from budget and other fiscal experts as part of developing a funding proposal.	Research team obtains input from budget and other fiscal experts as part of developing a funding proposal. **In addition, the research team reaches out to their local IRB or human research protection program (HRPP) office to:** • **Obtain input on budget for sIRB review, such as IRB fees.** • **Begin outreach to other institutions regarding sIRB arrangement (e.g., who will serve as the Reviewing IRB and which institutions will rely on that IRB).** • **Obtain a letter of support for the reliance arrangement.**
2	The institution's sponsored programs office submits the proposal to the funding agency.	The institution's sponsored programs office submits the proposal to the funding agency, including information **about the proposed reliance arrangement, such as:** • **A confirmation that the NIH sIRB Policy will be followed.** • **The proposed sIRB and proposed relying institutions.** • **The IRB agreement that will be used for the reliance arrangement, such as the SMART IRB Agreement, and a description of how that agreement addresses the sIRB policy's communication plan requirement.** • **Budget needs related to sIRB review, such as IRB review fees and additional resources required to support communication between the sIRB and the relying site study teams (e.g., coordinating center or regulatory personnel).**
3	Funding agency notifies institution that an award is likely and requests IRB approvals and other certifications.	Funding agency notifies institution that an award is likely and requests **sIRB approval** and other certifications.
4	Prime awardee and subawardees each obtain IRB approval for the study.	**SIRB approves study for prime and subawardees.**
5	Agency releases funds upon provision of IRB approval for the prime awardee.	Agency releases funds upon **provision of sIRB approval for study**.