Summary of Single IRB Guidance for Peer Reviewers

The NIH Single IRB (sIRB) Policy

For grant applications submitted for a due date of January 25, 2018 or later, and contract proposals responding to solicitations posted on/after January 25, 2018:

All domestic sites of a multi-site study conducting the same non-exempt human subjects research protocol will rely on a single IRB of record.*

• Non-U.S. sites are not required to use or rely on a single IRB

The policy applies to grants, contracts, cooperative agreements, and intramural research. It does not apply to career development (K), research training (T), and fellowship (F) awards.

There are 3 types of exceptions:

(1) Legal or policy requirements for local IRB review and (2) ancillary studies (time-limited) do not require NIH approval. (3) Exceptions for compelling justifications for local IRB review must be approved by the NIH sIRB Exceptions Review Committee (ERC).

See the Final NIH Single IRB Policy and the Guidance on Exceptions for more information.

No change to the peer review process; adherence to the sIRB Policy is not a review criterion

• Reviewers should give a cursory look to see if a plan is included in the application (PHS Human Subjects and Clinical Trial Information Form, Section 3.2).
• Presence/absence of sIRB plan does not influence the impact score or overall rating of human subjects (unless there are specific review criteria in the FOA).
• If an applicable sIRB Plan is missing, reviewers can add a comment to the review notes or inform the SRO during the meeting.
• Proceed with current peer review guidelines.