The Single IRB Plan Elements

The single IRB plan should include the following elements:

- Describe how you will comply with the requirement for single IRB review under the revised common rule at 45 CFR 46.114.
- If available, provide the name of the IRB that you anticipate will serve as the sIRB of record.
- Indicate that all identified participating sites will agree to rely on the proposed sIRB and that any sites added after award will rely on the sIRB.
- Briefly describe how communication between sites and the sIRB will be handled.
- Indicate that all participating sites will, prior to initiating the study, sign an authorization/reliance agreement that will clarify the roles and responsibilities of the sIRB and participating sites.
- Indicate which institution or entity will maintain records of the authorization/reliance agreements and of the communication plan.

Note: Applicants are advised to not include the authorization/reliance agreement(s) or the communication plan(s) documents in their application.

Note: Applicants are advised that if they anticipate research involving human subjects but cannot describe the study at the time of application, they should include information regarding how the study will comply with the single IRB requirement under the revised common rule at 45 CFR 46.114, prior to initiating any cooperative research in the delayed onset study justification.