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 the communication plan.

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

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