The study documentation may include the following:

1. Grant Application, IRB approved protocol or proposal.
2. IRB submissions and IRB acknowledgment and correspondence, including: (a) modifications, (b) protocol violations, (c) unanticipated problems, and (d) continuing review and status reports.
3. IRB approved Informed Consent documentations.
4. Study instruments.
5. Recruitment materials.
6. Training documentation.
7. Other relevant research management tools used by Investigator, including (a) delegation logs, (b) screening/enrollment log, (c) accountability logs, and (d) subject visit schedule logs.
8. Subsequent publications resulting from IRB approved protocols.