

OO9 – Provide the policies, procedures, charters, attestation, or bylaws (including institutional review board) that:

- Protect the rights of participants in human subject research
- Designates at least one nurse must be a voting member of the governing body responsible for the protection of human research participants
- **NEW! MANUAL UPDATE:** Provide a description and the organization’s policies and procedures as part of a formal exempt determination process that effectively address the local setting and programs of research.
- **OR**
- Provide a letter signed and dated by the chair of the governing body responsible for the protection of human research participants that attests to this requirement.
- **NEW! MANUAL UPDATE:** Include an attestation the organization has educated and trained appropriate staff to determine if the research is to be exempt from full IRB Review. Include the exempt determinations are approved by the Human Research Protections Program governing body.

Note: Due to the complexity of research activities, (following the 2018 requirements of the Office for Human Research Protections) organizations may need to utilize a combination of policies, procedures and/or attestations.

Review the chart below and choose the option that best aligns with your organization’s processes.

