

## Organizational Overview

9. 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*

*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*

*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.*

## Notes

If providing an attestation of "at least one nurse is a voting member on the governing body," the template provided on the website is required.

Note: Membership of at least one nurse as a voting member of the governing body must include the timeframe of all studies, presented on the research table (see OO10).

(<http://www.nursecredentialing>).