

0010

Choose the option which is applicable to the organization:

a. Organization Uses Full IRB Review Only:

Provide the policies, procedures, charters attestation, or bylaws (including institutional review board (IRB) 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.

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.

OR

b. Organization Uses Formal Exempt Determination Process Only:

- 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 signed and dated attestation which states 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.

OR

c. Organization Uses Both Full IRB Review and Formal Exempt Processes:

- Provide the policies, procedures, charters attestation, or bylaws (including institutional review board (IRB) that protect the rights of participants in human subject research and designates at least one nurse must be a voting member of the governing body responsible for the protection of human research participants.

AND

- 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 both of the following:
 - A letter signed and dated by the chair of the governing body responsible for the protection of human research participants that attest to this requirement.
 - A signed and dated attestation which states 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.

Protection of Rights of Participants in Human Subject Research

Option C

[Evidence OO10-1, IRB Form](#)