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Description of Amendment #2 (January 8, 2021) to VHA Directive 1200.05: Requirements for the Protection of Human Subjects in Research

Description of Amendment: Three revisions are present in the January 8, 2021 technical amendment to VHA Directive 1200.05. The amendments described in detail in the following tables are summarized as follows with revisions highlighted in red.

- Paragraph 2: Revised summary of changes.
- Paragraph 3.f: Added a "Note" to the definition of VA research to state that emergency use of a test article is VA research even though it does not require R&D Committee approval.
- Paragraph 9: Clarified that prospective IRB review and approval is not required for emergency use of a test article.

VHA Directive 1200.05	Amended (January 8, 2021) VHA Directive 1200.05
Paragraph 2: SUMMARY OF MAJOR CHANGES: This directive was further amended on March 3, 2020 to update information related to use of IRBs of medical or dental schools and commercial IRBs (see paragraph 5.f.(8)) and human fetal tissue and stem cells (see paragraph 19.c.).	**Paragraph 2: SUMMARY OF MAJOR CHANGES:** c. Amendment dated~~, This directive was further amended on~~ March 3, 2020 to updated information related to use of IRBs of medical or dental schools and commercial IRBs (see paragraph 5.f.(8)) and human fetal tissue and stem cells (see paragraph 19.c.). d. Amendment dated January 8, 2021 updates the emergency exemption found in the definition of VA Research (see NOTE:) and paragraph 9.b. (see NOTE:).
Paragraph 3. DEFINITIONS: jj. VA Research. VA research is research conducted by VA investigators (serving on compensated, WOC, or IPA appointments) while on VA time or on VA property. The research may be funded by VA, by other sponsors, or be unfunded. The research must be approved by the R&D Committee before it is considered VA research and before it can be initiated. All research activities approved by the R&D Committee are considered VA Research.	**Paragraph 3. DEFINITIONS:** jj. VA Research. VA research is research conducted by VA investigators (serving on compensated, WOC, or IPA appointments) while on VA time or on VA property. The research may be funded by VA, by other sponsors, or be unfunded. The research must be approved by the R&D Committee before it is considered VA research and before it can be initiated. All research activities approved by the R&D Committee are considered VA Research. NOTE: Any emergency use of a test article does not require R&D Committee approval but is VA research under this policy.

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Paragraph 9. IRB REVIEW OF RESEARCH: An institution's IRB of Record must: a. Review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this directive, including exempt research for which limited IRB review is a condition of exemption; b. Require that information given to subjects (or LARs as appropriate) as part of informed consent is in accordance with section 17 of this directive. The IRB may require that information, in addition to that specifically mentioned in section 17 of this directive, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects	**Paragraph 9. IRB REVIEW OF RESEARCH:** An institution's IRB of Record must: a. Review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this directive, except as provided in the NOTE below, including exempt research for which limited IRB review is a condition of exemption; b. Require that information given to subjects (or LARs as appropriate) as part of informed consent is in accordance with section 17 of this directive. The IRB may require that information, in addition to that specifically mentioned in section 17 of this directive, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects *NOTE: Prospective IRB approval is not required if an activity meets the requirements for use of the emergency exemption from IRB approval in 21 CFR 56.104(c); informed consent must be obtained from the subjects (or LARs) unless both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing the requirements described in 21 CFR 50.23(a).*

This is the second amendment to VHA Directive 1200.05 since it was signed on January 7, 2019. The amended VHA Directive 1200.05 is published on the VHA Publications page at: https://www.va.gov/vhapublications/publications.cfm?pub=1.

Please send any questions regarding this amendment through FIND Pro.