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Description of Amendment #1 (January 8, 2021) to VHA Directive 1200.08: Safety of Personnel and Security of Laboratories

Description of Amendment: Six revisions are present in the January 8, 2021 technical amendment to VHA Directive 1200.08. 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 5.O.(2): Revised triennial review requirement.
- Paragraph 6.b.(2)(a): Clarified that liaison member to the SRS from the R&D Committee is a non-voting member of SRS.
- Paragraph 6.c.(1): Clarified the policy by adding the word "any".
- Paragraph 6.f.(1)(b): Clarified the policy by using the word "evaluation" instead of "assessment"
- Paragraph 7.e.(2): Removed the geographic requirement to align with NIH's removal in the NIH Guidelines for use of external IBCs.

VHA Directive 1200.08	Amended (January 8, 2021) VHA Directive 1200.08
Paragraph 2: SUMMARY OF MAJOR CHANGES: This directive combines two previous VHA handbooks. It clarifies responsibilities for implementing and evaluating plans for research safety/biosafety, security, chemical hygiene and emergency management (formerly VHA Handbook 1200.08, Safety of Personnel Engaged in Research, dated March 6, 2009), and addresses the security of both VHA facilities in which research is conducted and agents used in that research (formerly VHA Handbook 1200.06, Control of Hazardous Agents in VA Research Laboratories, dated October 21, 2005). It incorporates new Federal regulations established since those handbooks were published.	**Paragraph 2: SUMMARY OF MAJOR CHANGES:** a. Amendment dated January 8, 2021, updates paragraph 5.o.(2), clarifies paragraph 6.b.(2)(a), changes wording of paragraph 6.f.(1)(b) and clarifies paragraph 7.e.(2). b. This directive combines two previous VHA handbooks. It clarifies responsibilities for implementing and evaluating plans for research safety/biosafety, security, chemical hygiene and emergency management (formerly VHA Handbook 1200.08, Safety of Personnel Engaged in Research, dated March 6, 2009), and addresses the security of both VHA facilities in which research is conducted and agents used in that research (formerly VHA Handbook 1200.06, Control of Hazardous Agents in VA Research Laboratories, dated October 21, 2005). It incorporates new Federal regulations established since those handbooks were published.

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Paragraph 5. RESPONSIBILITIES: o. Institutional Biosafety Committee. The IBC is responsible for oversight of local VA research according to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (see https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html). This includes, but is not limited to, the following: . (2) Approving protocol or research activities involving biohazards, which may be granted for a three-year period with re-certification annually.	**Paragraph 5. RESPONSIBILITIES:** o. Institutional Biosafety Committee. The IBC is responsible for oversight of local VA research according to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (see https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html). This includes, but is not limited to, the following: . (2) Approving protocol or research activities involving biohazards, including periodic review as defined in written policies and procedures. ~~which may be granted for a three-year period with re-certification annually~~
Paragraph 6. SUBCOMMITTEE ON RESEARCH SAFETY: b.(2) Ex-Officio Members. Ex-officio members must include: (a) A liaison member from the facility R&D Committee (non-voting).	**Paragraph 6. SUBCOMMITTEE ON RESEARCH SAFETY:** b.(2) Ex-Officio Members. Ex-officio members must include: (a) A liaison member from the facility R&D Committee who will serve as a non-voting member of the SRS.~~(non-voting).~~
Paragraph 6. SUBCOMMITTEE ON RESEARCH SAFETY: c. Exemption From the Requirement for SRS Review. (1) Research that only involves the collection and analysis of biospecimens by VA personnel within clinical areas or clinical research areas, or the performance of standard clinical procedures in clinical areas or offices is exempt from the requirement for SRS review and approval. Completion of the Research Protocol Safety Survey (RPSS) is not required (See http://vaww.va.gov/vaforms/medical/pdf/10-0398.pdf. NOTE: This is an internal VA Web site that is not accessible to the public).	**Paragraph 6. SUBCOMMITTEE ON RESEARCH SAFETY:** c. Exemption From the Requirement for SRS Review. (1) Research that only involves the collection and analysis of biospecimens by any VA personnel within clinical areas or clinical research areas, or the performance of standard clinical procedures in clinical areas or offices is exempt from the requirement for SRS review and approval. Completion of the Research Protocol Safety Survey (RPSS) is not required (See http://vaww.va.gov/vaforms/medical/pdf/10-0398.pdf. NOTE: This is an internal VA Web site that is not accessible to the public).

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Paragraph 6. SUBCOMMITTEE ON RESEARCH SAFETY: f. Annual Review. (1) Each PI's VA laboratory program must be reviewed by the SRS at a convened meeting on an annual basis. The review must include: (a) A list of projects that utilize SRS approved protocols; (b) An assessment of all SRS approved protocols (individual or umbrella) to ensure that the hazards, BSL, risk assessments, training of personnel and status of the project are up to date;	**Paragraph 6. SUBCOMMITTEE ON RESEARCH SAFETY:** f. Annual Review. (1) Each PI's VA laboratory program must be reviewed by the SRS at a convened meeting on an annual basis. The review must include: (a) A list of projects that utilize SRS approved protocols; (b) An evaluation ~~assessment~~ of all SRS approved protocols (individual or umbrella) to ensure that the hazards, BSL, risk assessments, training of personnel and status of the project are up to date;
Paragraph 7. INSTITUTIONAL BIOSAFETY COMMITTEE: e. A VA research program may use an external IBC hosted by a second VA facility subject to the following conditions: (2) The second VA facility must be located in the same community, in order to meet the NIH Guidelines requirement for community representation.	**Paragraph 7. INSTITUTIONAL BIOSAFETY COMMITTEE:** e. A VA research program may use an external IBC hosted by a second VA facility subject to the following conditions: (2) The second VA facility must meet the NIH Guidelines requirement for community representation.~~The second VA facility must be located in the same community, in order to meet the NIH Guidelines requirement for community representation.~~

This is the first amendment to VHA Directive 1200.08 since it was signed on April 24, 2019. The amended VHA Directive 1200.08 is published on the VHA Publications page at: https://www.va.gov/vhapublications/publications.cfm?pub=1.

Please send any questions regarding this amendment to the ORD Regulatory Mailbox at VHACOORDRegulatory@va.gov.