

VAMHCS RESEARCH & DEVELOPMENT SERVICE  
Administrative Process Module

RDS-040

Effective Date: XXXX

R&D Service Process Modules and Hot Topics

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Applicable Context:

[VAMHCS Policies 512-00-001 (Policies) and 512-00-007 (Standard Operating Procedures)];

Administrative and clinical issues which affect VAMHCS Medical Centers will be published as VAMHCS Policy Memoranda. Service Lines/Clinical or Administrative Center SOPs are authorized only when the policy or procedure is pertinent to the individual service line/clinical or administrative center.

Policies and SOPs are written in relatively general terms in order to give guidance and to allow enough flexibility to prevent noncompliance when some details change. They are frequently written to refer to VHA Handbooks or other written guidance rather than to specifically describe. This is due to the frequency with which VHA and other written guidance is created or revised.

To avoid confusion with the terms “Policy” and “Standard Operating Procedures”, VAMHCS advises that Services create different labels for their detailed internal processes. Therefore R&D Service has created the term “Process Module” (PM) to fill this need and is in the process of migrating its internal SOPs to the PM format.

[VHA]:

VHA frequently issues new or revised handbooks and guidance. Some of these are broad and far-reaching, making it difficult to create or revise local processes quickly. For example, some handbook revisions may affect multiple processes within the R&D Service, the VAMHCS, and oversight committees such as the VAMHCS R&D Committee and Subcommittee on Research Safety and the UMB IRB, IACUC, and IBC. Therefore, the need to implement VHA requirements in a piecemeal fashion and through the flexible mechanism of “Hot Topics” is important for achieving prompt compliance and often for improving efficiency of some processes.

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1. The following are methods for documenting R&D Service processes and policies:
    - a. VAMHCS Policies and Standard Operation Procedures (SOP) in the “151” category
    - b. VAMHCS R&D Service SOPs
    - c. VAMHCS R&D Service Process Modules (PM), and
    - d. VAMHCS R&D Service Hot Topics.

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2. R&D Service uses the VAMHCS Policy or VAMHCS SOP mechanisms when processes affect VAMHCS individuals, clinical centers, Services or other groups outside of the R&D Service. Implementation of VAMHCS Policies 512-00-001 and 512-00-007 in order to post policies or SOPs on the VAMHCS intranet require extensive formatting, non-intuitive organization, and a prolonged concurrence process.
3. R&D Service internal SOPs are being phased out through a transition to PMs. This requires splitting of current SOPs into numerous small (topic-specific) PMs. R&D Service SOPs (or parts thereof) remain in effect until they are rescinded, transitioned to PMs, or stated to be ineffective via Hot Topics or other communications. In some cases parts of R&D SOPs have been replaced with PMs or Hot Topics.
4. R&D Service Process Modules (PM) are simple, step-by-step written modules that give detailed instructions on operational activities. Many originated as sections of large R&D internal SOPs. Aside from instructing, they frequently include brief summaries of the regulatory context or other considerations under which they exist.
  - a. PMs are reviewed by relevant R&D personnel and/or committees/subcommittees before being submitted to the ACOS/R&D or designee for approval. All comments and suggestions are considered in order to make the PM as clear, consistent, and practical as possible.
  - b. PMs are approved by the ACOS/R&D or designee.
5. R&D Service Hot Topics are instructional messages to researchers on new or revised processes, reminders of current processes, information on general topics, etc. Because they can be prepared and approved relatively quickly, they can serve as a “bridge” when new processes need to be implemented more quickly than the SOP or PM can go through concurrence.
  - a. Hot Topics are written by the R&D Human & Animal Research Protections Officer (HARPO) or designee.
  - b. The Hot Topics are reviewed by relevant R&D personnel or others in order to make them as clear, consistent, and concise as possible.
  - c. Hot Topics are approved by the ACOS/R&D or designee prior to being distributed to the field.
  - d. If a Hot Topic is a “bridge” document for implementation of or change in a process, a formal PM or VAMHCS SOP should be completed within three months unless an extension or exemption is obtained in writing from the ACOS/R&D or designee.
6. Noncompliance with R&D Service SOPs or PMs should be considered on a case-by-case basis depending on seriousness of the noncompliance and whether the noncompliance significantly violates national or VAMHCS policies or procedures. On a local level, the most recent iteration of a policy or process supersedes older

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versions (even if the older versions have not been rescinded). Decisions on the noncompliance should be made by supervisors, R&D Service leadership, or oversight committees as applicable.

7. All R&D Service SOPs, PMs, and Hot Topics are available on the R&D Service website <http://www.maryland.va.gov/research/policies.asp>.
8. The HARPO logs, organizes, numbers, and tracks R&D Service SOPs, PMs, and Hot Topics. The log and the documents are on the R&D Admin Share drive.

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