

**DETERMINATION OF INSTITUTIONAL REVIEW BOARD REVIEW OF CASE
REPORTS AND RETROSPECTIVE CHART REVIEWS**

1. **PURPOSE:** To establish a service level policy that defines a case report and retrospective chart review and identifies when a case report must receive Institutional Review Board (IRB) and Research & Development (R&D) review and approval at the Portland VA Medical Center.

2. **POLICY:** All individuals conducting case reports must abide by the terms of this policy. Prior to conducting a case report, a clinician must submit a completed Application for Case Report Review to the IRB Coordinator to ensure compliance with this policy and the Health Insurance Portability and Accountability Act (HIPAA). Case reports that satisfy all of the four following criteria are not considered research and do not require IRB and R&D Committee approval:
 - a. case reports of patients by a clinician who has personally provided care for those patients;
 - b. case reports consisting of three or fewer patients;
 - c. case reports that observe or describe a disease process;
 - d. case reports that are not presented as a systematic investigation, do not include either statistical or systematic qualitative analysis, and are not designed to contribute to generalizable knowledge.

3. **DEFINITIONS:**
 - a. **Research:** Research is defined as an activity designed to develop or contribute to new generalizable knowledge through a process of hypothesis testing or data collection that permits conclusions to be drawn. Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective. Any prospective or retrospective collection of clinical data with the intent to contribute to generalizable knowledge constitutes human studies research. Examples of such clinical data collection include data collected for research seminars, posters, abstracts, manuscripts, and pilot data.¹ Questions regarding whether or not an activity is considered human subjects research should be directed to an IRB Coordinator.
 - b. **Case Report:** an observation or a description of a disease process in three or fewer patients cared for by the clinician preparing the report and not presented as a systematic investigation designed to contribute to generalizable knowledge.
 - c. **Retrospective Chart Review:** a retrospective review of medical charts for publication that does not meet the criteria of 5.a or 5.c below implies research.
 - d. **VHA Investigator:** A VHA investigator must be a VHA employee (Without Compensation (WOC) employees) or contract personnel. Reference: VHA Handbook 1605.1, December 31, 2002.

¹ Local medical center and affiliated institutional conferences for teaching, quality assurance or quality improvement activities, and patient care activities (for example, ward rounds, case conferences, departmental seminars, morbidity & mortality conferences, X-ray conferences, tumor boards) are specifically not considered research by this definition.

4. RESPONSIBILITIES:

- a. The **Associate Chief of Staff of Research & Development** is responsible for developing and managing policies and procedures regarding the determination of IRB and R&D Committee review and approval for case report(s).
- b. The IRB is responsible for reviewing case reports when a case report does not satisfy the four criteria stated in the policy section above.
- c. The **Research & Development Committee (R&D)** is responsible for reviewing case reports when a case report does not satisfy the four criteria stated in the policy section above and has been reviewed and approved by the **Institutional Review Board (IRB)**.
- d. The **Grants Program Specialist** is responsible for reviewing Application for Case Report Reviews and determining whether the HIPAA regulations have been satisfied and whether IRB and R&D Committee approval is necessary.
- e. **Clinicians** (Medical Center Staff and Residents) who conduct case reports are responsible for:
 - (1) Submitting an Application for Case Report Review to the Grants Program Specialist, prior to conducting a case report;
 - (2) Complying with the determination of the Grants Program Specialist;
 - (3) Ensuring that individually identifiable information (protected health information) is excluded from the published case report;
 - (4) Conducting case reports only of patients for whom they have personally provided care;
 - (5) Submitting the appropriate prospective IRB application for conducting case reports when the case report does not meet the four necessary criteria stated in the policy section above.

5. PROCEDURES:

- a. **Case Report: any clinician conducting a case report must adhere to the following procedures:**
 - (1) Submit an Application for Case Report Review to the Grants Program Specialist, prior to conducting a case report;
 - (2) If the case report involves the use of photographs that may possibly identify the patient, written permission from the patient is required prior to any presentation of the photographs.
 - (3) Adhere to the determination of the RACC or Grants Program Specialist.
- b. **Case Report requiring IRB and R&D Committee approval:**
 - (1) A case report of patients for whom the clinician has not personally provided care.
 - (2) A case report of more than three patients, regardless of whether the individual is a clinician that has personally provided care for the patients.

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- (3) A case report presented as a systematic investigation designed to contribute to generalizable knowledge.
 - (4) A case report presented as a systematic qualitative or statistical analysis.
- c. **Retrospective Chart Review: any individual conducting a retrospective review of medical charts for the following purposes does not require prospective IRB and R&D Committee approval:**
- (1) An investigative review, e.g., to review a physician's competency;
 - (2) Quality management issues, e.g., to ascertain delivery of health care needs;
 - (3) Compliance issues, e.g., in regard to third-party billing, or investigation of non-compliance.
 - (4) A review to obtain clinical information for teaching purposes.
- d. **Retrospective Chart Review: any individual conducting a retrospective review of medical charts for publication that does not meet the criteria of 5.a or 5.c above implies research and therefore requires prospective IRB and R&D Committee approval.** The individual must follow the following procedures:
- (1) Write a protocol
 - (a) Describe the research question
 - (b) Describe what information will be extracted from the medical record to answer that question
 - (c) Describe the risks and benefits of the research on the subject(s)
 - (d) Describe how confidentiality will be maintained
 - (e) Include a code sheet, if applicable.
 - (2) Complete the following forms, available from the Research & Development Website: (<http://www.visn20.med.va.gov/portland/research>)
 - (a) Proposed Project Questionnaire (PPQ), which provides background and tracking information to the Research Service
 - i. Requests an abstract (500 words or less) with the following headings:
 - (i) Objectives
 - (ii) Plan
 - (iii) Methods
 - (iv) Findings to Date
 - (b) Data Security Checklist and Principal Investigator's Certification
 - (c) Initial Review Questionnaire (IRQ), which allows the IRB to focus on the details necessary to provide a thorough review of the project
 - (d) Waiver of Informed Consent/Authorization, which the IRB uses to determine if all applicable regulations are satisfied.
 - (3) Submit all of the items in (1) and (2) above to the Research Service for review by the IRB and R&D Committee.
 - (4) Once final IRB and R&D Committee approvals are received, the retrospective review of medical records may begin.

6. REFERENCES:

Office of Research Compliance & Assurance Guidance (now Office of Research Oversight),
E-mail 03/10/2003

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Office of Human Research Protections Guidance, E-mail 03/10/2003
VHA Handbook 1605.1, December 31, 2003

7. CONCURRENCES:

Endorsed by the Research & Development Committee <date>

8. RESCISSION: HRPP: Policy & Procedure No. 7, Endorsed by the R&D Committee
05/19/2003 01/26/2004, and 08/01/2005

9. FOLLOW-UP RESPONSIBILITY: ACOS Research & Development Service (R&D)

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