NCQA

*Measuring the Quality of America's Health Care*

# VETERANS AFFAIRS HUMAN RESEARCH PROTECTION ACCREDITATION PROGRAM

## ADMINISTRATIVE POLICIES AND PROCEDURES

## STANDARDS VERSION 2.1

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# I. Overview

Human research is a critical enterprise, yielding medical advances and evidence-based practices that benefit millions of people. Thus, public and private investment in research continues to grow at a rapid rate. Research at the Department of Veterans Affairs has yielded breakthroughs in treatment for Veterans and non-veterans alike, and has made major contributions to scientific progress.

However, research involves risks, and without effective protections for the safety of human research participants, not only the public trust, but also the potential benefits of research, are at risk. The number of active research studies has skyrocketed since the current regulations and Institutional Review Board (IRB) system were created, placing considerable strain on researchers, IRBs and research programs. This strain has led to lapses in performance that have sometimes had tragic consequences. This situation intensified the call for more effective protection of human research participants over the past several years and has resulted in government shutdowns of research institutions, including some at VA facilities and at some of the most prestigious academic institutions in the country.

In this document, NCQA outlines an accreditation program for human research protection programs (HRPP) operating within the Veterans Affairs system. Its purpose is to establish standards of HRPP performance, and, to evaluate their performance in relation to those standards through independent, external review. Thus, NCQA's VA Human Research Protection Accreditation Program (VAHRPAP) will provide information to increase accountability of VA research programs. The information from accreditation can facilitate an institution's efforts to improve their HRPPs, and through accountability, create incentive for improvement.

## A. What is a Human Research Protection Program?

The Belmont Report outlines three key principles for protecting human subjects of research: respect for persons, beneficence and justice. These principles form the basis for the current regulations, guidelines and structures established to protect human participants in research. Numerous stakeholders to the research enterprise each play a critical role in applying these principles. Sponsors, research organizations, IRBs, other committees (such as radiation safety and conflict of interest committees) investigators and investigative staff all have distinct roles to play in protecting research participants. The HRPP is the integration of these roles and responsibilities into a systematic effort.

Regulations detail the basic responsibilities of IRBs, investigators and research sponsors for protecting human research participants. Federalwide Assurances and related documents, such as Multiple Project Assurances and VA Multiple Project Assurances, outline the responsibilities of institutions engaged in research for human research protection. The VAHRPAP focuses on the HRPP, which may integrate functions across several organizations including one or more VA Medical Centers and their academic affiliates.

Each HRPP organizes the functions that protect human research participants within its purview. A VAMC with its own R&D Committee and Human Studies Subcommittee, and investigators who are employees takes a different approach to meeting its responsibilities for the protection of human research participants than a VAMC that depends on the Human Studies Subcommittee of another VAMC or the IRB of its academic affiliate. The HRPP in all settings is responsible not only for assuring compliance with human research protection regulations and protecting human research participants, but for continuously improving the processes used and the outcomes achieved. Each HRPP must have, or make arrangements for, IRB review of research, and it must assure that both this review and the conduct of research within its influence protects human participants and meets regulatory requirements. The HRPP must function as a comprehensive and organized *system* to protect those who would volunteer in its research.

## B. Purpose of Accreditation

The purpose of the Veterans Affairs Human Research Protection Accreditation Program (VAHRPAP) Standards Version 2.1 is to set performance expectations for Veterans Affairs Medical Centers (VAMCs) that conduct human research. The major goals of the NCQA VAHRPAP Accreditation are to:

1. Support continuous improvement
   Regulations set out fundamental requirements for protecting human research participants. HRPPs must continuously strive to carry out these requirements in a manner that optimizes human research protection. NCQA standards initially focus on regulatory compliance but will evolve to address the institution's self-monitoring and improvement activities as it seeks better, more effective ways to fulfill its responsibilities.

2. Establish procedural and functional guidelines for institutions with HRPPs
   NCQA's standards address institutional responsibilities for human research protection and provide a framework to assist the institutional leadership in meeting these responsibilities.

3. Focus on research participants and outcomes
   NCQA's standards for HRPP evaluation include a focus on results for the whole research population, as well as issues of concern to individual participants of research. The standards also address whether the HRPP takes appropriate actions, and evaluates and improves the effectiveness of its actions, to assure that risks are minimized.

## C. Development of VA Human Research Protection Accreditation Program

In response to the closing of the VA Greater Los Angeles Health Care System's research program and in the wake of other university and non-university research program suspensions, Dr. Kenneth Kizer, then VA Under Secretary for Health, testified before Congress on April 22, 1999 on "Oversight of Research in the Veterans Health Administration." In his address, Dr. Kizer announced two major initiatives to assure the public and veterans that VA research programs meet or exceed established quality standards. One of the initiatives, development of a new Office for Research Compliance and Assurance (ORCA) now the Office for Research Oversight (ORO), would provide VHA with the assurance that research conducted by VA

scientists is done with maximal regard for issues of: 1) human and animal subject protection; 2) safety of laboratory personnel; and 3) research integrity. The second initiative established an external accreditation program assessing VA research involving human participants. In April 2000, VA awarded a contract to the National Committee for Quality Assurance (NCQA) to establish an accreditation program for VA human research.

NCQA's proposal to the VA and subsequent project design outlined a vision for program development that follows a phased approach. During the initial phase, when the concept of an organized and systematic Human Research Protection Program (HRPP) is new and when external assessment is first introduced, the standards are firmly grounded in Federal regulations and guidance. NCQA directly assesses VA Medical Center (VAMC) compliance with standards that closely follow existing regulations and guidelines, while stimulating VAMCs to improve their HRPPs beyond Federal requirements. This will facilitate the shift from regulatory compliance to innovation in HRP and implementation of best practices.

In later phases, as the HRPPs become more established, the standards will reach beyond the Federal regulations and guidance. The focus will be more performance based and incorporate identified best practices in human research protection. During these phases, NCQA will evaluate VAMCs through a combination of direct assessment and review of VAMC self-evaluation/Continuous Quality Improvement (CQI) findings. Finally, standards will primarily consist of performance criteria, and NCQA will evaluate VAMCs primarily through the review of VAMC practices and QA/QI findings. The phased approach outlined above is intended to encourage exceptional HRPPs capable of sustained, effective quality improvement.

## D. Development of VAHRPAP Standards Version 2.1

To develop the accreditation program, NCQA drew on relevant regulations, policies and guidance to establish initial standards for human research protections at VAMCs. NCQA convened a Program Standards Committee (PSC), comprised of experts in human research including VA field representatives, to review and comment on various drafts of the standards. The Committee commented on the organization, content and emphasis of the standards, various approaches to scoring, and performance thresholds. The Program Advisory Group, more broadly constituted than the Standards Committee, provided input on a variety of issues and concerns related to program design that had direct bearing on the standards. NCQA then issued draft standards for public comment and conducted a series of pilot accreditation surveys of VAMCs. NCQA used comments from all these sources to guide revisions to the standards. NCQA published VAHRPAP Standards Version 1.0 in August 2001 and Version 1.1 reflecting minor technical revisions in November 2001.

NCQA conducted 23 site surveys over nine months using VAHRPAP Standards Version 1.1 and solicited feedback from surveyors, VA Medical Centers (VAMCs), VA Central Office (VACO) staff, Program Accreditation Committee (PAC) members, Program Standards Committee (PSC) members, and the public. Consistent with its plan to improve standards and maintain relevancy through regular revision, NCQA used this experience and feedback to revise the standards. NCQA proposed, and VA Office of Research and Development approved the following objectives for the first revision to the standards:

1. revise the scoring to provide partial credit for partial compliance
2. develop a point system to make accreditation decisions predictable and transparent
3. streamline standards and reduce redundancy where possible
4. add explanations and examples to clarify the meaning and intent of the standards.

NCQA revised the standards accordingly and vetted them with the VA Advisory Group (VAAG), a group of VA personnel convened by the Office of R & D, and Program Standards Committee, and through a public comment period. NCQA made revisions to address these comments, and this set of standards reflects this extensive review. Standards Version 2.1 was approved by VA Office of Research and Development (VA ORD) in April of 2003 and will be in effect until April 30, 2005.

## E. Eligibility for Accreditation under VAHRPAP

1. VA Medical Centers Eligible for National Committee for Quality Assurance (NCQA) accreditation must:
   a. be organized as a medical center of the United States Department of Veterans Affairs
   b. be organized to conduct research involving human subjects, as defined by Code of Federal Regulations Title 38 Part 16
   c. hold an approved assurance from the Department of Health and Human Services Office for Human Research Protection (OHRP)
   d. have an infrastructure for human research protections (e.g., standard operating procedures, job descriptions, budgets, a properly composed IRB, etc.) for a minimum of one year
   e. have enough active protocols to constitute a valid sample for evaluation where the standards require protocol file review
   f. comply with applicable federal, state and local laws and regulations, including any requirements for licensure
   g. operate without discrimination on the basis of sex, race, creed or national origin.

2. This accreditation program is designed to accommodate a variety of organizational structures and arrangements, including a variety of affiliations. Many VAMCs collaborate with each other in conducting research. In such cases, the VAMC's HRPP remains responsible for all aspects of human research protections, even if it discharges some of those responsibilities through an affiliation with another VAMC or a university. The key to carrying out such distributed functions is to establish clear accountabilities such that all human research protection functions are carried out in an integrated manner. The accreditation applies regardless of whether a VAMC has its own IRB, uses the IRB of another VAMC, operates a joint IRB or uses the IRB of an academic affiliate. Specific standards may apply in different circumstances. It is possible that several VAMCs are so thoroughly interconnected in performing their human research protection functions that they constitute a single HRPP network. In such situations NCQA will accredit the VAMCs together as members of a HRPP network. When NCQA accredits a HRPP network the accreditation status applies to all members of the network, and is indivisible.

3. NCQA defines the institution eligible for review based on the management structure and operational systems that support the human research protection functions that NCQA accredits. NCQA's goal is to arrive at accreditation decisions that reflect the institution, as defined by its management structure, resources and programs that are accountable for protecting human research subjects. If two or more VAMCs share an IRB or other elements of a Research and Development (R&D) program, NCQA works with the institutions to coordinate the accreditation survey(s).

4. Some VAMCs work with academic affiliates that are independently pursuing other HRP accreditation, such as that offered by the Partnership for Human Research Protection (PHRP) or the Association for the Accreditation of Human Research Protection Programs (AAHRPP). NCQA has an arrangement to conduct a more focused survey of VAMCs that use the IRBs of their PHRP or AAHRPP-accredited academic affiliate. NCQA surveys the VAMC for only one category of standards (Institutional Responsibilities) and issues an accreditation decision that combines the results of the VAHRPAP and PHRP or AAHRPP surveys. See Appendix A for details of combined accreditation decisions.

## D. Obligations of the Parties

By submitting the intent to apply and a survey application and, thereby, applying for an NCQA survey, the VAMC agrees to do the following:

1. release to NCQA the information that NCQA deems pertinent
2. refrain from transmitting to NCQA any protected health information (PHI) as defined by HIPAA privacy rules. If materials containing PHI are necessary to demonstrate compliance with NCQA accreditation standards, the VAMC may show such materials to NCQA surveyors when they conduct the on-site portion of the survey
3. hold NCQA, its employees, directors, officers, contractors, surveyors, and agents harmless from any claims the institution may have relating to the NCQA VAHRPAP review, all review and appeal processes, and accreditation status and summary results
4. abide by the terms of the application, these Administrative Policies and Procedures, NCQA's Rules on Falsified Documents and Fraudulent Information, the Standards for Accreditation, and any additional NCQA policies, procedures and rules, which may be developed in the future for the conduct of or relative to the VAHRPAP
5. notify NCQA of any decision by a state or federal agency, including ORO or other VA Office, with respect to an investigation of the HRPP, request for corrective action, imposition of sanctions or restrictions to its assurance. Such notification must be sent to NCQA no later than 10 business days after the institution receives notice of such an action
6. notify NCQA of any violation of any federal or state laws or any regulatory noncompliance within 10 business days of becoming aware of the violation
7. accept all final NCQA decisions regarding the VAMC's accreditation status, including any conditions placed on the accreditation
8. agree that NCQA's accreditation determination does not constitute a warranty by NCQA to any third parties, including, but not limited to, sponsors, government agencies, consumer, or research participants, regarding the quality of the VAMC or its research.

9. agree that NCQA's accreditation process does not take the place of, or relieve the VAMC of its responsibility to conduct, it's own ongoing evaluation, assessment and monitoring procedures
10. agree that NCQA makes no representation to other organizations regarding the HRPP and that the protection of human research subjects is solely the responsibility of the VAMC
11. not misrepresent its accreditation status (including, but not limited to, the scope and meaning of such status as defined herein) or suggest that it has received another level of accreditation by NCQA when such representation is not accurate
12. notify NCQA of any material changes in its structure or operation in accordance with these polices and the application, including changes in designated IRBs at the next annual attestation
13. refrain from hiring or contracting with or offering any inducement to any individual who is scheduled for, or in the last 12 months has participated in, a survey of its HRPP.

NCQA Obligations:

1. upon scheduling a VAMC for accreditation, NCQA sends the VAMC a written timeline of key milestones related to that site's accreditation review
2. NCQA acknowledges receipt of application materials
3. following review of application materials, NCQA promptly notifies the VAMC of any required materials that are known to be missing or otherwise needed to demonstrate that the VAMC meets NCQA standards
4. agree that unless NCQA and the VAMC (and if applicable, the affiliated IRB) agree otherwise, information collected as part of the VAHRPAP by NCQA shall be kept confidential, except as indicated in the section "Reporting Results" or as required by VA policy, Federal law, rules or regulations, state or local law or regulations
5. NCQA will conduct the survey process with qualified personnel
6. All survey personnel will be credentialed and trained in the survey process
7. The size and composition of the NCQA survey team will reflect the complexity of the HRPP and number of IRBs surveyed
8. NCQA will provide both surveyors and VAMC the opportunity to identify potential conflict of interest
9. NCQA will conduct the survey process in the timeframes agreed to in this document. The final report will be distributed within 90 days of the last on site survey day
10. NCQA will respond to all inquires from VAMCs.

# II. Standards

## A. Structural Changes from VAHRPAP Version 1 Standards

The revisions made to the standards include deletions, additions, consolidations and clarifications. NCQA has reorganized standards and elements to eliminate duplication, place similar content together and remove criteria that exceed current regulation. Version 1.1 contained 130 elements while Version 2.1 contains 59 elements. Version 2.1 standards contain no new content.

## B. Framework for VAHRPAP Standards

NCQA's VAHRPAP standards are available on NCQA's web site in PDF form. The standards, scoring guidelines and administrative policies outlined in this document comprise the entire program for accreditation of VA Human Research Protection Programs. NCQA evaluates HRPP functions across a continuum, beginning with a documented process or standard operating procedure (SOP) through effective implementation of the process and the achievement of desired results. There are two general types of requirements – *Documented Process* requirements and *Performance* requirements. *Documented Process* requirements address policies, procedures or other formal plans and are important to ensuring that the protection of human research subjects is systematic and can be sustained through changes in personnel. NCQA evaluates two separate aspects of *Documented Processes*: the completeness of the content of the process and its longevity, which is referred to as "time in place." Some *Documented Process* requirements that represent newer performance expectations, or those that are not current standard of practice, have no corresponding longevity requirement. If such a requirement is in effect for a specific *Documented Process* element, it is listed as a factor within that element. For initial surveys only, the "time in place" factor is not applicable. It is scored as though it is met, without need for any supporting documentation. *Performance* requirements focus on actions taken, implementation of policies and results achieved.

NCQA evaluates compliance with each element over the full year preceding the date the application is due. This "look back period" ends on the due date of the application, generally eight weeks prior to the on-site survey. NCQA does not consider any actions taken by the VAMC after this date. The look back period applies differently for elements that address different types of requirements.

- Documented processes
  The look back period is only applicable for documented processes containing a factor addressing "time in place." For initial surveys this factor is scored as "met"
- Reports
  NCQA reviews actions taken over the full year look back period
- Files
  The last 3 months of the look-back period is randomized first, and, if less than 16 files are available for this period, NCQA considers files from the previous quarters of the year. This process of graduated randomization is employed for the initial survey only. All subsequent surveys will utilize a sample randomized over the full year.

Appendix B discusses the File Review process and rationale.

The VAHRPAP Standards Version 2.1 are organized into four categories that represent major functions performed as part of human research protection. Each category has a three-character identifier. The standards categories are as follows:

- **Institutional Responsibilities (INR)** Institutions and their leadership are responsible for ensuring the rights, safety and well being of human research participants. INR outlines requirements for the institutional leadership, management of conflict of interest, education and training in HRPP, as well as oversight and quality improvement of the HRPP

- **IRB Structure and Operations (IRB)** The IRB is responsible for the review of proposed research. This category outlines requirements for the IRB's organization, composition, meeting arrangements and documentation and IRB responsibility to obtain complete and relevant information to support the IRB's review of research
- **Consideration of Risks and Benefits (CRB)** All research should be designed to provide important scientific knowledge and to maximize possible benefits and minimize possible harms to participants. This category contains requirements related to balancing the risks and benefits of research
- **Informed Consent (ICS)** Informed consent is critical to the protection of human research participants' dignity and autonomy. The Informed Consent category outlines the requirements for obtaining and documenting informed consent.

## C. Description and Structure of a Standard

NCQA standards are authoritative statements about acceptable performance or results. The Schematic Standard below explains the purpose and content of each component of a standard. A Glossary of Terms used throughout this document and the Standards may be found in Appendix C.

## Schematic Standard

## Standard ABC#: Standard Title point(s)

*[NCQA standards are authoritative statements about acceptable performance or results. Each standard includes a statement of an attribute or expectation and a statement of the standard's intent. Each standard has a number within a category, using the three-character category identifier and consecutive numbers (e.g., INR1). Each standard has a designated number of points, which is a sum of the points assigned to all the elements that the standard comprises. Both applicable standard points and applicable element points are shown.]*

### Intent

*[A brief statement explaining the purpose of the standard in lay terminology.]*

### Element 1A: point(s)

[*A standard may contain more than one element. An element is a specific component of a standard that NCQA individually evaluates and scores. Elements are comprised of factors which are variables used for scoring purposes.*

*Each element has a designated number of points; element points sum to the standard points*

*Elements are alphabetically lettered within a standard (e.g., IRB4A)*

*Factors are numbered within each element. Elements may contain one or more evaluative factors, which specify the criteria for compliance.*

*An institution's scoring level (a percentage) multiplied by its element points determines an institution's score on an element.*

*Where an element includes multiple numbered factors, the scoring indicates the number of factors that the institution must meet to achieve each scoring level.*

**Scoring**

| 100% | 75% | 50% | 0% | N/A |
|---|---|---|---|---|
| | | | | |

[*Each element has designated element points, or total possible points. There is a single scoring methodology for each element. The scoring indicates what the institution needs to do to achieve each of the four scoring levels for an element*.

*Some elements are designated* must pass. *This means that the institution must achieve at least a 50% score on the element in order to be accredited. If the institution scores below 50% on any* must pass *element it cannot be accredited.]*

**Data source**

[*Data sources are types of documentation or evidence that NCQA reviews in assessing compliance with an element.*

*NCQA specifies four types of data sources to be used in theVAHRPAP:*

1. ***Documented processes****–Written statements describing procedures. They may include local policies and procedures, standard operating procedures (SOPs) process flow charts, contracts, bylaws, execution plans for quality assurance, instruction manuals and template forms or other mechanisms that describe an actual process used by the VAMC. Documented processes must be local and specific to the individual VAMC being surveyed.*

2. ***Reports****–Aggregated sources showing evidence of action including management reports, key indicator or quality assurance reports, meeting minutes, survey results and other documentation of actions the VAMC has taken.*

3. ***Records or files****–Actual protocol files (including associated minutes and consent forms), records of training, log books, pharmacy dispensing logs or other documentation that shows direct evidence of action taken (including, for some elements, receipt of information). NCQA selects a random sample of files for review using the list of active protocols that the VAMC submits with its application.*

4. ***Materials*** *– Any prepared material or content that the organization provides to its IRB members, investigators, employees, patients, research subjects or the public, including written communication, radio spots or video clips, web site postings, scripts, patient/subject instructions, brochures or advertisements.]*

**Scope of review**

[*The scope of review defines the limit, or level at which, NCQA reviews each element. There are two scopes:*

***Once for the institution—****NCQA scores this element once for the institution.*

***Once for each IRB****—NCQA scores this element once for each IRB used by the VAMC. Results for IRBs are averaged together using a weighted average based on the proportion of the organization's studies that are reviewed by each IRB*.]

**Explanation**

[*The explanation provides additional information to the VAMC, such as the context for the element, terms used, underlying methodology and the evaluation process. The explanation also describes the period for which NCQA assesses the VAMC's performance on an element. This is referred to as the "look back period.*"]

**Examples**

[*Examples show one or more ways of demonstrating compliance with the element*.]

| | |
|---|---|
| **Exception** | [*Exceptions from the element are listed here. Two types of exceptions are presented: (1) situations in which a factor or an element is not applicable and (2) actions or types of evidence that might be considered to meet the standard, but do not*.] |
| **Regulatory support/reference** | [*Regulatory sources and references identify the VA and Federal regulations, policies or guidance and other references that support the element*.] |

# III. Procedures and Instructions for Accreditation

## A. Changes to the Accreditation Process

NCQA has revised the accreditation process to increase interaction with VAMCs throughout. Those steps involving interaction or opportunity for VAMCs to add, clarify or dispute findings are identified under the heading of "Survey Process" below.

## B. Survey Types

NCQA conducts five types of surveys of VAMCs that seek and maintain accreditation.

1. **initial accreditation survey** —
   NCQA evaluates the VAMC's HRPP against all VAHRPAP standards for the first time. Based on the findings, NCQA awards the VAMC an accreditation status. NCQA provides the VAMC with a summary report including element scores, recommendations and accreditation status.

2. **follow-up survey —**
   A VAMC surveyed under Version 1.1 Standards may be required to submit periodic progress reports and undergo a follow-up on-site review to determine compliance with conditions set by the Program Accreditation Committee (PAC). This does not apply to accredited sites in Version 2.1.

3. **accreditation renewal survey** —
   In order to renew its accreditation status, a VAMC must undergo an accreditation renewal survey prior to the expiration of the previous accreditation status. Regardless of the previous accreditation outcome, the VAMC must undergo a full accreditation survey at least once every three years to maintain continuous accreditation. More information regarding the requirements for resurvey may be found in the section of this document addressing accreditation outcomes. VAMCs attaining one-year accreditation will require a full survey prior to the expiration of accreditation. VAMCs attaining 3-year accreditation must submit the following information annually:
   - attestation of continued compliance with the standard version under which they received accreditation
   - attestation that no substantive changes have been made to the HRP, or an explanation of any such changes
   - results of any external inspection in the last year
   - updated contact information.

4. **discretionary survey** —
   The purpose of a discretionary survey is to confirm compliance with the standards after a significant event or change, or, after information is identified about non-compliance with regulations or standards.

NCQA will determine the scope of the discretionary survey in accordance with the material change or event. It may include inquiries to the VAMC or VACO, request for evidence of continued compliance with the standards and elements pertaining to the event or action in question, up to and including a full resurvey. NCQA will notify the VAMC and VA ORD of its intent to investigate within 14 calendar days. Adverse decisions resulting from a discretionary survey are subject to due process.

Material changes, situations or events that may result in a discretionary review include:

- Events or reports from regulators, sponsors or other sources
  - reflecting a change in compliance with the standards
  - indicating potential for harm to human participants of research
- Loss of or restriction to FWA
- Loss of or restriction to affiliate accreditation if VAMC has been accredited under combined accreditation process
- Request for survey from ORD based on internal criteria
- Material reorganization of HRPP
  - change in IRB of Record
  - merger with another HRPP i.e. university affiliate or another VAMC.

At the discretion of NCQA, the accreditation status of the VAMC may continue or be suspended during the inquiry process.

5. **unannounced survey —**
   NCQA initiates an unscheduled on-site visit only in response to an allegation that the VAMC provided NCQA with Falsified Documents or Fraudulent Information. The purpose of an unannounced on-site survey is to confirm or refute an allegation that the VAMC provided NCQA with documentation and or information that is either falsified or fraudulent as defined in Appendix D. The site will not be notified in advance, and all findings will be reported to VA ORD, and as appropriate, to State and Federal Agencies governing the conduct of clinical research and human research protection. Each VAMC must submit a signed agreement (See Appendix D) to the effect that it will not provide NCQA with falsified or fraudulent documentation of its activities pertaining to the VAHRPAP accreditation process. This signed document must be received by NCQA with the application for accreditation.

   An unannounced survey may also be conducted at the request of VA ORD, based on internal criteria.

## C. Survey Personnel

NCQA staff and surveyors have experience in the areas of clinical research and human research protection and undergo training on the VAHRPAP standards and the survey process. Each on-site survey team has a member with experience in clinical research and a member with experience in human research protection. All survey team members are credentialed and certified as having successfully completed an NCQA training program on the VAHRPAP standards and the survey process.

NCQA will make every attempt to provide a specific individual from NCQA staff to serve as a main contact for that site. This NCQA staff member will be responsible for responding to any questions the VAMC staff may have regarding the standards or the accreditation process.

The size and composition of the survey team varies depending on the complexity of the HRPP surveyed and in particular, the number of IRBs and physical locations that must be visited. At a minimum, a survey team includes one clinical research surveyor and one administrative surveyor, and it may include additional surveyors, NCQA staff members and surveyors-in-training. NCQA ensures that surveyors have no conflict of interest with the institution under review.

## D. Survey Process

The sequence of stages for the evaluation of the VAMC's HRPP is designed to assure the collection and thoughtful review of all information pertinent to the evaluation of the VAMC's compliance with the standards. NCQA evaluates materials submitted by the VAMC prior to the on-site survey visit and records findings in a data collection tool (DCT) also used by the on-site survey team, which further evaluates the HRPP, and verifies selected information previously submitted during the off-site survey.

**1. Scheduling —**

NCQA works with VA Office of Research and Development (VA ORD) to establish the sequence of surveys for the calendar year in six-month blocks. VA ORD identifies the sites to be visited 20 weeks prior to the beginning of the six-month block and identifies any dates when surveys may not take place. Once the sequence is established, NCQA works with each site to set specific survey dates during the assigned block. NCQA may not agree to survey a VAMC during a different timeframe without the express permission of VA ORD. NCQA confirms the dates for on-site survey and application / data submission at least 16 weeks prior to the on-site survey, and obtains information needed to compose a survey team. The application and data submission are due to NCQA no later than eight weeks prior to the on-site survey date. Prior to the visit, NCQA communicates with the VAMC regarding the members of the survey team as well as all logistical requirements.

As soon as the survey team is confirmed, NCQA provides the institution with biographical sketches (bio) of the individuals who compose the on-site team. If the institution perceives a conflict of interest (e.g., a "direct financial relationship" exists), it is responsible for notifying NCQA—in writing—of any such objection within 5 business days of receipt of surveyor information. NCQA will then assess the situation and if merited, select an alternative surveyor(s) and present his or her name and bio to the institution. NCQA reserves the right to make a final determination regarding a conflict of interest.

The dates of the application submission and the on-site survey are final once confirmed by NCQA. Cancellations of survey dates may be accomplished for the following reasons:

- Force Majeure
- Regulatory action halting research

- Request from VA ORD

Any request for cancellation or change of survey dates must be forwarded through and approved by VA ORD to NCQA.

2. **Application —**
On the scheduled due date (eight weeks prior to the on-site survey date), the VAMC submits its completed application along with annotated supporting documentation that demonstrates how it meets the standards. Electronic submissions are encouraged. The submission may include instructions for NCQA surveyors to visit the institution's Web site or query its on-line systems remotely. However, website content is frequently updated. Therefore, if this method is included as part of the submission, the VAMC must also supply a means to identify the published date of the web materials. The VAMC is responsible for providing access to relevant information from affiliated institutions, such as university IRBs. NCQA and the institution agree that all documents submitted are final on the date the application is due. NCQA reviews this submission and may communicate with the VAMC to clarify or request additional supporting documents. No documentation developed after the data submission due date will be considered.

3. **Off-site Survey —**
NCQA evaluates the application and supporting materials submitted by the VAMC prior to the on-site survey visit and records findings in a data collection tool (DCT). This DCT is a spreadsheet specifically designed for collecting the information and applying the standards and will also provide the basis for the reporting process. NCQA provides the VAMC with informal feedback during this period. Approximately four weeks prior to the on site survey date, NCQA sends a preassessment DCT, reflecting the elements evaluated to date, to the VAMC Medical Center Director or designee. The VAMC has 7 days to comment and submit additional supporting documents. NCQA incorporates any new information into the evaluation process and, as appropriate into the DCT.

4. **On-site Survey —**
NCQA surveyors assess compliance with any elements that require further verification, confirm findings wherever the VAMC's submission was inconclusive and conduct the file review. The file review is finalized at the end of the on-site survey and is not subject to further revision. The on-site survey is a site visit that includes interviews with key staff members, a tour of IRB and pharmacy facilities, system queries (as applicable), and protocol file reviews. NCQA uses interviews primarily to explain, clarify and confirm documentary evidence. During the on-site survey, NCQA reviews any elements that were determined to require further verification during the off-site survey, and evaluates elements of performance that can only be assessed on site (e.g., IRB records and protocol files). The VAMC's IRB staff (or staff of the affiliate, if applicable) is requested to participate with surveyors in the file review. NCQA requests the assistance of the IRB Coordinator or other relevant staff when the surveyors encounter difficulty in locating or identifying evidence of compliance. If NCQA surveyors are unable to locate evidence that a file meets NCQA standards, VAMC staff will be asked to locate and provide the required documentation while the file review is underway. In this manner, VAMC staff will be aware of deficiencies in the files, and will be

able to supply additional documentation that may be separated from the rest of the protocol. All documentation provided during the on-site visit will be considered; however, the surveyors may disagree with VAMC staff about whether a particular document demonstrates compliance with an element. The surveyors will discuss all such negative findings with the VAMC staff prior to completing the file review. At the completion of the on-site visit, the survey team conducts a closing conference with individuals selected by the VAMC. Typically these would include the CEO/Director, Chief of Staff, Associate Chief of Staff, Chair of the R&D Committee, the VAMC HRPP Official, and Chair of the IRB and others from the VAMC or affiliated IRB. During the conference, the survey team summarizes its findings regarding the VAMC's HRPP and the extent to which the program complies with the standards evaluated on-site. The surveyors do not make decisions about the institution's accreditation status. In order to protect against the potential for, or appearance of, conflict of interest, surveyors must confine their discussion to findings related to the standards they surveyed. Surveyors are not permitted to offer direct advice to the VAMC about how to improve its Human Research Protection Program.

5. **Draft Report —**
   Following completion of the on-site visit, NCQA compiles the data into the DCT and produces a Draft Report, which includes the evaluation and scoring for all elements. The report is a tabulation of findings and scores for each element. During this process, the VAMC may be contacted to provide additional documentation or to further clarify outstanding issues. NCQA sends the Draft Report to the institution Medical Center Director or designee for review and comment. (NCQA also submits copies of the Draft Report to VA ORD and ORO). In response, the institution may submit comments regarding any factual errors or omissions within two calendar weeks of receipt of the Draft Report. Protocol file review results are not disputable after the close of the on-site visit as it is only during the visit that the documentation is available for review, and findings are reviewed with VAMC staff at the time of the on-site survey. Upon timely receipt of the institution's comments, NCQA revises the Draft Report, including element scores, as appropriate.

6. **Final Accreditation Report —**
   NCQA submits the revised Draft Report to the Program Accreditation Committee (PAC). The PAC reviews the report and makes an accreditation decision. Copies of the final report are distributed to the institution Medical Center Director or designee, VA ORD and ORO, within ninety days after the last on-site review day.

# IV. ACCREDITATION OUTCOMES and RESPONSES

## A. Accreditation Outcomes

The PAC receives the revised Draft Report and determines the accreditation outcome based on a VAMC's numerical score and the professional judgment of the PAC.

Thresholds for accreditation outcomes are as follows:

| Accreditation Outcome | Accredited (3 - year) | Accredited (1 - year) | Not Accredited |
|---|---|---|---|
| Score | 85-100 | 55-84.99 | 0-54.99 |

NCQA does not round scores up or down. The PAC makes the final accreditation decision, which is effective on the date the decision is delivered to the VAMC. To maintain accreditation, the institution must undergo a survey against all applicable standards prior to the expiration of its accreditation status and at least every three years and meet all obligations outlined in these policies and procedures. See Appendix E for PAC Decision Rules.

A VAHRPAP survey results in one of the following three accreditation outcomes:

1. **Accredited 3-year —**
   The HRPP receives at least 85 points, scores at least 50% on all "*must pass*" elements and only minor deficiencies exist. In addition to performance on standards, the VAMC agrees to meet its obligations and reporting requirements. The institution receives a NCQA seal indicating its accredited status.

   Duration of Accreditation
   Three years, with satisfaction of all reporting requirements. During the three-year period the VAMC must annually provide an attestation that they continue to comply with all standards, that there have been no substantive changes to the HRPP and updated contact information. Failure to submit this information or provide reports as listed in Obligations of the Parties will result in a notice of pending lapse of accreditation. Continued failure will result in revocation of accreditation.

   Conditions for renewal

   Prior to the expiration of the accreditation, VAMC must undergo an Accreditation Renewal Survey against the standards then in effect.

2. **Accredited 1-year —**
   This is an accredited status. The HRPP receives at least 55 but fewer than 85 points and scores at least 50% on all "*must pass*" elements; improvements are needed to the HRP system. The institution receives a NCQA seal indicating its accredited status.

   Duration of accreditation status: One year. In order to allow a full year for process improvement, the accreditation renewal survey must be scheduled prior to the expiration of accreditation, but may take place within fifteen months of the accreditation decision.

3. **Pending Accreditation —**
   In situations where the VAMC's accreditation decision will be rendered jointly with another accrediting body, the accreditation will be reported as "pending" until both bodies have rendered a decision. If the affiliate's accreditation decision is not made within 365-days following the VAMC's pending decision, the HRPP cannot be accredited, and must be resurveyed. See Appendix A for joint accreditation decisions.

4. **Not Accredited —**
   The HRPP receives a score of less than 55 points or less than 50% on any "*must pass*" element. These elements identify critical deficiencies in the HRPP that could lead to serious sanctions by ORO, OHRP or FDA, or that imperil human research subjects. A VAMC that receives a "Not Accredited" decision is eligible to reapply for accreditation when it meets all eligibility requirements for the VAHRPAP and receives authorization from ORD to reapply for accreditation.

5. **Operations Adversely Affecting Safety —**
   In the event that NCQA finds any aspect of an institution's HRPP may adversely affect the safety and protection of humans participating in research, such findings may be considered for accreditation purposes, even if NCQA standards do not specifically address such operations. Unanticipated problems involving risks to subjects and others and/or serious and/or continuing noncompliance with Federal regulations may be considered for accreditation purposes. If NCQA identifies any condition that poses a potential threat to the safety of research participants, the findings must be relayed immediately to the institution's Chief Executive Officer/Director or designee and to VA ORD and ORO. However, even when an institution is not provided immediate notice from NCQA of a condition posing a safety threat, NCQA may consider and assess the condition in its subsequent accreditation decision.

## B. Due Process

1. **File Review Dispute —**
   In the event that VAMC staff believes that surveyors have erred in their assessment of file review documentation, the VAMC may request immediate adjudication of the issue. The following steps may be followed until the dispute is resolved or determined that it cannot be resolved:
   a. should site representative not agree with surveyor's decision, they must bring it to the surveyor's attention
   b. surveyors will confer
   c. if no consensus can be reached between the VAMC and the survey team, the site may request that NCQA staff, if not on-site, be consulted through teleconference. Disputed evidence may be faxed or scanned and emailed to NCQA for consideration. NCQA will issue a determination at that time
   d. If the dispute persists after NCQA has conferred judgement, surveyors must document on the DCT the nature of the dispute, including identification of the specific information that was determined to be missing or insufficient. This information will become part of the DCT and be available for review by the PAC.

2. **Appeal —**
   A VAMC may comment on the contents of its Final Accreditation Report and appeal its accreditation outcome. A VAMC may seek to correct material errors in the survey that would result in a change in the compliance scoring with respect to any element if the change would result in a revised accreditation outcome. A VAMC may not appeal individual element scores apart from an appeal of the accreditation outcome. Any VAMC whose on-

site survey occurred on or after May 1, 2002 *cannot* seek appeal of the portion of its score associated with protocol file review, except as outlined in the file review dispute resolution process. The grounds for appeal are:

- material factual inaccuracies in the survey report
- material misapplication of the standards
- failure to consider material documentation or information that was available at the time of the survey.

In order to protect the integrity of the accreditation process, the VAMC may not submit—and the Appeal Committee does not consider—documentation that represents actions taken by the institution subsequent to the start of the survey, including actions taken after the date of the application and data submission (eight weeks prior to the on-site survey). The procedure for appeal is as follows:

a. A written request for appeal must be received within 30 calendar days after the date of the VAMC's Final Accreditation Report. The request must state at least one of the grounds for appeal identified above, and include a listing of the standards for which appeal is being requested. The request does not need any accompanying documentation
b. Upon receipt of the request for appeal, NCQA issues an acknowledgment letter to the VAMC. The VAMC has 14 calendar days from the date of this communication to submit supporting documentation
c. The institution must detail grounds for its appeal and provide documentation that was available at the time of the survey of its compliance with VAHRPAP standards
d. Documentation acceptable as evidence for appeal includes evidence available at the time of the on-site survey and in effect prior to the due date of the application. This evidence may include:
    - references (including page & paragraph number) to documentation materials used by the team while on-site
    - references to documentation originally submitted to NCQA with the original application or the response to the preliminary report
    - references to documentation submitted to NCQA in VAMC comments on the draft report
e. Protocol file review results are not disputable after the close of the on-site survey. Therefore, except as noted above, VAMCs may not challenge the protocol file review findings during the appeal process
f. Upon receipt of a complete appeal, NCQA prepares materials for the next scheduled meeting of the Appeal Committee
g. Appeal Committee members whom NCQA determines to have a conflict of interest with a VAMC seeking appeal do not participate in the appeal decision-making process. The Appeal Committee considers all of the appeal materials submitted by an institution, the final accreditation report and an NCQA staff analysis of the appeal. The Appeal Committee bases its review only on the record before it and on the VAHRPAP standards
h. Appeal Committee meetings occur monthly. Appeal requests with complete appeal materials received prior to the submission deadline (4 calendar weeks prior to meeting date) are considered at the next scheduled meeting.

i. Upon completion of its review, the Appeal Committee renders an accreditation decision and an amended final report, if applicable, is produced. The Appeal Committee's decision, rendered at any stage in the appeal process, is final.

The effective date of accreditation for an appeal decision is the date of the original accreditation decision that precipitated the appeal.

# Appendix A

## Consolidated Accreditation Outcome
## VA Medical Center using the IRB of an AAHRPP-Accredited Affiliate

| AAHRPP Accreditation of Affiliate HRPP | Score on NCQA Review of VAMC Institutional Responsibilities Standards | Overall VAMC Accreditation Outcome |
|---|---|---|
| Full Accreditation | >85% | Accredited 3 years |
| Qualified Accreditation | >85% | Accredited 3 years |
| Provisional Accreditation | >85% | Accredited 1 year |
| Accreditation Withheld | >85% | Not Accredited |
| Full Accreditation | 55-84% | Accredited 1 year |
| Qualified Accreditation | 55-84% | Accredited 1 year |
| Provisional Accreditation | 55-84% | Accredited 1 year |
| Accreditation Withheld | 55-84% | Not Accredited |
| Full Accreditation | <55% | Not Accredited |
| Qualified Accreditation | <55% | Not Accredited |
| Provisional Accreditation | <55% | Not Accredited |
| Accreditation Withheld | <55% | Not Accredited |

To get a passing accreditation status (3-year or 1-year), the VAMC must have a passing score from NCQA VAHRPAP (>55%).

## Consolidated Accreditation Outcome

## VA Medical Center using the IRB of a PHRP-Accredited Affiliate

| PHRP Accreditation of Affiliate | Score on NCQA Review of VAMC Institutional Responsibilities Standards | Overall VAMC Accreditation Outcome |
|---|---|---|
| Accredited (3 years or 1 year) | >85% | Accredited 3 years |
| Not Accredited | >85% | Not Accredited |
| Accredited (3 years or 1year) | 55-84% | Accredited 1 year |
| Not Accredited | 55-84% | Not Accredited |
| Accredited (3 years or 1 year) | <55% | Not Accredited |
| Not Accredited | <55% | Not Accredited |

To get a passing accreditation status (3-year or 1-year), the VAMC must have a passing score from NCQA VAHRPAP (>55%).

# Appendix B

# Technical Document
# File Review

## File Sampling Process

### *Protocol File Sampling*

NCQA evaluates many elements by reviewing protocol files, including IRB minutes and other IRB documentation, information submitted to the IRB by investigators, correspondence between the IRB and investigators, and other documents that indicate information was sent to, received by, considered by, decided, or communicated by the IRB. VA Medical Centers that conduct human studies may have anywhere from one or two active protocols to several hundred active protocols at any point in time. Each research program is unique in size and scope. In the very large research programs, it is not practical for NCQA to evaluate performance on each and every protocol, and this is not necessary to determine whether the Human Research Protection Program meets accreditation standards. Instead, NCQA uses a sampling procedure to determine whether HRPPs are performing at an appropriate level.

### *Sampling Approach*

NCQA uses a random sampling procedure to inform the protocol review process and to determine whether investigators and IRBs are performing at an acceptable level. Minimum acceptable performance is defined as 81% average compliance with a lower 95% confidence boundary of 54% compliance. NCQA evaluates sixteen protocol files that went through initial review and sixteen protocol files that went through continuing review during the look-back period, for each IRB used by the VAMC. Additional, derivative samples are reviewed to evaluate determination of exempt status, expedited review actions and informed consent issues. For each element, NCQA reviews 16 files for compliance with the element (or with each of its factors).

### *Sampling Procedure*

Along with the application on the due date, the VAMC submits to NCQA an electronic listing of all active protocols including the protocol name, IRB name, initial approval date and type if available (i.e. full review or expedited), and the most recent continuing review date and type. The VAMC also submits a list of all exempt protocols if available, including the protocol name, IRB name, and exemption date, with an exemption date during the 12 months prior to the date of the application. NCQA uses these lists to generate random samples for review. Two working days prior to the survey, NCQA sends an initial review file list the VAMC to pull for surveyors. NCQA also provides surveyors with continuing review, expedited review, and exempt file review sample lists along with over-sample lists to draw from if replacement files are needed.

### *Multiple IRBs*

When a VAMC uses multiple IRBs for the review of its protocols, NCQA selects complete samples, as described below, for each IRB used. The results of the file review for each IRB are averaged, based on the proportion of all studies in the associated population that are reviewed by the IRB in question. The populations associated with each sample are as follows:

| Sample | Associated Population |
|---|---|
| Initial Review | All protocols with a non-expedited initial approval date in the 12 months prior to the application date. |
| Continuing Review | All protocols with a non-expedited continuing review approval date in the 12 months prior to the application date. |
| Expedited Review | All protocols with initial approval or continuing review approval dates by expedited review in the 12 months prior to the application date. |
| Informed Consent | All protocols in initial review sample. |
| Exempt from IRB Review | All protocols determined to be exempt from IRB review in the 12 months prior to the application date. |

For example, if there are three IRBs and IRB 1 conducts 60% of the VAMC's non-expedited initial approvals in the year prior to the application date, IRB 2 conducts 10% and IRB 3 conducts 30%, each IRB's score on each element scored on the initial review sample would be weighted by its proportionate contribution to the initial review of the VAMC's protocols. If, for example, a particular IRB conducts no expedited reviews, then it would not contribute to the scoring for the elements based on the expedited review sample.

### *Initial Review Sample*

The sample consists of 16 protocol files for initial review conducted by the full IRB with an initial approval date in the 12 months prior to the application date (or, for sites undergoing an Introductory Survey, all protocol files reviewed by the IRB at its most recent meeting). NCQA supplies the VAMC and surveyors with the original sample of 16 files prior to the site visit. NCQA provides the surveyors with an additional list of initial review files that can be used to replace files in the original sample, if needed.

### *Replacement of files from the original sample*

Surveyors may replace files from the original sample if any of the following conditions is met:

- Initial review was improperly classified as conducted by the full IRB when in fact, it was conducted by expedited review
- Protocol file is logged out to a federal or state regulator, monitor, or legal office because of an active investigation or lawsuit.

Surveyors may *not* replace files from the original sample if they are lost, incomplete, or signed out to any other office from which they should be readily retrievable.

If files from the original sample must be replaced, the replacements are made in order from the top of the replacement file list, until a sample of 16 is complete, or until there are no more initial review files on the replacement list.

***Continuing Review Sample***

The sample will consist of 16 protocol files that underwent continuing review by the full IRB with a continuing review approval date in the twelve months prior to the application date. NCQA supplies the surveyors with the original sample of 16 files prior to the site visit. NCQA also provides the surveyors with an additional list of continuing review files that can be used to replace files in the original sample, if needed. If the VAMC has fewer than 16 continuing review files, all continuing reviews conducted in the past year are reviewed. There may be some continuing review files in the sample that were also in the initial review sample if both initial and continuing review were conducted within the past year. These files, if any, are reviewed against initial review and continuing review elements.

***Replacement of files from the original sample***

Surveyors may replace files from the original sample if any of the following conditions is met:

- Continuing review was improperly classified as conducted by the full IRB when in fact, it was conducted by expedited review
- Protocol file is logged out to a federal or state regulator, monitor, or legal office because of an active investigation or lawsuit.

Surveyors may *not* replace files from the original sample if they are lost, incomplete, or signed out to any other office.

If files from the original sample must be replaced, the replacements is made in order from the top of the replacement file list, until a sample of 16 is complete, or until there are no more continuing review files on the replacement list.

***Expedited Review Sample***

The sample consists of expedited actions from 16 *different* protocol files that include qualifying expedited actions within the past year. NCQA will select qualifying expedited actions from the list of active protocols provided by the IRB according to the following criteria:

- First, up to six initial reviews conducted by expedited review during the 12 months prior to the application date if available
- Second, up to six continuing reviews conducted by expedited review during the 12 months prior to the application date if available
- Third, surveyors will select enough expedited reviews of protocol amendments to bring the total number of files with qualifying expedited actions to 16.

One expedited action from each file, up to 16 expedited actions, is included in the sample. Serious adverse event reports, informed consent form changes, and Investigator Brochure revisions do not qualify for inclusion in this sample.

***Completing the Expedited Review Sample***

Surveyors must complete the expedited review sample on site as described in the third bullet above. Surveyors will first examine the six files with expedited initial review and the six files with expedited continuing review provided by NCQA, if available. If any of these files turn out not to include the indicated expedited actions then they are removed from the expedited review sample. The surveyor will then continue selecting files with qualifying expedited actions until they have a sample of 16 expedited actions, each from a different protocol. Files with qualifying expedited actions will be selected as follows:

1. First, if the expedited review sample from NCQA contains fewer than six initial reviews, and if any initial review files were eliminated from the original (non-expedited) initial review sample because they were conducted by expedited review, these may be added to the expedited review sample. The expedited review sample may include a maximum of six initial reviews.
2. Second, if the expedited review sample from NCQA contains fewer than six continuing review files, and if any continuing review files were eliminated from the original (non-expedited) continuing review sample because they were conducted by expedited review, these may be added to the expedited review sample. The expedited review sample may include a maximum of six continuing reviews.
3. Third, The following procedures should be used to complete the sample of 16 expedited actions:
    - From files included in the (non-expedited) Initial Review sample, select the first expedited protocol amendment in each file that occurred *after* the initial review.
    - If additional files with expedited actions are required, go to the (non-expedited) Continuing Review sample and select the first expedited protocol amendment in each file that occurred *after* the continuing review.
    - If additional files with expedited actions are required, go the Initial Review replacement list and select the first expedited protocol amendment that occurred *after* the initial review.
    - If additional files with expedited actions are required, go the Continuing Review replacement list and select the first expedited protocol amendment that occurred *after* the continuing review.

If the VAMC indicates that it performs no expedited reviews, surveyors must confirm this while conducting file reviews. Surveyors may *not* replace files from the original expedited review sample for any reason except as specified in this section.

***Informed Consent Sample***

The Informed Consent elements will be scored based on the information in the Initial Review sample. No additional sample is necessary.

***Exempt from IRB Review Sample***

The sample consists of 16 protocols determined within the year prior to the application date to be exempt from IRB review. NCQA will supply the VAMC and surveyors with the original sample of 16 protocols prior to the site visit. If the VAMC has fewer than 16 exempt protocols, all protocols determined in the past year to be exempt will be reviewed. If the VAMC does not exempt research from IRB review, there will be no sample.

***Statistical Basis for the Sampling Procedure***

NCQA evaluates protocol files based on random samples, as described above. The sampling procedures are designed to provide valid, unbiased estimates of the organization's adherence to the review criteria. The sample size of 16 provides estimates that are sufficiently precise to allow for meaningful differentiation between IRBs that are performing at different levels without imposing undue file review burdens.

For a single factor element with 16 files under review, the table below identifies the 95% upper and lower confidence bounds around the proportion of "Accepts."

| Exact Confidence Limits, Proportion of "Accept" | | | | | |
|---|---|---|---|---|---|
| Sample Size | Accept | Reject | Proportion | LCB | UCB |
| 16 | 16 | 0 | 1 | 0.794 | 1.00 |
| 16 | 15 | 1 | 0.938 | 0.698 | 0.998 |
| 16 | 14 | 2 | 0.875 | 0.616 | 0.985 |
| 16 | 13 | 3 | 0.812 | 0.543 | 0.960 |

For scoring purposes, 15 or more "Accepts" gives the IRB 100 percent of the possible points for that factor. Similarly, 14 "Accepts" translates to 75 percent of the possible points and 13 "Accepts" translates to 50 percent of the possible points. This scoring system makes it very unlikely that institutions failing to comply with the element criteria more than half the time would receive any points ($p<.001$).

For multi-factor elements the estimates are even more precise since the denominator of the proportion of "Accepts" is larger, typically a multiple of 16. For example, a seven factor element with a sample size of 16 would yield estimates with confidence limits of approximately +/- 6%. In situations where the number of files available for review is less than 16, typically it will be because all files are being reviewed, hence there is no sampling error.

In summary, the final accreditation outcome is unlikely to be affected by sampling variation since it is based on several independent samples and multiple element scores.

## Scoring

### *Scoring at the Element Level*

Each element has a maximum possible number of points. The scoring indicates what the institution needs to do to achieve each of the four scoring levels for an element (some scoring levels may not be applicable for some elements):

- 100%
- 75%
- 50%
- 0%.

The points earned for an element are the maximum possible element points multiplied by the scoring level. For example, if IRB3D carries a total of 0.7 possible points, and the institution achieves a scoring level of 75%, then the points earned are .7x75%, or .525. Scores are not rounded.

### *Factors that are Not Applicable*

Some elements contain multiple factors. In specified circumstances, one or more factors may not be applicable. The element points remain unchanged. The applicability of individual factors does not affect the point value of the element. The institution is not accountable for complying with factors that are not applicable. In general, where factors are known to be not applicable some of the time, the scoring reflects that, and is expressed in terms of the number of applicable factors met (or not met). However, if a factor is not applicable and the scoring does not contemplate the possibility, the institution's score for the element is the same as if the not applicable factor were met.

### *Points for Elements that are Not Applicable*

Some elements may be not applicable in their entirety. In this situation, the element points are subtracted from the total points available for the accreditation program. The institution's accreditation score is the sum of all points earned divided by the total number of points available (considering only points for elements that are applicable).

### *Scoring File Review Elements*

Elements evaluated by file review may consist of a single item (single-factor elements) or multiple items (multiple-factor elements). The proportion of "Accept" for single-factor file review elements is the proportion of files that meet the element. Typically, in a sample of 16 files, the proportion would be X out of 16. However, if the element is not applicable in some of the files, the file would be removed from both the denominator and the numerator, and the proportion would be calculated as the number of compliant files out of the number of files for which the element is applicable. This approach also applies if the number of files available for review is less than 16.

Multiple-factor elements are scored similarly. For each element, the denominator is the multiple of the number of files times the number of applicable factors to be evaluated.

Two Factor-Element with Sample of 16 Files

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | | | | |

In the example above, there are 16 files and 2 factors, so the denominator of the proportion is 32, assuming both factors are applicable in all files. The proportion of "Accept" is the number of file/factor combinations that are met, divided by 32.

Once the proportion of "Accept" is calculated for an element, it is converted to a scoring level according to the following table:

| Scoring Level | 100% | 75% | 50% | 0% |
|---|---|---|---|---|
| Proportion of "Accept" | 90-100% | 85-89% | 80-84% | <80% |

Multiple-factor exception: The exception to this scoring procedure is that if one half or more of the files fail for any one factor in the element, the element score is 0%.

**Total Accreditation Score**

The institution's accreditation score is the sum of all points earned divided by the total number of points available (considering only points for elements that are applicable) and multiplied by 100. Consider the following example:

Scoring Example

| Element | Points Available | Scoring | Points Earned | Total Score |
|---|---|---|---|---|
| 1 | 0.7 | 100% | 0.7 | |
| 2 | 1.2 | 50% | 0.6 | |
| 3 | 3.0 | 75% | 2.25 | |
| 4 | 2.0 | NA | 0 | |
| Total | 4.9 | ---- | 3.55 | 72.449 |

The institution receives points for elements 1, 2 and 3, but element 4 is NA. If element 4 were applicable the total points available for the accreditation program would be 6.9, however because element 4 is NA for this institution, the points for element 4 are removed from the possible points when calculating the Total Score.

Thresholds for accreditation outcomes are as follows:

| | Accredited | Accredited with Conditions | Not Accredited |
|---|---|---|---|
| Total Score | 85-100 | 55-84.9 | 0-54.9 |

Following the example above, the institution would receive an accreditation outcome of Accredited with Conditions, because its score of 72.449 is between 55 and 84.9 points.

# Appendix C

## Glossary of Terms

## Definitions

**Active Study** – A study which has received IRB approval at any time during or previous to the look back period and is open at any point in time during the look back period.

**Adverse Event (AE)** – Any untoward event associated with a research study. The event does not necessarily have a causal relationship with treatment or study intervention. An AE can be any unfavorable and unintended sign, symptom or disease, whether expected or not. Also called: Adverse Effect; Serious Adverse Event; Unexpected Adverse Event.

**Affiliate's Human Research Protection** – The HRPP of a VAMC's academic affiliate. See HRPP.

**Assurance** – See **Federalwide Assurance**, **Multiple Project**, and **VA Multiple Project Assurance**.

**Authorized Institutional Official**– An officer of an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the Federal regulations regarding the involvement of human subjects in research. (OHRP)

**Benefit** – A valued or desired outcome; an advantage. (OHRP)

**Category** – A logical grouping of standards. Within the standards, there is a hierarchy of organization. The **Category** is the highest level of the hierarchy, and provides organization. Within each **Category**, standards are grouped into **Standards**, **Elements**, and **Factors**.

**Certificate of Confidentiality** – When data are collected from subjects about sensitive issues (such as illegal behavior, alcohol or drug use, or sexual practices or preferences), researchers can obtain an advance grant of confidentiality from the Public Health Service. This certificate will provide protection against involuntary disclosure of the research subject's identity and the subject's participation in the study, even if subpoenaed.

**Compensation** -- Payment or consideration i.e. medical care provided to subjects injured in research; does not refer to payment (remuneration) for participation in research. (OHRP)

**Competence** – Capacity to act on one's own behalf. The ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. (OHRP)

**Confidentiality** – Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure. (OHRP)

**Continuing Review** – Periodic, planned review by the IRB of active research for the purpose of approving, requiring modifications, disapproving, terminating or suspending the study. **Continuing Review** must occur at least annually, as determined by the **IRB**. See also **Ongoing Monitoring**.

**Data and Safety Monitoring Board (DSMB)** – A committee of scientists, physicians, statisticians and others that collects and analyzes data during the course of a research study to monitor for adverse effects (events) and other trends (such as an indication that one treatment is significantly better than another, particularly when one arm of the study involves a placebo control) that would warrant modification or termination of the study or notification of subjects about new information that might affect their willingness to continue in the study. (OHRP)

**Documented Process** - Written statements describing procedures. They may include local policies and procedures, standard operating procedures (**SOP**s), process flow charts, contracts, by laws, execution plans for quality assurance, instruction manuals and template forms or other mechanisms that describe an actual process used by the organization. Documented processes must be local; originated or formally adopted by the institution being surveyed.

**Element** - The scoreable component of a **Standard**. **Standard**s are made up of multiple **Element**s, each of which can be separately assessed and which provide additional detail about the performance expectation.

**Expedited Review** – Review of proposed research by the **IRB** chair or a designated voting member or group of voting members rather than by the convened **IRB**. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research. (OHRP)

**Factor** – One part, or component, of an **Element**. **Element**s may be made up of one or more **Factor**s.

**FDA Form 3454** – The financial disclosure form required by the FDA to reveal/identify any potential financial conflict of interest that an investigator(s), sub-investigator(s) or their spouse and children may have that is applicable to the submission of marketing applications for human drug, biological product or device for each covered study.

**Federalwide Assurance (FWA)** – An agreement or contract between the institution and OHRP, on behalf of the Secretary, DHHS, stipulating the methods(s) by which the organization will protect the welfare of research subjects in accordance with the regulations. An approved assurance is a condition which must be met to receive DHHS support for research involving human subjects. It specifies the organization's responsibilities for meeting the requirements of 45 CFR 46. The **FWA** replaces all other previous forms of assurance (i.e., **MPA**, **SPA**, **VA MPA**, etc.) All VA facilities conducting human research will be required to maintain a **FWA**.

**Food and Drug Administration (FDA)** – The federal agency responsible for the regulation of food, drugs, biologics, medical devices and cosmetics, including the human subject research performed for **FDA**-regulated articles.

**Formal IRB Agreement** – A written agreement outlining the details of the relationship between organizations, including the responsibilities of each. Such an agreement is used by the VAMC to delineate the terms and conditions under which it may utilize another entity's **IRB** for review of the VAMC's human research.

**Full Review Board** – Review of proposed research at a convened meeting at which a majority of the membership of the **IRB** is present, including at least one member whose primary concerns are in nonscientific areas. (OHRP)

**Human Research Protection Program (HRPP)** – The systematic and comprehensive approach by an organization to ensure human subject protection in all research. The implementation of any part of the program may be delegated to specific committees, individuals or entities (i.e., academic affiliate or another VAMC) by the organization.

**Human Subject** – A living individual about whom a research investigator (whether professional or students conducting research) obtains data through intervention or interaction with the individual or identifiable information. Also called research participant.

**Human Studies Subcommittee** (of the **R&D Committee**) – The VAMC's **IRB** is constituted as a subcommittee to the **R&D Committee**.

**Institution** – Refers to an individual VAMC. The institution retains ultimate responsibility for human subject protection in research conducted at their facility and/or by their staff.

**Institutional Review Board (IRB)** – An independent committee comprised of scientific and non-scientific members established according to the requirements outlined in Title 38, part 16 (same as Title 45, part 46 and Title 21, part 56) of the U.S. Code of Federal Regulations. The **IRB** may also be referred to as the **Human Studies Subcommittee** of the R&D Committee. Other committees with the same structure and/or similar functions are also considered to be **IRB**s.

**Investigational Device Exemption (IDE)** – The process by which the **FDA** permits a device that otherwise would be required to comply with a performance standard or have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device.

**Investigational New Drug Application (IND)** – The process by which new drugs or biologics, including the new use of an approved drug, are registered with the **FDA** for administration to human subjects. An **IND** number is assigned by the **FDA** to the drug or biologic for use in tracking.

**Investigational Drug** – Any drug used for research purposes is considered investigational regardless of whether or not the research is conducted under an IND.

**Investigator (Principal Investigator)** – An individual who conducts an investigation, i.e., under whose immediate direction research is conducted, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

**Investigator /Sponsor** – A term defined in the **FDA** regulations as an individual with responsibility for initiating and conducting a research study.

**IRB Documentation** – Any written evidence of the **IRB**'s consideration, evaluation, and/or assessment of proposed or active research.

**Legally Authorized Representative** – An individual, judicial or other body, authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in procedure(s) involved in research.

**Materials** – Any prepared material or content that the organization provides to its **IRB** members, investigators, employees, patients, research subjects or the public, including written communication, radio spots or video clips, web site postings, scripts, patient/subject instructions, brochures or advertisements.

**MedWatch** – The **FDA** Medical Products Reporting Program, is an initiative designed to educate health professionals about the critical importance of monitoring for and reporting adverse events and problems to **FDA** and/or the manufacturer and to ensure that new safety information is rapidly communicated to the medical community, thereby improving patient care. The purpose of the MedWatch program is to enhance the effectiveness of postmarketing surveillance of medical products as they are used in clinical practice and to rapidly identify significant health hazards associated with these products.

**Minimal Risk** – The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**Multiple Project Assurance (MPA)** – An agreement or contract between the institution and OHRP, on behalf of the Secretary, DHHS, stipulating the methods(s) by which the organization will protect the welfare of research subjects in accordance with the regulations. Approval of the MPA is a condition of receipt of DHHS support for research involving human subjects. It spells out the organization's responsibilities for meeting the requirements of 45 CFR 46. **FWA**s will replace **MPA**s.

**Must Pass Element** – Any element which requires a score of 50% or higher to receive any accreditation status other than "not accredited" regardless of the total survey score earned.

**Ongoing Monitoring** – Review by the **IRB** of such information as adverse events reports, protocol amendments, reports of protocol deviations and other information about ongoing research studies, during the period for which the protocol is approved. This is not synonymous with continuing review, although many of these activities also take place as a part of continuing review.

**Policy** – A locally written principle or rule to guide decision-making.

**Practice** – An activity that is actively and routinely performed, regardless of whether it is required in policy or specified in procedure.

**Preliminary Assessment** – A report from NCQA to a VAMC disclosing the scores earned on those elements of the accreditation based upon data submitted through the application instrument.

**Procedure** – See **Standard Operating Procedure (SOP)**.

**Protocol** – A written plan for a research study that includes, at a minimum, a description of the objective, rationale, design and methods to be used in the conduct of the research.

**Protocol File** – The documents maintained by the **IRB** administration containing the protocol, investigator's brochure, **IRB**/investigator communications and all other supporting materials.

**Quality Improvement (QI)** – The effort to assess and improve the performance of a program or institution. **QI** includes quality assessment and implementation of corrective actions to address any deficiencies identified.

**R & D Committee** – The Research and Development committee of the VAMC. This committee has numerous responsibilities for human research protection.

**Records or Files** – Protocol files (including associated minutes and consent forms), records of training, log books, pharmacy dispensing logs or other documentation that shows direct evidence of action taken (including, for some elements, receipt of information).

**Reports** – Aggregated sources showing evidence of action including, **QA/QI** reports, management reports, "key indicator" or "balanced scorecard" reports, meeting minutes, survey summary reports and other documentation of actions the institution has taken.

**Research** – A systematic investigation, including development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**Risk** – The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and the magnitude of possible harm may vary from minimal to significant. (OHRP)

**Safety Reports (IND/IDE)** – Written reports from sponsors notifying the FDA and all participating investigators of any adverse experience associated with the use of a **FDA**-regulated article that is both serious and expected.

**Serious Adverse Event (SAE)** – Any event that results in death, a life threatening situation, hospitalization or prolonged hospitalization, persistent or significant disability/incapacity or a congenial anomaly/birth defect. **SAE**s require reporting to the sponsor and the **IRB**.

**Significant Risk Device** – An investigational medical device that presents a potential for serious risk to the health, safety, or welfare of the subject. (OHRP)

**Sponsor** – Any person or entity who takes responsibility for ~~and~~ or initiates a clinical study. The sponsor may be an individual, pharmaceutical company, device manufacturer, governmental agency, academic institution, private organization or other organization. An investigator who is a sponsor is an **Investigator/Sponsor** under **FDA** regulations.

**Standard** – A broad description of performance expectation.

**Standard Operating Procedures (SOP)** – A locally written set of steps to be followed for the uniform performance of a function or activity.

**Unexpected Adverse Event** – Any adverse event that has not previously been observed (e.g., included in the investigator brochure).

**VA Multiple Project Assurance Contracts** – VA MPA Contracts between the individual VAMC or HCS and VHA Central Office, Office of Research and Development.

## Appendix D

### Rules on Falsified Documents and Fraudulent Information

Information provided by an organization that is seeking NCQA accreditation is a critical component of NCQA's assessment of the organization. The accuracy and veracity of that information is essential to the integrity of NCQA's accreditation process. Such information may be verbal in nature, may be obtained through direct observation by NCQA reviewers, or may be derived from documents supplied by the organization. NCQA insists that each organization seeking accreditation engage in the accreditation process in good faith. Failure to participate in good faith including, but not limited to, falsification of any document used to evaluate compliance with NCQA Standards for Accreditation ("NCQA Standards"), may be grounds for denial of accreditation status or revocation of accreditation status from an accredited organization.

1. For purposes of these Rules, Falsified Documents are documents provided by an applicant that have been redrafted, reformatted, or fabricated, in whole or in part, to substantiate compliance with NCQA Standards. Fraudulent Information includes oral statements made by an applicant or accredited organization to substantiate compliance with NCQA Standards or to otherwise influence the outcome of an NCQA review, which are false or otherwise misleading.

2. Falsified Documents and Fraudulent Information must never be submitted by an organization to NCQA in the accreditation or reaccreditation process. Any efforts to do so will be construed as a violation of the organization's obligation to engage in the accreditation process in good faith.

3. Notwithstanding the foregoing, additional materials prepared by the organization for the purpose of summarizing or otherwise explaining original documents may be submitted to NCQA, so long as these materials are properly identified as such, dated and accompanied by the original documents.

4. Each organization is required to submit to NCQA the attached Certification that attests to the accuracy and veracity of the documents and other information that the organization will provide to NCQA to substantiate the organization's compliance with NCQA Standards. The Certification is to be signed by the Chief Executive Officer and the Medical Director of the organization.

5. No accreditation award or survey report will be released to an organization until NCQA has received a properly signed Certification from the organization.

6. Whenever NCQA has cause to believe that an accredited organization may have provided Falsified Documents or Fraudulent Information to NCQA, NCQA shall conduct an appropriate evaluation of the situation which shall include, except as otherwise authorized by NCQA, an unannounced on-site survey of the organization. Such a survey will use special protocols that are designed to address both the alleged falsification or fraud and the degree of actual organization compliance with the standards that are the subject of the allegation.

7. Whenever NCQA is reasonably persuaded that an organization has provided Falsified Documents or Fraudulent Information in seeking to achieve or retain accreditation status, it shall take appropriate action which will, under usual circumstances, be a decision to deny accreditation or to revoke the accreditation status of an accredited organization.

8. Any organization that is subject to disciplinary action under (7) above may also be the subject of appropriate notification by NCQA to responsible federal and state government agencies.

9. Whenever an organization fails to become accredited on the basis of the violation of these Rules, the organization shall be prohibited from seeking NCQA accreditation for a period of one year unless NCQA, for good cause, waives all or a portion of this waiting period.

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## CERTIFICATION

We, the undersigned officers of _____
(the "Organization"), hereby certify the following to NCQA:

1. We have read and understand NCQA's Rules on Falsified Documents and Fraudulent Information (the "Rules").

2. Any and all documents and other information which the Organization will provide to NCQA to substantiate the Organization's compliance with NCQA Standards for Accreditation will be neither Falsified Documents nor Fraudulent Information as defined in the Rules.

By:_____ By:_____
Medical Center Director Assistant Chief of Staff for Research

Date:_____ Date:_____

## Appendix E

## PAC Decision Rules

Accreditation outcomes for the VAHRPAP are based on achieving a specified proportion of the total points available for the program, whether the institution is accredited for its entire HRPP or surveyed for its Institutional Responsibilities only because its affiliate is separately accredited. This document outlines the circumstances that support PAC decisions outside the point system.

| Accreditation Outcome | Accredited 3-years | Accredited 1-year | Not Accredited |
|---|---|---|---|
| **Total score** | 85-100 points (or percent of points available) | 55-84.99 points (or percent of points available) | <55 points (or percent of points available) |

In addition to the point system, there are four *must-pass* elements. In order for a VAMC to be accredited (one or three years), it must achieve at least the 50% scoring level on each of the four *must-pass* elements.

For VAMCs undergoing a survey for their Institutional Responsibilities only, the decision rules apply to the results of the affiliate's accreditation and to the VAMC's score on the Institutional Responsibilities standards, described elsewhere.

For VAMCs undergoing full surveys, in addition to the point system and the *must-pass* rule, the PAC must apply the following decision rules:

| Condition | Decision Rule |
|---|---|
| VAMC scores less than 50% of available points for any single category | Lower accreditation outcome by one level: Accredited 3 years becomes Accredited 1 year; Accredited 1-year becomes Not Accredited. |
| VAMC scores less than 50% of available points for any two categories | Not Accredited |
| VAMC falsifies documents or otherwise knowingly provides fraudulent or misleading information or material in support of its accreditation survey | Not Accredited |
| VAMC operations expose research subjects to exceptional risks in a manner not otherwise addressed by the standards, for example, by:<br>• conducting research without IRB approval<br>• conducting research without subjects' consent and without IRB waiver of consent requirements<br>• allowing research to continue unrestricted in the face of serious non-compliance with ethical guidelines or regulatory requirements, that the institution knew or should have known about. | Not Accredited |