Veterans Health Administration
Research & Development
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Ethical Considerations: Research Compliance

What is meant by "Research Compliance"?

Research Compliance can mean many different things to different groups of individuals and organization involved in research activities. Typically, human research compliance addresses adherence to rules, regulations, policies, and standards of conduct that govern research.

How do I know which policies to follow?

There are numerous federal requirements regarding human research. Some of the key requirements include:

- The Common Rule– codified at Title 38 Code of Federal Regulations (CFR) Part 16
- FDA Regulations 21 CFR Parts 11,50,54,56,312,314,812 and 814
- Title 38 CFR 17.85
- VHA Handbook 1108.04 Investigational Drugs and Supplies
- VHA Handbook 1200.05 Protection of Human Subjects
- VHA Handbook 1200.1 The Research and Development Committee

Depending upon where your research is conducted, there may be other rules and regulations which may apply to your research activities. For example, the Institutional Review Board (IRB) you are using may have specific rules for submitting your research protocol for review. The institution from which you are recruiting subjects may have specific regulations for posting of advertisements.

At first glance, it may seem that adhering to regulations and associated paperwork is tedious and unnecessary. However, these rules and regulations are designed to promote quality and enhance the protection of human subjects.

What types of activities are involved with research compliance?

There are numerous types of activities that fall under the realm of research compliance. Audits of research studies by research auditors or quality assurance personnel are traditional types of research compliance activities. Other types of research compliance activities include use of assessment tools before a study begins to identify areas of potential noncompliance, educational seminars, web-based tutorials, mentors, and remediation programs. Also, facilities are responsible for ensuring their Human Research Protection Program (HRPP) is adequate, and each R&D Committee is responsible for IRB oversight. Any type of activity that promotes the quality conduct of a human research study can be classified within research compliance.

What is an example of noncompliance?

"The research protocol I am conducting requires a complete blood count (CBC) and a serum glucose to be drawn when the subjects arrive for their first study visit. The study coordinator forgot to draw the CBC, and I found out when the subject arrived for the second study visit. How serious is this and what do I do?"

Not all deviations from the rules and regulations require intensive remediation. However, one single incidence of serious non-compliance can jeopardize an investigator's and/or an institution's ability to conduct research. In the above example, the investigator may be able to draw the CBC on the second study visit, and the deviation would be considered a minor incident of research non-compliance. On the other hand, if the omitted CBC was an important base-line safety parameter, this may be a serious deviation. The investigator must follow the study-specific written guidelines for reporting deviations from the protocol.

An incident of research noncompliance must be evaluated individually against its impact on subject safety. Most importantly, the investigator needs to (1) report the deviation to the appropriate offices, committees or individuals, and (2) evaluate why the omission occurred and revise or develop standard operating procedures to prevent it from reoccurring.

Whom can I contact to answer my questions?

Your local IRB is a good initial source for information and guidance. VA researchers can also seek guidance from numerous agencies within the VA, including the Office of Research and Development (ORD), Program for Research Integrity Development and Education (PRIDE), Center on Advice and Compliance Help (COACH), and the Office of Research Oversight (ORO). The Office for Human Research Protections (OHRP), U.S. Food and Drug Administration (FDA), and Office of Research Integrity (ORI) are non-VA federal regulatory agencies that researchers can also consult for regulatory advice.

VA COACH
Center On Advice & Compliance Help
Helping VA facilities protect veterans in research

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