



## ■ ETHICAL CONSIDERATIONS:

# The Common Rule

### What is The Common Rule?

The Common Rule is a short name for “The Federal Policy for the Protection of Human Subjects” and was adopted by a number of federal agencies in 1991. Each agency incorporated the policy into its own Code of Federal Regulations (CFR), with VA adapting it in Title 38 CFR Part 16, and the Department of Health and Human Services (DHHS) in 45 CFR Part 46, Subpart A.

The Common Rule applies to human subjects research conducted, supported or otherwise subject to regulation by the VA. If VA investigators receive support from DHHS (NIH, CDC, etc.), then parts of 45 CFR Part 46 also apply. The Common Rule:

- Describes the types of research subject to regulation
- Defines key terms such as research, human subject and minimal risk
- Requires a written assurance of compliance with The Common Rule
- Sets forth requirements for an Institutional Review Board’s (IRB) membership, authority, review procedures, records and criteria for approval
- Lists the general requirements for informed consent

### What is a Federal Wide Assurance (FWA)?

Each institution engaged in research covered by The Common Rule is required to provide written assurance that it will comply with The Common Rule. This written, legally binding assurance is called the FWA. For VA institutions, the FWA is signed by the Medical Center Director as the responsible Institutional Official.

Once signed, the FWA is sent to the VISN Director and the VA Office of Research Oversight (ORO) for concurrence, prior to being sent to the DHHS Office of Human Research Protections (OHRP) for approval. The FWA must designate one or more IRBs that have registered with OHRP as the institution’s IRB(s) of record.

The FWA must be obtained prior to conducting any research involving human subjects.

### What is an Institutional Review Board (IRB)?

The IRB is a committee comprised of scientists and non-scientists that has been established to protect the rights and welfare of human research subjects.

The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction, as specified by both the federal regulations and local institutional policy.

An IRB’s decision to disapprove, suspend or terminate research cannot be overruled by the Research Development (R&D) Committee or Medical Center Director. If an IRB of another institution is used, there must be a Memorandum of Understanding outlining both parties’ responsibilities.

### Which research requires IRB review and approval?

The Common Rule defines research as a systematic investigation—including research development, testing and evaluation—designed to develop or contribute to generalizable knowledge. It also defines a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains:

- Data through intervention or interaction with the individual, **or**
- Identifiable, private information

The Common Rule lists categories of research exempt from the requirement for IRB approval. Any research project involving human subjects thought to be exempt must be submitted to the IRB for determination of exempt status.

### What are the additional requirements for research involving human subjects?

Research involving human subjects must also be reviewed and approved by the institution’s R&D Committee prior to initiation of the research. The research must also comply with VHA requirements for tissue banking and the involvement of vulnerable persons such as pregnant women and those who are cognitively impaired and economically or educationally disadvantaged.

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