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Fast Facts June 2014

The Common Rule: Protection of Human Research Subjects

The Common Rule (45 CFR Part 46, Subpart A) protects most human subjects involved in federally-funded research. Except in specified circumstances, research institutions subject to the Common Rule must secure informed consent from each human subject, receive approval from an Institutional Review Board (IRB), and submit assurance of compliance with the regulation in writing to the appropriate federal department or agency before research can begin.

What Research Does the Common Rule Apply to?

The Common Rule applies to all human subject research that is conducted or supported by one of the 18 federal departments and agencies who follow the Common Rule, unless the research falls within one of the exceptions. The Common Rule generally does not apply to human subject research involving education practices, tests or procedures that are used to study public behavior, existing and publically-available data, evaluations of public benefit programs, and certain consumer food studies.

What is the "Informed Consent" Requirement?

Each potential human subject must first be presented with information regarding the research, including information about potential risks and benefits, information about the expected scope of confidentiality, disclosure of other possible treatments or procedures that could benefit the subject, and information regarding compensation or medical treatment should injury occur. Participation must be voluntary and additional consent requirements are permitted. Documentation of informed consent must be signed by the subject or someone legally authorized to sign on the subject's behalf. The informed consent requirement can only be waived if the research is conducted by a local or state government on public benefits or if the research does not pose more than a minimal risk and cannot be carried out without alteration to the informed consent requirement.

What Does the IRB Review Process Entail?

IRBs are made up of at least five members from professionally diverse backgrounds and may approve, disapprove, or require modifications to research proposals. The criteria for approval include that the risks to the subjects are reasonable and minimized, that subjects are selected equitably, that the informed consent requirement is satisfied, and if applicable, that appropriate safeguards to protect the confidentiality of subject information are included. Expedited review is possible in a narrow set of circumstances, including when the research has been approved in recent years with minor changes. IRBs must complete continuing review at least once a year. An IRB may suspend or terminate approval of research if the research does not comply with the Common Rule or with the requirements set out by the IRB.

For more information on state and federal laws related to research, click here. For more information about the Common Rule, see the full summary here. *Follow us on Twitter at **@HealthInfoLaw***