RESEARCH WITH SUBJECTS LIKELY TO MANIFEST OR DEVELOP DECREASED DECISIONAL ABILITY

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

PURPOSE:

Federal regulations and the MCW IRB require that subjects provide written consent prior to their involvement in human subjects research unless the IRB has approved a waiver of consent procedures per 45 CFR 46.116(c)(d) or 45 CFR 46.101(i).

If an adult lacks capacity to consent, federal regulations require that informed consent is obtained from a legally authorized representative (LAR).

MCW IRB considers subjects who have or are likely to develop decreased decisional abilities as a vulnerable population. For all vulnerable populations, Federal regulations require that the IRB ensures that "additional safeguards [are] included in the project to protect the rights and welfare" of all subjects that are "likely to be vulnerable to coercion or undue influence."

This document outlines institutional requirements, and provides guidance to faculty and staff who may wish to engage in research with subjects who currently have decreased decisional ability or are likely to develop decreased decisional ability in the future.

DEFINITIONS:

consent process, and provide the LAR with documentation of the subject's wish to continue participation after becoming decisionally impaired.

For most projects, informed consent should not be elicited and documented on the same day that the subject is first presented with information about the project. This principle is particularly important for projects that raise questions about decreased decisional ability in some subjects. Questions from potential subject and family members should be encouraged, and handouts of frequently asked questions and answers regarding specific human subject protections may be prepared. Communication between members of the research team, subjects, and their families is key to successful research participation.

Individuals who are decisionally impaired may need more time to consider the information they are given about a research protocol. Information should be provided incrementally to facilitate understanding. Planning built-in waiting periods within the consent process may be useful to allow potential subjects time to consult with family members about participation.

Finally, for all projects that raise questions about some of the subjects' ability to participate in the consent process, Investigators should plan and deliver ongoing educational efforts with subjects during the lifetime of the project to enhance research subjects' understanding and appreciation of their role in the research. Because informed consent is an ongoing process throughout the course of a protocol, assessing and enhancing comprehension at each stage is essential. Single sheet summaries of important information about key elements of a project may be useful when provided on a regular basis.

For projects which represent a "minor increase over minimal risk" (e.g., MRI with sedation, indwelling catheters for short duration), the IRB may recommend additional safeguard protections on a project-by project-basis.

REFERENCES:
45 CFR 46.101(i)
45 CFR 46.102 (c)
45 CFR 46.116(c)(d)
21 CFR 50.3 (1)

SUPPORTING DOCUMENTS:
IRB SOP: Legally Authorized Representatives (LARs): Who Can Consent to Research on Behalf of an Adult Subject with Decreased Decisional Ability

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