U-MIC TRANSCRIPT
Informed Consent in an Emergency Care Setting

In certain circumstances, it is possible to obtain legally effective informed consent in an urgent or emergency care setting. In other cases, an urgent health issue may compromise individuals' ability to make objective and fully informed decisions about whether to take part in research.

Whether consenting an individual in an emergency setting is appropriate depends on

- the expected medical condition of the prospective subject population
- the nature of the research
- whether there will be sufficient time for potential subjects (or their legally authorized representatives) to consider study participation
- and whether the circumstances for obtaining informed consent appropriately minimize the possibility of coercion or undue influence

When determining whether informed consent in an emergency setting is appropriate for a particular study, the IRB and the researcher must consider several variables, such as:

- What is the likely health and emotional condition of the patient population being considered for the proposed research
    - For example, will potential subjects be conscious but receiving emergency care?

      or

    - Will potential subjects be undergoing preparation prior to surgery?
- What is the likely ability of this population during consent to process information, ask questions, and consider the risk involved?

  and

- What is the timing of the consent process? Is it so close to the receipt of care that the patient might blur the distinction between treatment and research?

Because individuals receiving urgent or emergent medical care may be vulnerable to coercion or undue influence—even if temporarily—additional protections may be required to ensure that a subject's consent to participate in research is truly voluntary and sought under circumstances that minimize the possibility of coercion or undue influence. It may also be possible in some cases to obtain consent from a legally authorized representative (such as in the case of decisionally incapacitated individuals).

If a study meets the criteria defined in federal regulations and in the University of Michigan Medical School's 2007 position statement regarding exception from informed consent for emergency care

research, a researcher may be permitted to enroll human subjects in an emergency setting without obtaining their informed consent.

Visit the OHRP web site—or contact the IRB—for more information about obtaining consent in urgent and emergency care settings.

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