U-MIC TRANSCRIPT
Exception from Informed Consent Requirements for Emergency Research

The Food and Drug Administration's regulation at 21 CFR 50.24 allows a narrow exception to the requirement to prospectively obtain and document informed consent from research subjects. According to the regulation, IRBs may approve certain emergency research protocols in which subjects are unable, due to their medical condition, to give informed consent at the time of enrollment.

Protocols involving exception from informed consent must be performed under a separate investigational new drug application or investigational device exemption even if an IND or IDE for the same drug or device already exists.

Regulatory criteria require that human subjects must be in a life-threatening situation, available treatments must be unproved or unsatisfactory, and there must a need for the collection of scientific evidence to determine certain interventions' safety and effectiveness.

The IRB must determine that obtaining informed consent is not feasible because

- subjects' medical condition prevents them from giving consent
- subjects' condition requires intervention before it's feasible for a legally authorized representative (or LAR) to give consent
- and there is no reasonable way to identify potential subjects in advance

Next, the IRB must find that the research offers subjects potential direct benefit; this determination is based on the following factors:

- subjects face a life-threatening situation that necessitates the intervention
- animal and other pre-clinical studies demonstrate the potential for direct benefit in humans
- and the risks of the research are reasonable considering
    - eligible subjects' medical condition
    - the risks and benefits of standard treatment
    - and the potential benefits of the proposed intervention

The IRB must determine that the proposed research could not practicably be conducted without the exception from informed consent.

The proposed research plan must define

- the period during which the proposed intervention is expected to be effective in treating subjects' condition—this is called the therapeutic window
- how the researcher will attempt to contact each subject's LAR and, if feasible, obtain his or her consent within the therapeutic window
- and how the researcher will summarize attempts to contact and obtain consent from each subject's LAR

IRBMED must review and approve an informed consent document and process for use in instances

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where it is feasible to obtain consent from subjects or their LARs.

Similarly, IRBMED must review and approve procedures or information that researchers will use when giving LARs and family members an opportunity to object to a subject's involvement in the research.

Before beginning the research, the researcher must also provide additional protections of the rights and welfare of subjects. These include

- consultation with representatives of the communities in which the research will be conducted and from which subjects will be drawn
- public disclosure to those communities, prior to initiating the research, of plans to conduct the research and its expected risks and benefits
- public disclosure of sufficient information following completion of the research, to make the communities and other researchers aware of subjects' demographics and the study's results
- and establishment of an independent data monitoring committee to oversee the research

The IRB is responsible for ensuring that procedures are in place to inform, as soon as feasible, each subject, his or her LAR, or a non-LAR family member of

- the subject's involvement in the research
- details about the research
- all information contained in the informed consent document
- and the right to withdraw from the research at any time without penalty if the subject, an LAR, or a member of the subject's family so wishes

If an LAR or family member has agreed to the research and the subject's condition improves, the researcher must inform the subject about the research as soon as feasible.

Contact the IRB for more information about exception from informed consent in emergency care research.

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