Exception From Informed Consent

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Outline

- What is an Exception From Informed Consent?
- Process for Review of Exception From Informed Consent Submissions
- Requirements for an Exception From Informed Consent
- References

	Waiver of Consent	Alteration of Consent	Waiver of Documented Consent	Exception from Informed Consent (EFIC)
Consent Process?	No	Yes	Yes	Eventually[v]
Consent Document/ Information Sheet?	No	Yes	Yes	Yes
Elements of Consent Changed or Missing?	No	Yes	Maybe*	Maybe*
Consent Signed by Subject/LAR?	No	Maybe*	No	Eventually[v]

*The alteration of consent may be combined with the waiver of documented consent or EFIC when all criteria are met.

[v]EFIC requires that there be a consent process and signed consent when practicable. For subjects enrolled without consent, researchers must continue to attempt to obtain consent after enrollment.

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What is an Exception From Informed Consent?

- Anytime:
  - A subject is in a life-threatening situation; and
  - There is not time to obtain consent from the subject or LAR before the research intervention occurs; and
  - It isn't possible to obtain informed consent ahead of time; and
  - The IRB approves the research proceeding without informed consent.
- Generally few and far between
- Requires community consultation and public disclosure
  - Does not require "community consent"

Process to Review EFIC Submissions

IRB Review

- Verify the study qualifies for EFIC determination
- Review and approve community consultation and public disclosure plans

Community Consultation

- Researcher conducts community consultation and initial public disclosure plan
- Researcher summarizes community input and provides to IRB

IRB Review

- Review the community consultation and public disclosure summary
- Ensure all other criteria for approval are met
- Determine whether the study can be approved as EFIC

Requirements for Exception From Informed Consent

- The research is not subject to regulation by a Common Rule agency other than DHHS or DoD
- The research does not involve prisoners as subjects
- The research does not involve pregnant subjects, fetuses, non-viable neonates, or neonates of uncertain viability

Requirements for Exception From Informed Consent

Study Characteristics:

- The subjects to be enrolled are in a life-threatening situation
- Available treatments/interventions are unproven or unsatisfactory
- The collection of scientific evidence is necessary to determine the safety and effectiveness of particular interventions
  - Could include randomized placebo-controlled investigations
- Participation holds out the prospect of direct benefit to subjects
- Appropriate animal and other preclinical studies support the potential for direct benefit to subjects
- Risks of the study are reasonable in relation to:
  - The medical condition of the potential class of subjects; and
  - The risks and benefits of standard therapy; and
  - What is known about the risks and benefits of the intervention or activity
- The protocol defines the therapeutic window based on scientific evidence

Requirements for Exception From Informed Consent

Consent Considerations:

- The IRB reviews and approves a consent process and consent document in accordance with OIA-314
- Obtaining informed consent is not feasible because:
  - Subjects will not be able to give consent due to their medical condition
  - The intervention must be administered before obtaining LAR consent is feasible
  - There is no reasonable way to prospectively identify likely subjects
- The research could not be practicably carried out without the waiver
- The investigator has committed to attempting to contact
  - A LAR for consent within the therapeutic window
  - A non-LAR family member to see if they object to the subject's enrollment within the therapeutic window
- The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object
- Family member means any of:
  - Spouse, Parents, Children (including adopted children), Siblings, Spouses of Siblings, and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship

Requirements for Exception From Informed Consent

Additional Protections for Subjects' Rights and Welfare:

- *Consultation with representatives of the communities in which the research will be conducted and from which subjects will be drawn
  - "Community Consultation"
- *Public disclosure **prior to initiation** of the risks and expected benefits to the communities in which the research will be conducted and from which subjects will be drawn
- Public disclosure **after completion** of sufficient information to apprise the community and researchers of the study, demographics of the research population, and its results
- Establishment of an independent data monitoring committee to exercise oversight of the research

NOTE: Initial IRB approval will allow the research team to conduct items with a *. Subsequent IRB approval will allow conduct of the study.

Requirements for Exception From Informed Consent

Informing Subjects, LARs, and/or Family Members After Enrollment:

- Subjects, their LARs (if subject still incapacitated), or (if LAR not available) their family members will be informed at the earliest opportunity of:
  - The subject's enrollment in the research; and
  - The details of the investigation; and
  - Any other information contained in the informed consent document
- If a LAR or family member is informed and the subject's condition improves, the subject is also to be informed as soon as feasible
- If consent is not obtained and the subject dies before a LAR or family member can be contacted, information about the research is to be provided to the LAR or family member, if feasible

Requirements for Exception From Informed Consent

FDA Requirements:

- A licensed physician not participating in the research must concur with the IRBs findings
  - May be an IRB member or consultant to the IRB
- The protocol must be conducted under a separate IND or IDE clearly indicating it is for subjects who cannot consent

DoD Requirement:

- The Secretary of Defense must approve a waiver of the advance informed consent requirement

References

- 10 USC 980
  - DoD allowance for informed consent waiver
- 21 CFR 50.24
- DHHS Emergency Research Consent Waiver
- OIA-419