

SOP: SC 503 Version No: 05 Effective Date: 12/3/10	EMERGENCY RESEARCH EXCEPTION FROM INFORMED CONSENT	Supercedes Document Dated: 7/1/08
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POLICY

Steering Committee approved 10/17/11

The federal regulations for the protection of human subjects in research require informed consent with-few exceptions. However, federal regulations provide an exception for a limited class of research activities involving human subjects who are in need of emergency medical intervention but who cannot give informed consent because of their life-threatening medical condition, and who do not have an available legally authorized person to represent them. The intent of the regulation is to allow specified research on life-threatening conditions for which available treatments are unproven or unsatisfactory and where it is not possible to obtain informed consent while establishing additional protections to provide for safe and ethical studies.

1.1. Research in Emergency Settings

1.1.1. For review of FDA-regulated research involving waiver of informed consent for planned emergency research, the Primary Reviewer takes the IRB through the determinations in SC 503-A to determine whether the research can be approved under applicable regulations and to make all other required determinations. The IRB provides protocol-specific determinations justifying each regulatory determination to the RSPP staff taking minutes, and the RSPP staff document in the minutes the regulatory determinations and protocol-specific findings justifying those determinations.

Protocols involving an exception to the informed consent requirement must be performed under a separate investigational new drug application (IND) or investigational device exemption (IDE) that clearly identifies such protocols as protocols that may include subjects who are unable to consent. The submission of those protocols in a separate IND/IDE is required even if an IND of the same drug product or an IDE for the same device already exists.

1.1.2. For review of research that is not FDA -regulated and that involves waiver of informed consent for planned emergency research, the primary reviewer takes the IRB through the determinations in SC 503-B to determine whether the research can be approved and to make all other required determinations. The IRB provides protocol-specific determinations justifying each regulatory determination to the RSPP staff taking minutes, and the RSPP staff document in the minutes the regulatory determinations and protocol-specific findings justifying those determinations.

1.1.3. If the study does not involve an FDA-regulated product but is funded by HHS, information regarding the IRB's basis for the waiver of informed consent will be submitted to the agency Secretary for concurrence that the waiver is appropriate, in accordance with HHS guidance set forth at 61 Fed. Reg. 51531-33 (Oct. 2, 1996).

1.1.4. If the IRB determines that it cannot approve a research protocol because the research does not meet the criteria in the exception or because of other relevant ethical concerns, the IRB will document its findings and provide these findings promptly

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in writing to the investigator and to the sponsor of the research.

2. SCOPE

This SOP applies to all research studies involving human subjects who are in need of emergency medical intervention but who cannot give informed consent because of their life-threatening medical condition.

3. APPLICABLE REGULATIONS, GUIDELINES AND STANDARDS

21 CFR 50.24

45 CFR 46.101(i), 46.116 and 46.117

FDA IRB Information Sheets 1998

61 Fed. Reg. 51531-33 (Oct. 2, 1996)

AAHRPP Elements II.3.G., II.4.B., and II.4.C.

4. REFERENCES TO OTHER APPLICABLE SOPS

SOP 701

SOP 1201