



FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL
AND MASSACHUSETTS GENERAL HOSPITAL

Title:	Exception from Informed Consent Requirements for Emergency Research
Department:	Human Research Affairs/Research Management
Policy Type:	<input checked="" type="checkbox"/> Partners System-wide <input type="checkbox"/> Partners System-wide Template <input type="checkbox"/> Partners Corporate <input type="checkbox"/> Partners Corporate Departmental <input type="checkbox"/> Entity
Applies to:	Employees, Professional Staff or Other Agents of Brigham and Women's Hospital (BWH), Faulkner Hospital (FH) and Massachusetts General Hospital (MGH)
Approved by:	Chief Scientific Officer
Approval Date:	September 9, 2010
Effective Date:	September 9, 2010
Revision Date(s):	
Next Review Date:	September 9, 2013
Contact Person:	Director, Human Research Review and Compliance

KEYWORDS:

IRB, Institutional Review Board

PURPOSE:

The purpose of this policy is to define the procedures the Partners Human Research Committees (PHRC) follow when reviewing an exception from informed consent requirements for emergency research or emergency research consent waiver.

DEFINITIONS:

See Definition of Human-Subjects Research

POLICY STATEMENT:

The PHRC will approve exceptions from informed consent requirements for planned emergency human-subjects research only if the PHRC finds and documents that the research satisfies all of the requirements of 21 CFR 50.24 for an exception from informed consent requirements for emergency research and 45 CFR 46.101(i) for emergency research consent waiver.

PROCEDURES:

Investigators requesting an exception or waiver from the requirement to obtain informed consent for planned emergency research must provide sufficient information in the protocol submission for the PHRC to find and determine whether the research satisfies all of the requirements of 21 CFR 50.54 for an exception from informed consent requirements for emergency research and 45 CFR 46.101(i) for emergency research consent waiver.

The emergency research consent waiver does not apply to research involving fetuses, pregnant women, and human in vitro fertilization (Subpart B of 45 CFR 46) and research involving prisoners (Subpart C of 45 CFR 46).

For the purposes of the emergency research consent waiver “family member” means any one of the following legally competent persons: spouses; parents; children (including adopted children); brothers, sisters, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship.

Protocol Submission Requirements

When submitting research requesting an exception from informed consent requirements for emergency research, the investigator must address each of the required PHRC findings and determinations in the protocol submission, specifically:

- Justification for the research;
- Justification for waiver of informed consent;
- Relation of risks to anticipated benefits;
- Informed consent procedures and an informed consent document consistent with 21 CFR 50.25 and 45 CFR 46.116;
- Impracticability of conducting the research without the waiver of informed consent;
- Therapeutic window and consent process;
- Plan for community consultation;
- Plan for public disclosure prior to and after completion of the clinical investigation;
- Establishment of an independent data monitoring committee to oversee the clinical investigation;
- Procedures followed when attempting to contact a family member who is not a legally authorized representative, within the therapeutic window and asking whether he or she objects to the subject’s participation in the clinical investigation when obtaining informed consent is not feasible and a legally authorized representative is not reasonably available;
- Procedures to inform, at the earliest feasible opportunity each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of the subject’s inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent document, that he or she may discontinue the subject’s participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
- Procedures to inform the subject should the subject’s condition improve; and
- If feasible, procedures to provide the subject’s legally authorized representative or family member with information about the clinical investigation should the subject die before a legally authorized representative or family member can be contacted.

PHRC Findings and Determinations

The PHRC must make and document the following findings and determinations:

1. Conducting the research is justified because:
 - The human subjects are in a life threatening situation;
 - Available treatments are unproven or unsatisfactory; and
 - The collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
2. Waiving informed consent is justified because:
 - The subjects will not be able to give informed consent as a result of their medical condition;
 - The intervention under investigation must be administered before consent from the subjects' legally authorized representative is feasible; and
 - There is no way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.
3. The risks are reasonable in relation to the anticipated benefits because:
 - Subjects are facing a life-threatening situation that necessitates intervention;
 - Approval animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects; and
 - Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.
4. The clinical investigation could not practicably be carried out without the waiver.
5. The investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a legally authorized representative contacted for consent within the window rather than proceeding without consent. The investigator will summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the time of continuing review.
6. The IRB has reviewed and approved informed consent procedures and an informed consent document consistent with 21 CFR 50.25 and 45 CFR 46.116. These procedures and the informed consent document are to be used with subjects or their legally authorized representatives in situations where use of such procedures and documents is feasible. The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the clinical investigation consistent.
7. The following additional protections of the rights and welfare of subjects will be provided:
 - Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn;

- Public disclosure to the community in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation, or plans for the investigations and its risks and expected benefits.
- Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results;
- Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation; and
- If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the subject's family member who is not a legally authorized representative, and asking whether he or she objects to the subject's participation in the clinical investigation. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.

Additional PHRC Responsibilities

The PHRC is responsible for ensuring that procedures are in place to inform, at the earliest feasible opportunity each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent document. The PHRC must also ensure that there is a procedure to inform the subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. If the legally authorized representative or family member is told about the clinical investigation and the subject's condition improves, the subject is also to be informed as soon as feasible. If a subject is entered into a clinical investigation with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the clinical investigation is to be provided to the subject's legally authorized representative or family member, if feasible.

Record Keeping

The PHRC determinations required above must be retained by the PHRC for at least 3 years after completion of the clinical investigation, and the records will be accessible for inspection and copying by the FDA.

Investigational New Drug (IND) or Investigational Device Exemption (IDE)

Protocols involving an exception to the informed consent requirement under FDA regulations 50.24 must be performed under a separate IND or 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 for the same drug product or an IDE for the same device already exists. Applications for investigations involving an exception to the informed consent requirement may not be submitted as amendments to an existing IND/IDE.

Notifying Investigators and FDA of Disapproval of a Clinical Investigation Involving Exception from Informed Consent Requirements for Emergency Research

If the PHRC disapproves a clinical investigator because the investigation does not meet the criteria in the exception requirement above, the PHRC must document its findings and provide these findings promptly in writing to the investigator and to the sponsor of the investigation. The

sponsor of the clinical investigation must promptly disclose this information to FDA and to the sponsor's clinical investigators who are participating or are asked to participate in this or a substantially equivalent clinical investigation of the sponsor, and to other IRB's that have been, or are, asked to review this or a substantially equivalent clinical investigation by that sponsor.

OTHER APPLICABLE PARTNERS HEALTHCARE POLICIES:

Informed Consent of Research Subjects

REFERENCE:

45 CFR 46

21 CFR 50, 56, 312, 812

OHRP Report Informed Consent Requirements in Emergency Research

DEVELOPMENT AND CONSULTATION

Human Research Office

Reviewed by:	Original Review Date:	Revision Approval Dates: