	University of Puerto Rico Medical Sciences Campus Human Research Subjects Protection Office	Effective: 9/1/2008
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PROCEDURES FOR DETERMINING EXEMPTIONS

DHHS regulations describe six categories of research that may qualify for exemption of 45 CFR 46 requirements. Although the regulations do not address a maximum risk level, it is implicit within the concept of exempt research that there must be very little, if any associated risk.

FDA regulation 21 CFR 50.24 defines criteria for exception of informed consent in emergency research. A separate policy below addresses this situation.

Policy:

The IRB retains final judgment for determining if a research activity qualifies for exempt review status. Exemptions may be granted for two groups of activities. The first are those activities that do not constitute research with human subjects as specifically defined by Federal regulations (45 CFR 46.102 (d) (f)). The other group includes those activities designated as exempt by 45 CFR 46.101(b).

To determine if a research activity is exempt from 45 CFR 46 requirements in accordance with the federal policy, the researcher shall complete the electronic application form and submit it to the IRB.

Procedure:

The UPR MSC IRBs are responsible for reviewing the preliminary determinations of exemption by investigators and for making the final determination based on the CFRs. All nonexempt research will be reviewed in accordance with 45 CFR 46.

If an investigator believes that his or her research activities may be exempt from review, the investigator should submit an electronic application through the IRBWISE for the research study indicating the category of exemption requested.

The IRB office staff will pre-review the research project application to make a preliminary determination of exemption. Investigators are contacted as appropriate to provide clarification and/or documentation prior to IRB review. Once complete, the application, including all of the supporting documents, is forwarded to the corresponding Chairperson. Only submissions fulfilling all IRB administrative requirements (such as complete proposal, survey instruments and letters of authorization, etc.) will be forwarded for IRB review. The IRB Office will forward submissions to the corresponding IRB Chair at least one week prior to the panel meeting. Urgent items can be forwarded to any Chair at any time.

The Chair or his or her designee will review the application. If the research is clearly exempt, the investigator will be notified in writing and the decision reported at the next convened meeting of the corresponding IRB panel's and the meeting minutes. If the research is not clearly exempt, and the application contains sufficient information, the request will be forwarded to the IRB Committee for review at its next convened meeting. Research which is not exempt may be suitable for review under expedited review procedures. The investigator will be notified in writing of the final decision.

When research is determined to be exempt, the meeting minutes and the letter to the investigator will include a citation to the applicable regulatory section that was the basis for the exemption.

45 CFR 46 Defined categories for exempt review:

Research in which the only involvement of human participants is in one or more of the following categories may be exempt from IRB review:

(a) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(b) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(c) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(d) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(e) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or

alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(f) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

No research is exempt if any of the targeted populations for this research consists of persons who are:

- Legally incompetent;
- Significantly mentally ill or impaired; or
- Vulnerable to extraordinary institutional coercion, such as prisoners, residents of 24-hour skilled nursing facilities, or anyone who is involuntarily confined.