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I. PURPOSE

To outline the criteria required for approval by the CHOP IRB.

II. POLICY STATEMENT

All research that involves human subjects must be approved by the IRB before the research activities commence. The research must meet certain criteria before study related procedures can be initiated. The criteria are based on the principles of justice, beneficence and autonomy as discussed in the Belmont Report and as specified in Federal regulation (45 CFR 46.111 and 21 CFR 56.111). In addition, certain other criteria unique to the CHOP system may apply and must be met as well.

III. SCOPE

These policies and procedures apply to all IRB members and staff and to research submitted to the IRB.

IV. DEFINITIONS


Sound Research Design: means that the study has (1) well defined goals and objectives which have scientific and social value, (2) scientific validity consistent with the stated objectives, (3) is feasible, (4) the researcher is capable of successfully conducting the proposed research and (5) the plan provides sufficient evidence to ensure the likelihood of fruitful results.

V. PROCEDURES

In order for a research project to be approved the IRB must make a number of findings.

A. Meets the criteria of 45 CFR 46.111 and 21 CFR 56.111


1. Risks to subjects are minimized:
 - (a) By using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to undue risk, and
 - (b) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result.
 - (a) In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and

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benefits of therapies that subjects would receive even if not participating in the research). The IRB will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment the IRB will take into account the following:
 - (a) The purposes of the research,
 - (b) The applicable population with the disorder or condition, and
 - (c) The setting in which the research will be conducted.
 - (d) The IRB will be particularly cognizant of the special problems of research involving potentially vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or their legally authorized representative, in accordance with and to the extent required by appropriate local, state and federal regulations. (SOP 706)
5. Informed consent will be appropriately documented as required by local, state and federal regulations. (SOP 701)
6. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. (SOP 803)
7. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.
8. When some or all of the subjects, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study and in the IRB review process, to protect the rights and welfare of these subjects. (SOP 501-505)
9. Studies are reviewed at periods appropriate to the degree of risk research subjects are exposed due to their participation in the study. (SOP 404)


B. Meets the institutional requirements established by Ancillary Committees (as applicable)

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1. The following documents must be available for the IRB to review at the time of the convened meeting:
 - (a) Scientific Review Committee review form (for investigator-initiated prospective studies not subject to external review)
2. The approval from the following must be available for the IRB to allow initiation of the research.
 - (a) Biosafety Committee review
 - (b) Radiation Safety committee
 - (c) Pharmacy
 - (d) Radiology
 - (e) Pathology
 - (f) Technology Transfer
 - (g) Conflict of Interest Committee determination (if a potential COI is disclose)

C. Research Conducted at Locations Outside of CHOP

Under criteria for approval in cases where research conducted by a CHOP investigator will take place in locations distant from CHOP, the CHOP IRB will review and incorporate as relevant, the OHRP guidance on Knowledge of Local Research Context.

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VI. ROLES AND RESPONSIBILITIES


Title	Responsibility
Director, Human Subject Research	Director, HSR and Analysts are responsible for ensuring that IRB reviewers have all the tools and resources needed to complete their research reviews
Chair, CPHS	IRB Chairperson (or designee) is responsible for ensuring that the research satisfies the criteria for IRB approval.

VII. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.111	21 CFR 56.108, 56.111
	OHRP Guidance on Knowledge of Local Research Context: http://www.hhs.gov/ohrp/humansubjects/guidance/local.htm

VIII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 305: Cooperative Agreements	SOP 501: Vulnerable Subjects
SOP 502: Pregnant Women, Fetuses and Neonate	SOP 503: Prisoners
SOP 504: Children (Additional Protections)	SOP 505: Minors Who are Not Children in the Research Context
SOP 701: Informed Consent Documentation	SOP 706: Waiver of Informed Consent
SOP 803: Data and Safety Monitoring Plans	SOP 707: Requirements for and Documentation of HIPAA Authorization in Research

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IX. ATTACHMENTS

The IRB Reviewer Forms are embedded in the electronic IRB management system. Additional reviewer forms and checklists with criteria for approval are available on the IRB website.

X. REVISIONS:

3/21/08: Revised due to changes in IRB office staff responsibilities and AAHRPP recommendations and inclusion of HIPAA required elements.

4/6/09: Revised to refer to HIPAA required elements in SOP 707

6/15/10: Revised to update the links to reviewer forms, to reflect changes in the names of ancillary committees, and to add information for research conducted outside of CHOP.

2/13/2013: Editorial changes.

XI. APPROVAL:

 Director, Human Subject Research

 Date

 Chair, Committees for the Protection of Human Subjects

 Date