I. PURPOSE

The purpose of this SOP is to outline the criteria required for approval by the CHOP IRB.

II. POLICY STATEMENT

All non-exempt research that involves human subjects must be approved by an IRB before the research activities commence. The research must meet specified 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). Additional institutional requirements may apply.

III. SCOPE

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

IV. DEFINITIONS

Relying Institution: The institution that has assigned an external IRB to serve as the Reviewing IRB under an IRB Authorization Agreement.

Sound Research Design: 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 non-exempt human subjects research 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 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.

   (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 or individuals with impaired decision-making capacity, 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, individuals with impaired-decision making capacity, 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. (**SOPs 501, 502, 503, 504** and **505**)

9. Studies are reviewed at periods appropriate to the degree of risk research subjects are exposed due to their participation in the study, in accordance with regulatory requirements. (**SOP 404**)

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

1. The following documents must be available for the IRB to review at the time of the convened IRB meeting:

   (a) Scientific Review Committee review according to the CHOP Policy on the Scientific Review of Protocols.

2. The approval from the following groups must be available for the IRB to allow initiation of the research, as applicable.

   (a) Institutional Biosafety Committee

   (b) Radiation Safety Committee

   (c) Contracting

   (d) IND/IDE Support Office

   (e) Medical Device Committee

   (f) Pharmacy

   (g) Radiology

   (h) Pathology

   (i) Primary Care

   (j) Adolescent Clinic

   (k) Legal Counsel

   (l) Conflict of Interest Committee

C. Meets the additional local context requirements for Relying Institutions

In order for human subjects research to be approved by the CHOP IRB for a relying institution, the IRB must also determine that the research is approvable in consideration of the relying institution's local research context (OHRP Guidance on Knowledge of Local Research Context).

VI. ROLES AND RESPONSIBILITIES

Title	Responsibility
Director, Human Subjects 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 404: Continuing Review of Approved Research	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 Elements of Consent and Waiver of Written Authorization
SOP 803: Data and Safety Monitoring Plans	

IX. ATTACHMENTS

The IRB Reviewer Forms are embedded in the electronic IRB management system.

CHOP Scientific Review of Protocols Policy can be found at https://intranet.research.chop.edu/display/deptoctr/Scientific+Review+of+Protocols.

X. REVISIONS:

3/21/08:	Revised due to changes in IRB 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.
9/25/2018:	Revised to include editorial changes and to update the SOPs referenced in the policy.
1/22/2019:	Revised to update SOPs referenced in this policy.

XI. APPROVAL:

Director, Human Subjects Research	Date
Chair, Committees for the Protection of Human Subjects	Date