I. PURPOSE

The purpose of this SOP is to describe the process for reviewing research that will be conducted by CHOP researchers outside of the United States.

II. POLICY STATEMENT

The IRB will review human subjects research studies involving subjects enrolled at international sites by CHOP researchers to ensure that (1) the research complies with all federal regulations and CHOP IRB SOPs and (2) that local regulations governing human involvement in research are adequate to ensure proper protections for subjects. When the IRB determines that the research is exempt from the requirements of 45 CFR 46, the investigators are responsible for ensuring that research complies with local regulations and requirements.

III. SCOPE

These policies and procedures apply to all non-exempt human subjects research submitted to the IRB that is being conducted by CHOP researchers at an international location and that will be under a local IRB/ethics committee. CHOP will only approve non-exempt research that has documented approval from the local IRB, Research Ethics Committee or other comparable regulatory or ethical body as appropriate to the country or region.

IV. DEFINITIONS

Ethics Committee: A group of individuals who have knowledge about the local laws and/or traditions/customs who are also responsible for ensuring the safety and ethical treatment of subjects in proposed research projects.

International Location: A location outside of the United States.

Ministry of Health: A government office responsible for providing and supervising health services; often responsible for reviewing and approving research activities in the country.

V. PROCEDURES

A. Additional Requirements

In addition to the usual requirements for approval for non-exempt research involving human subjects as outlined in **SOP 105**, when CHOP researchers will conduct or supervise research conducted outside the United States, the IRB will consider the following:

1. The experience of the CHOP investigator in working in this area or region and the investigator's knowledge of the area or region as it relates to the research.
2. The appropriateness of the provisions for the CHOP researcher to ensure ongoing

review and approval from the CHOP IRB.

3. The appropriateness of the provisions for reporting unanticipated problems involving risks to subjects or others, complaints and non-compliance to the CHOP IRB.
4. A process for obtaining consent that is appropriate given the local laws/customs/traditions.
5. Documentation of local IRB or Ethics Committee review and approval. When applicable, there will be appropriate coordination and communication between the CHOP IRB and the local Research Ethics Committee.

B. Research Funded by the Department of Defense

When the research is funded by the Department of Defense, or involves DoD personnel, the CHOP IRB will adhere to the policies as outlined in **SOP 107**.

VI. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46	21 CFR 50 / 21 CFR 56
International Compilation of Human Research Protections: http://www.hhs.gov/ohrp/international/HSPCompilation.pdf	OHRP Guidance on International Research: http://www.hhs.gov/ohrp/international/
Council for International Organization of Medical Sciences: http://www.cioms.ch/	

VII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 105: IRB Review Process	SOP 107: Department of Defense Funded Research

VIII. RESPONSIBILITIES

Title	Responsibility
Chair, CPHS	The IRB Chair is responsible for reviewing submissions eligible for expedited review or selecting a designee and ensuring that local requirements for human subjects research are met.
Analyst, IRB	IRB Analyst is responsible for processing and assisting the IRB reviewer with studies being conducted internationally.
Investigator	The investigator is responsible for ascertaining and complying with all local requirements for the protection of human subjects research.

IX. ATTACHMENTS

X. REVISIONS:

5-29-2013: Revised to include coordination and communication between the CHOP IRB and the local Ethics Committee

7-22-2015: Revised to address exempt research

9-25-2018: Revised to include editorial changes.

XI. APPROVAL

Director, Human Subjects Research _____ Date _____

Chair, Committees for the Protection of Human Subjects _____ Date _____