Harvard Pilgrim Health Care, Inc.
Harvard Pilgrim Health Care Institute, LLC
Office of Sponsored Programs

Policy and Procedure

TITLE: Applicability of Local and International Laws

PURPOSE:

To describe the process for identifying applicable laws in the localities where human subjects research is conducted and for resolving differences between federal, international, state and local laws.

PERSONS AFFECTED:

This policy & procedure (P/P) applies to all Harvard Pilgrim Health Care, Inc. (HPHC) and Harvard Pilgrim Health Care Institute, LLC (HPHCI) (collectively, HPHC/I) personnel engaged in research, teaching or research administration activities in support of the charitable and educational mission of HPHC.

POLICY:

Whether human subjects research is conducted in the United States (U.S.) or abroad, HPHC/I personnel are responsible for understanding and observing the laws as well as the cultural context of the locality where that research occurs. When there are differences between federal, international, state, and local laws, those involved in the research activity shall apply the law(s) that provide the research subjects with the most protection. When the research is sponsored by a U.S. federal agency, the regulations of that agency normally apply to research conducted abroad. However, the federal sponsoring agency may determine that the foreign laws or regulations afford protections that are at least equivalent to those protections provided by federal law, or are consistent with the principles of the Belmont Report, and may approve the substitution of the foreign procedures in lieu of the procedural requirements required under federal law.

DEFINITIONS:

See the GLOSSARY for definitions of the terms listed below:

Children
Guardian

Health Care Agent
Laws
Legally Authorized Representative

PROCEDURE:

1. Institutional Review Board (IRB) members and investigators are required to know, understand and consider all laws applicable to a particular study, regardless of the jurisdiction where the research is conducted.

2. For each research project, the principle investigator ("PI") shall submit the following documents with the Initial Application:

- list of the jurisdictions (states and countries) where research will be conducted;
- list of citations and summary of all applicable regulation and statutes related to the conduct of research and including, where applicable regulations and statutes that provide additional protection for vulnerable populations, privacy, genetic testing, genetic information, mental health treatment, substance abuse treatment, and reporting of child, elder, or spousal abuse; and
- a description of cultural context, when applicable.

3. When research involves children, wards, adults with impaired decision-making capacity, and other protected populations, the PI must submit copies of all applicable laws pertaining to identification of the "legally authorized representative" (LAR) in all jurisdictions where the research activity will take place. This includes, but is not limited to laws that identify "child", "guardian" and "health care agent" or any other individual involved in decision-making in that jurisdiction.

4. After obtaining the lists of jurisdictions and legal citations and copies of laws from the PI, the Senior Compliance Manager (SCM) shall consult with the Research Integrity & Compliance Officer (RICO).

5. The legal consult shall include a review of the project, identification of the legal risk, and review and application of the applicable law for the jurisdiction of the proposed research.

6. The SCM shall prepare and ensure that the IRB members are educated on the applicable law before the IRB review of the project.

7. During IRB review, in accordance with the Belmont Report principles, the IRB shall ensure that the research subjects are afforded the highest level of protection possible.

8. For more information regarding research that involves children and children who are wards, see the *Policy and Procedure on Informed Consent.* For more information regarding research that involves adults with a diminished capacity to consent, see *Policy and Procedure on Additional Protections for Vulnerable Subjects*.

9. For non-HPHCI sites engaged in human subjects research when HPHC is the prime recipient of federal funding, and the sites obtain their own IRB or Ethics Review Board (ERB) approval, the PI shall include copies of IRB or ERB approval to serve as confirmation that the sites meet requirements of federal, state, local and international laws. The IRB may request additional information as needed.

10. For non-HPCI sites engaged in human subjects research, where HPHC IRB serves as the IRB of record for the sites, state and local context issues will be identified as applicable on the HPHC Cede Request Form for consideration. The IRB may request additional information as needed.

11. Investigators should contact the IRB Office for guidance regarding applicability and the resolution of differences of specific federal, state, local and international laws regarding the conduct of research involving human subjects. The IRB Office may refer the issue to the RICO.

12. When appropriate, during a convened IRB meeting, the IRB shall discuss the applicability of specific laws and cultural context during review and record the results of the discussion in the minutes and may seek additional guidance from the RICO who serves as an ex-officio IRB member who may refer the matter to internal or external legal counsel as applicable.

13. The SCM may seek guidance from RICO during administrative review of the *New Project* submission. The SCM shall record any notes in the comments section of the package in IRBNet which are available to all IRB members prior to and during review.

14. A cultural consultant who has the appropriate expertise may be retained by the IRB as needed.

15. When reviewing research activities conducted in foreign countries, the IRB shall conduct initial and continuing review as well as review of modifications and post approval monitoring in accordance with all applicable HPHC policies and procedures and may review translations of all relevant research documents (including informed consent, recruitment materials, and questionnaires, etc.).

16. Please see *Policy and Procedure on Multi-Site Research* for more details regarding the process for IRB review involving cooperative research conducted at different geographic locations and/or in collaboration with other institutions, including the steps the IRB follows to communicate among the sites involved in the multi-site study on issues other than IRB review, such as reporting of unanticipated problems, protocol modifications, interim results and compliance monitoring.

REVISION HISTORY:

Department: OSP – Research Integrity & Compliance	**Title**: Applicability of Local and International Laws
Effective Date: 01/21/19	**Owner:** Senior Compliance Manager
Replaces P/P Dated: IRB SOP (02/08/17); P/P (07/17/18)	

Related Documents: Policy and Procedures: *Informed Consent, Multi-Site Research*; Reviewer Sheets: Initial Review, Continuing Review, Amendment, Exemption Determination; Supplement A: Special Protections for Children; Cede Request form
References: 45 CFR 46.101; 45 CFR 46.102(i); 45 CFR 46.402(d)-(e); 21 CFR 50.3(l); 21 CFR 50.3(o); 21 CFR 50.3(s); 21 CFR 56.103(c); Federal Register Volume 71, Number 130 (Friday, July 7, 2006) [Pages 38645-38646]; AAHRPP Elements I.1.G. and I.3