



Document Title : **FHI 360 Standards for Research Involving Human Subjects**

Effective Date : 2019-07-12

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Approval Statement : *Electronic signatures and signature dates of those individuals who prepared and approved this document are maintained in the FHI 360 Enterprise Document Management System database.*

Title	FHI 360 Standards for Research Involving Human Subjects	Policy:	POL 06002
		Effective Date:	2019-07-12
		Version:	4

PURPOSE:

To define the ethical, regulatory, and quality standards for the conduct of human subject research at FHI 360.

SCOPE:

This policy applies to FHI 360 staff involved in the conduct of research involving human subjects. Additional requirements may be applicable depending on Sponsor agreements/contracts.

DEFINITIONS:

1. *Clinical trial/study* – Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The term clinical trial and clinical study are synonymous. (Source: ICH E6(R2)).
2. *Human subject* – A living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimen; or (ii) Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens (Source: 45 CFR 46.102(e)(1)).
3. *Investigational product (IP)* – A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication or when used to gain further information about an approved use. (Source: ICH E6(R2)).
4. *Research* – A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. (Source: 45 CFR 46.102(1)).
5. *Sponsor* – An individual, company, institution or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial (Source: ICH E6(R2)).

POLICY:

1. FHI 360 staff shall apply the following ethical, scientific and regulatory requirements in the design, conduct, recording, and reporting of research involving human subjects. Compliance with these requirements provides assurance that the rights, safety, and well-being of human subjects are protected and that the data generated are credible.

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- 1.1. FHI 360 human subject research shall be guided by the ethical principles of the Belmont Report (1979) and the principles that originate from the Declaration of Helsinki.
 - 1.2. FHI 360 staff shall apply Title 45 Code of Federal Regulations (CFR), Part 46, including subparts A, B, C and D (as applicable) to all federally funded research. The fundamental commitment to the protection of human subjects shall be applied to all human subject research conducted by FHI 360, regardless of funding source or site of the research.
 - Studies conducted under a US Food and Drug Administration (US FDA) Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) shall comply with applicable 21 CFR regulations, including 21 CFR 50 - the US FDA regulations for human subject protections.
 - 1.3. FHI 360 human subject research activities shall be implemented in compliance with applicable laws and regulations. Where there are discrepancies between local ethical standards, local laws and regulations, and/or international standards, these will be resolved in consultation with qualified staff in the Office of International Research Ethics (OIRE) and/or Clinical Regulatory and Compliance (CRC) department and/or sponsor (as applicable).
 - 1.4. Clinical trials shall be conducted according to the standards of the International Council for Harmonization Guideline for Good Clinical Practice (ICH E6(R2)).
 - 1.5. FHI 360 staff are responsible for implementing and maintaining quality assurance and quality control systems with written procedures that define the research activities to ensure that studies are conducted and data generated, documented (recorded), and reported in compliance with the protocol, and applicable regulatory requirement(s).
 - 1.6. Human subject research shall be monitored to assess the protection of subjects' rights and welfare, and to ensure that the study is being conducted in accordance with the protocol and applicable regulatory requirement(s).
 - Deviations from the Institutional Review Board (IRB)/independent ethics committee (IEC) approved protocol must be documented and reported in accordance with FHI 360 policies and standard operating procedures.
 - 1.7. FHI 360 staff are responsible for securing agreement from all involved parties to ensure direct access to all study related sites, source data/documents, and reports to allow for monitoring and auditing by FHI 360 qualified staff, the sponsor (when applicable), and inspection by health regulatory authorities.
 - 1.8. Agreements/contracts made with the investigator/institution and any other parties involved with the research study (including sponsors) shall be in writing, as part of the protocol or in a separate agreement.
 - 1.9. Exceptions to this policy may be allowed with written approval from the Business Unit Director, the appropriate research director (or equivalent), CRC Director, and sponsor representative (when applicable).
 - Exceptions shall be documented (1) in the study protocol, if appropriate and feasible; and (2) by a memorandum to the study files with attached written approvals.
2. RESPONSIBILITIES:
- 2.1 Study team leaders, applicable department research directors and principal investigators conducting human subject research are responsible for designing and implementing research activities in accordance with this policy.
 - 2.2 FHI 360 staff is responsible for ensuring the implementation of study procedures according to these standards and documenting any deviations according to established procedures.

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For policy interpretation or questions please contact: Director, Office of International Research Ethics or Director, Clinical Regulatory and Compliance.

RELATED DOCUMENTS:

1. Policies

- POL 06003: Communication with Regulatory Authorities Governing Clinical Research
- POL 06004: Training Requirements for Staff Engaged in Research Involving Human Subjects
- POL 06005: Protection of Human Subject Committee (PHSC)
- POL 06006: Criteria for Protection of Human Subjects Committee (PHSC) Approval of Research
- POL 06007: Institutional Review Board Review for FHI 360 Studies
- POL 06011: Children as Research Participants
- POL 06013: Identification, Assessment and Reporting of Unanticipated Problems and other Adverse Events Involving Risks to Human Subjects or Others
- POL 06014: Research Integrity and Misconduct
- POL 06015: Written Translation Requirements for FHI 360 Human Subject Research
- POL 06016: Handling of Investigational and Non-Investigational Products in Human Subject Research Activities
- POL 06017: Financial Conflict of Interest in Research Activities Funded through US Public Health Service

2. Standard Operating Procedures

- SOP 00001: Management of FHI 360 Policies, Standard Operating Procedures and Associated Documents

3. Appendices

- NA

REFERENCES:

1. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, US Department of Health, Education and Welfare (1979). The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, US Federal Registry 18:44(76):23192-7.
2. US Code of Federal Regulations Title 45 Part 46: Protection of Human Subjects
3. US Code of Federal Regulations Title 21 Part 50: Protection of Human Subjects
4. WMA Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, last amended October 2013.
5. ICH Guidelines: <http://www.ich.org/home.html>

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POLICY REVISION HISTORY:

POL#	Date Reviewed (DD MMM YYYY)	Summary of Changes
118	May 2000	New
118	November 2002	Changes reflected in 118A
118A	October 2004	Changes reflected in 118B
118B	November 2004	Changes reflected in 118C
118C	December 2004	Number change to 118.03
118.03	January 2007	Changes reflected in 118.04
118.04	October 2009	Changes reflected in 118.05
POL 06002	December 2012	New POL# for migration to EDMS
POL 06002	April 2014	Editorial changes and update to requirements
POL 06002	August 2015	Minor change to replace references to RAQA with CRC. Corrected related documents with updated titles. Removed a related document since it's obsoleted. Minor template formats.
POL 06002	January 2017	Updated scope, deleted clinical research definition and updated the definitions for clinical trial/study and investigational product. Added definition for sponsor. Updated policy names and added SOP Manual as a related document. Added ICH as a reference. Deleted Appendix reference since the Belmont Report is listed as a reference.
POL 06002	21 MAY 2019	Updated definitions to comply with ICH GCP E6(R2) and revised common rule 45 CFR 46.