

Columbia University
Central Institutional Review Board
Standard Operating Procedure:
Conflict of Interest and Financial Disclosure Requirements for Relying Sites
XXX Consortium

Effective Date: March 18, 2016

I. Background

The **XXX Consortium** (the “Consortium”) has been formed to conduct one or more research studies (each, a “Consortium Study”) involving multiple research sites (each, a “Site”). A central Institutional Review Board (“IRB”) will be used for all Consortium Studies. The Columbia University (“Columbia”) IRB has been designated as the central IRB (the “CU CIRB”) for the Consortium. As the central IRB, the CU CIRB will be responsible for the review of protocols relating to Consortium Studies (each, a “Consortium Protocol”) and the oversight of those aspects of Consortium Studies that are within the purview of an IRB (“IRB Oversight”). The Columbia University Central Institutional Review Board Standard Operating Procedure: Reliance Process, dated February 23, 2016, relating to the Consortium (the “CU CIRB Reliance SOP”) describes the process by which a Site becomes a Relying Site with respect to Consortium Studies and a Participating Site with respect to a particular Consortium Study, as well as the process for reviewing Consortium Protocols and certain other matters.

This Standard Operating Procedure (“SOP”) describes the requirements relating to conflict of interest and financial disclosure requirements for Relying Sites.

Capitalized terms used herein without definition are defined in Section II.

II. Definitions

CFR: Code of Federal Regulations

CIRB Facilitator: as defined in the CU CIRB Reliance SOP

CIRB Liaison: as defined in the CU CIRB Reliance SOP

Columbia: as defined in Section I.

Columbia Compliance: as defined in Section III(B)(2).

Consortium: as defined in Section I.

Consortium Protocol: as defined in Section I.

Consortium Study: as defined in Section I.

CU CIRB: as defined in Section I.

CU CIRB Reliance SOP: as defined in Section I.

FCOI: as defined in Section III(A).

FCOI Report: as defined in Section III(B)(1).

FDA Regulations: 21 CFR Part 54 (Financial Disclosure by Clinical Investigators); 21 CFR 312.53 and 21 CFR 812.43 (Selecting Investigators and Monitors).

Participating Site: as defined in the CU CIRB Reliance SOP

PHS: Public Health Service.

PHS Consortium Study: any Consortium Study that is funded by the PHS.

PHS Regulations: 42 CFR Part 50 Subpart F and 45 CFR Part 94 (Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors).

Relying Site: as defined in the CU CIRB Reliance SOP.

SOP: as defined in Section I.

III. Institutional Responsibilities and Procedures

A. Confirmation of FCOI Policy

As provided in Section III(A) of the CU CIRB Reliance SOP, each Relying Site must confirm that it has fully implemented its own institutional policy on financial conflict of interest in research, pursuant to which, among other things, such Relying Site collects and reviews investigator financial interest disclosures; identifies any financial conflict of interest (“FCOI”) that relates to any Consortium Study in which such Relying Site is a Participating Site; and manages such FCOIs. If the Consortium intends to obtain funding from the PHS, each Relying Site must also confirm that its policy complies with the PHS Regulations.

B. Reporting and Management of FCOIs

The following shall be required with respect to the reporting and management of any identified FCOI:

1. Prior to conducting any activities with respect to a Consortium Study, each Participating Site must report any identified FCOI relating to such Study to the CIRB Facilitator, who will in turn report it to the CIRB Liaison. Each such report (a “FCOI Report”) shall be submitted when the Participating Site receives the Consortium Protocol from the CU CIRB, if identified at such time, or promptly at any other time. Each FCOI Report must explain how the Participating Site has managed the FCOI. For PHS Consortium Studies with respect to which the

Participating Site is a subawardee of Columbia, the requirement to submit a FCOI Report to the CU CIRB is in addition to, and does not replace, other FCOI reporting requirements of the Participating Site as a subawardee.

2. The CU CIRB will work with the Columbia Office of Research Compliance and Training (“Columbia Compliance”) as appropriate to review any FCOI Report. Columbia Compliance may consult with the Columbia Conflict of Interest Committee as needed. The CU CIRB may impose more, but not less, stringent requirements than the Participating Site with respect to management of the FCOI.
3. The Participating Site will require individuals with a disclosed or otherwise identified FCOI to comply with any conflict management plan imposed by the Participating Site and/or by the CU CIRB. Columbia may choose to accept a management plan that has been developed by the Participating Site.
4. To the extent possible and as allowed by law, all reports disclosing FCOIs and all related information and written materials provided pursuant to this SOP shall be kept confidential and shared only with the CIRB Liaison, the CIRB Facilitator, CU CIRB members and staff, CU Compliance, and other need-to-know individuals identified on a case-by-case basis. For clarity, this subsection shall not be interpreted to limit the Participating Site’s ability to comply with any law or regulation requiring the Participating Site to make certain information publicly available.

C. Compliance With FDA Financial Disclosure Requirements

The sponsor of a Consortium Study involving an Investigational New Drug (IND) or Investigational Device Exemption (IDE) that is covered by the FDA Regulations is responsible for obtaining and maintaining documentation of financial information from clinical investigators in compliance with such Regulations, as applicable.