

Shanghai Health Study Review Panel Roles and Responsibilities

Ethics Review Panel:

Membership: The initial membership of the Ethical Review Panel (ERP) will be determined by the Business Oversight Committee. Members will have expertise in bioethics. Following initial formation, the ERP will be responsible for adding appropriate members up to its authorized limit. The Board may seek advice from others, including a Consortium Oversight Committee, on filling its authorized limit and may request an increase in that limit. The ERP should have at least three members; one each from the U.S., Europe, and China.

Responsibilities: The responsibility of the ERP is to make the recommendations necessary to ensure that the research conducted under this program meets internationally accepted ethics standards and reflects relevant cultural or other patterns in Shanghai. To meet this responsibility, the panel: (1) reviews and approves the protocols and consent forms before the research commences to ensure that recommendations of the earlier ethics review process have been incorporated; (2) reviews any changes in the protocols or the consent forms before they are implemented; (3) reviews, at periodic in-person meeting, the conduct and progress of the research to see that the ethics standards are being followed; (4) responds, on an as-needed basis, to issues raised by the Principal Investigators, the Scientific Review Panel, or the Consortium. Its recommendations will be given to the Oversight Committee who will distribute them to the appropriate individuals and who will oversee any response to them.

Meetings: The Ethics Review Panel will have an annual meeting as described above to review conduct of the research as it relates to ethics issues. Members will also be invited to attend the Consortium Annual Meeting. All other business will be conducted by conference calls and/or email exchanges.

Interactions: In order to facilitate interaction with other bodies: (1) the chair of the ERP and SRP (or his designee) will be an ex officio member of the SRP and ERP, respectively, and will attend its meetings and participate in its conference calls; (2) the Principal Investigators will be responsible for submitting proposed changes and annual reports to the ERP through the Technical Committee; (3) the ERP will be available to respond to concerns raised by the SRP, Oversight Committee, Technical Committee, Communications Committee and Principal Investigators.

Support: The Oversight Committee will provide to the Ethics Review Panel reasonable support to accomplish its mission including: (1) costs of travel to the annual meetings (one or more of which may be in Shanghai) and costs of running that meeting; (2) costs of the conference calls; (3) consulting fees for the members

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and the chair at an agreed rate; and (4) support staff to facilitate the activities and communication needs for the ERP.