Category: Regulatory – Work in Progress

Partnering With Foreign Collaborators and the Institutional Review Board to Document Human Subjects Protection Requirements for Sites Outside of the United States

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1. Background

Changes in the Common Rule for human subjects research require that sponsor institutions provide a mechanism to document assurances of equivalent protections for non-federally funded projects without a federal-wide assurance at foreign sites. To conform to the same or equivalent ethical and regulatory standards in which research conducted in the United States is held and to applicable local laws, we developed a partnership process with our Institutional Human Research Protection Program office to ensure that adequate provisions are in place for research sponsored by St. Jude Children's Research Hospital (St. Jude) that is conducted outside of the U.S. This process ensures we have sufficient information about the local research context and laws by reviewing written materials or discussing the planned research with local institutional review board (IRB) officials. Our process also ensures that the required information and documents are available for adequate review by the St. Jude IRB.

2. Goals

Our goal was to establish a centralized and standardized way to collect, document, and appraise equivalent human subjects protection (HSP) requirements for non-U.S. sites.

3. Solutions and Methods

We established a two-step centralized mechanism to document assurances of equivalent protections. First, in the Department of Global Pediatric Medicine (GPM), which collaborates on studies conducted in low- to middle-income countries (LMICs), we designed a guidance document and worksheet with specific elements that address the scope of standards at collaborating foreign institutions. The worksheet includes questions that address local institutional responsibilities and regulations, as well as research ethics committee responsibilities, such as the appropriate scope and quality of review and processes for informed and voluntary participation. Once collaborating institutions provide this information, it is then included in their regulatory files and is available upon request to our IRB. The forms are available in English and in Spanish. Second, St. Jude investigators who sponsor research activities at non-U.S. sites submit the "Transnational Non-U.S. Research Site Assessment" form to the St. Jude IRB for review and approval. This form includes information derived from Step 1 and comprises four sections. It is submitted along with new study applications and can be accompanied by supplementary information obtained in Step 1.

4. Outcomes

Presently, we have established documentation from four countries including Peru, Ecuador, Bolivia, and Paraguay and at eight sites. During in-country regional scientific workshops sponsored by GPM, we conduct training and education sessions on the equivalency process and engage in additional discussions to further our appreciation of local contexts.

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5. Lessons Learned

The variable knowledge level of foreign site personnel regarding HSP procedures is challenging, particularly with colleagues in LMICs. However, the opportunity presented by this variability led us to propose recording video educational sessions on HSP procedures to broadly disseminate these materials and ultimately further compliance with HSP requirements.