**Proposed Language for Grant Applications Requesting to Use U of C BSD as Reviewing IRB**

The University of Chicago Biological Sciences Division supports three Institutional Review Board Committees which oversee more than 3,600 active human subjects’ research protocols. Each Committee is fully constituted to review research conducted by BSD faculty or conducted within the University of Chicago Medical Center. IRB Committee membership includes physicians, nurses, other clinicians, and representatives from legal as well as our surrounding community. The IRB Committees are chaired by Dr. Christopher K. Daugherty, Professor of Medicine. In addition, each IRB Committee has a Vice-Chair who is responsible for the oversight of IRB meetings for a designated Committee.

The three IRBs are charged with the responsibility for review and oversight of all research involving human subjects carried out in the BSD and UCMC, and to assure the protection of the rights and welfare of all research subjects. The ethical principles which guide the IRB are consistent with the Declaration of Helsinki of the World Health Organization and the Belmont Report. The IRB policies and procedures also ensure that applicable protocols comply with the rules and regulations of: the Federal Policy for the Protection of Human Subjects (56 FR 28003; often referred to as the "Common Rule"), the Department of Health and Human Services (DHHS) Regulations (45 CFR Part 46), the regulations of the Food and Drug Administration (FDA) (21 CFR Parts 50 and 56), and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45CFR Parts 160 and 164).

The University of Chicago is a member of the SMART IRB, which enables the BSD IRBs to serve as reviewing IRB for external institutions on multisite projects. The BSD IRBs have accepted the SMART IRB Standard Operating Procedures to ease the process for sites relying upon our institution. The BSD IRBs have written policies and procedures for serving as a reviewing IRB. The BSD IRBs have undergone audit by the University of Chicago Internal Audit program, the purpose of which is to provide the Board of Trustees and senior University administration with an independent assessment of the University’s system of internal controls.  The BSD IRBs are also continually audited by the Food and Drug Administration.

To facilitate the review, approval, and ongoing oversight of human subjects’ research, the University utilizes an electronic submission application (AURA-IRB). This system is maintained and continually upgraded through the Enterprise Applications System section of IT Services. AURA-IRB is compliant with 21CFR part 11 FDA regulations.

The Office of Clinical Research provides administrative support for the BSD IRBs, employing a Director of Regulatory Compliance for Human Subjects, an Associate Director of Regulatory Compliance for Human Subjects, an Associate Director for Education/Quality Assurance, an IRB Reliance Manager, and 8 IRB Administrators.