MEMORANDUM

To: The Dartmouth Clinical Research Community  
Re: Use of Commercial IRBs (cIRBs)  
Date: June 18, 2013

For several years there has been an on-going discussion at the national level regarding the use of alternative models of IRB review, including agreements between IRBs, creating national IRBs, and utilizing commercial IRBs.

The Dartmouth Committee for the Protection of Human Subjects (CPHS) currently collaborates with many other IRBs, either serving as the IRB of Record or ceding review to another IRB for appropriate clinical research studies. The Dartmouth CPHS has been at the forefront of collaborating with the National Cancer Institute by utilizing the NCI central IRB. An important part of this collaboration has been to have appropriate local oversight to protect the rights and welfare of research participants while eliminating duplication of resources and effort.

As a result of conversations between the Dartmouth Provost's Office and the Dartmouth Clinical Trials Office Governance group, the CPHS Office will now consider requests for the use of an accredited commercial IRB for multi-center phase III or IV corporately sponsored clinical trials. This will apply when the study has already been approved by a commercial IRB and Dartmouth will be added as one of the sites. Agreements with commercial IRBs are contracts that define roles and responsibilities of Dartmouth and the commercial IRB. For example, serious adverse events must be reported to the Dartmouth CPHS as well as to the commercial IRB of record. As such, it is important that the Dartmouth CPHS review proposed agreements with commercial IRBs and accept them on behalf of Dartmouth. Other important aspects of conducting a clinical trial will remain the responsibility of the Institution, including conflict of interest review and clinical trial contract and budget negotiation. The Department Chair (or their delegated authority) will attest to the scientific merit of the protocol via signing the Request to Defer Form. No other CPHS Forms are required. A Dartmouth CPHS chairperson will receive the protocol and model consent form. The CPHS chair will make the determination to accept or decline the commercial IRB review. The CPHS will not review the project unless the Dartmouth CPHS chair declines the use of the commercial IRB.

We have in place master agreements with Western Institutional Review Board (WIRB) and Quorum. The CPHS Office will work closely with the Clinical Trials Office and the clinical research community to pursue the appropriate use of a commercial IRB. Researchers who want to use commercial IRBs should contact Elizabeth Bankert, Assistant Provost and Interim IRB Director.

Regards,

Martin Wybourne

cc: Howard Hughes, Chair, CPHS A  
Dan O'Rourke, Chair, CPHS B and D  
Jack van Hoff, Chair, CPHS C  
Elizabeth Bankert, Assistant Provost and Interim Director, CPHS  
Alan Green, Director, SYNERGY  
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