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MEMORANDUM

TO: **Human Subjects Investigators and Study Staff**

FROM: **Randolph W. Hall, PhD**

DATE: **April 24, 2017**

SUBJECT: **Changes in IRB Procedures**

I am writing to let you know about some changes in IRB procedures aimed at a more efficient IRB review process.

1. **Faster Review/Minimized Editing of Consent Forms for Multi-Center Trials on HSC.** The HSC IRB is working to make it easier for study teams to create informed consent forms. Toward this end:

   Informed Consent Template - Industry Sponsor, Cooperative Group, or External IRB
   Condensed template language can be found on the OPRS website [http://oprs.usc.edu/hsirb/hsirb-forms/]. This template can also be used when relying on an external (non-USC) IRB, excepting for the National Cancer Institute Central IRB.

   HSIRB Informed Consent Template
   This template should be used when there is no consent form from an industry sponsor or cooperative group. It includes the essential elements of consent, instructions for use, the California Subjects Bill of Rights, conflict of interest requirements, considerations for long-term specimen use and other institutional requirements.

2. **Prioritizing Time Sensitive Funding** JIT submissions are now identified early in the iStar application, to ensure that reviews are expedited. Average turn-around has been less than two weeks since the process was instituted.

3. **Simplified Exempt Review on UPC** ISTAR applications reviewed by the UPC IRB for exempt research no longer include a section on recruitment or informed consent. Exempt studies are not required to use an informed consent document. The application provides a link to the template consent forms if researchers still choose to use them

4. **Reducing Burden to Provide Financial Information** The IRB policy on review of research funds has been clarified and simplified. As a result, in most cases a

budget no longer needs to be submitted. Instead, the IRB will rely on access to budget information through Kuali Coeus, or rely on the attestation of departments or schools as to the adequacy of funding.

5. **Scientific Review** As part of its application for NIH funding, the CTSI and USC committed to a process for scientific review on non-cancer investigator-initiated clinical trials (the cancer center will continue to review cancer studies) that have no prior scientific review. The CTSI process has been integrated into iStar for ease and consistency of review.

6. **Departmental Option to Reduce Number of Approvals in Keck School:** It has been the IRB practice to secure approvals from both division chiefs and clinical department chairs in the Keck School of Medicine. Department chairs now have the option of eliminating one level of approval, whereby either approval at the division level or approval at the department level is sufficient. On the UPC, we will continue the practice of not requiring department approval, except under exceptional cases. In the Ostrow School and Pharmacy School, single level approval will remain the practice.

I would appreciate receiving your suggestions for further expediting IRB processes, which can be sent to vpres@usc.edu.