Appendices

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A. Federalwide Assurances (FWAs)

The University of Southern California maintains assurances of compliance with the Office for Human Research Protections (OHRP) to comply with the requirements set forth in 45 CFR Part 46, as well as the Terms of Assurance. USC's assurances can be accessed at: oprs.usc.edu/review/fwa

B. IRB Reviewer Checklists / Guidelines

The checklists provide insight into how applications are initially assessed by the IRB. Topics include new applications, informed consent, research with pregnant women, research with prisoners, research with children and more. The checklists can be accessed at: http://oprs.usc.edu/files/2013/01/Reviewer_Guidelines.doc

C. UPIRB Forms and Instructions

Methods of consent and documentation will vary according to the level of review and nature of the research. Templates containing the required elements of consent can be accessed at: oprs.usc.edu/upirb-forms

D. HSIRB Forms and Instructions

Methods of consent and documentation will vary according to the level of review and nature of the research. Templates containing the required elements of consent and common biomedical research procedure can be accessed at: oprs.usc.edu/hsirb-forms

E. USC Human Subjects Research Booklets

The USC Human Subjects Protection Program has developed booklets available to users online or in hard copy by request. Topics and titles include Responsible Conduct of Research, Making Sense of Human Subjects Research, Informed Consent and More. The booklets are available at: oprs.usc.edu/booklets

F. IRB Reliance Agreements

USC has established reliance agreements to simplify the IRB review process for projects taking place between USC and partner sites. Under the Memoranda of Understanding (MOU), IRB Authorization Agreement (IRBAA), Master Reliance Agreement (MRA), Collaborative Review Agreement (CRA), and Ceded Review -one Institution will give the responsibility of the IRB review process to another Institution that will provide the IRB review and approval, and typically ongoing oversight. USC's agreements with CHLA, Hebrew Union College, Rancho Los Amigos, Rand Cooperation, and many others may be found at oprs.usc.edu/initiatives/agreements

G.Glossary of Medical Terms

A compilation of common medical terms used in healthcare and research is available at: oprs.usc.edu/education/glossary

H.USC Flexibility Policy and Coalition

The Flex Policy permits extended IRB approval and new exempt and expedited review categories for non-federally funded research. The Flexibility Coalition consists of Institutions that have developed similar policies. Information about the policy and coalition is available at: oprs.usc.edu/flex

I. Verification that IRB Contingencies were Satisfied

Contingencies are modifications requested or required by the IRB that must be satisfied before final IRB approval is granted. Designated IRB reviewers can verify that contingencies were satisfied depending on the level of expertise required. Explanation of contingency types and designated reviewer examples are available at: oprs.usc.edu/files/2013/01/Verification-of-IRB-Contingencies.pdf

J. IRB Requirements for Research with Other Sites

Research conducted at non-USC sites (or transferred to USC) may be subject to additional IRB requirements/documentation. A summary of requirement is available at: oprs.usc.edu/files/2013/02/IRB-Required-Documents-for-Research-with-Other-Sites.pdf

K. Requirements for Department of Defense (DOD) Supported Research and Reviewer Checklist

Research supported by the Department of Defense (DOD) is subject to additional IRB requirements/documentation depending on study specifics. Summary requirements are available at: oprs.usc.edu/files/2013/01/DOD-Summary-Requirements.pdf**.** DOD Reviewer Checklist available at: http://oprs.usc.edu/files/2013/03/DoD_Checklist.doc

L. Informing Participants about Significant New Information and Findings (SNIFs)

SNIFs must be provided to participants when the new information may affect their willingness to continue in a study. A flowchart to determine when a SNIF form, consent form or both are required is available at: https://oprs.usc.edu/files/2013/02/SNIF-consent-chart-6.30.14.pdf

M. USC Research Sponsored by Federal Agencies

USC complies with requirements stipulated by other federal agencies when they serve as sponsors or have oversight of research conducted at USC. A chart with specific federal agency regulations is available at: https://oprs.usc.edu/files/2013/01/USC-Research-Sponsored-by-Federal-Agencies.pdf

N. Requisites for Single IRB

All sites participating in human subjects research funded by NIH must utilize a centralized, single IRB (sIRB) beginning September 25, 2017. The sIRB will provide IRB review for all "participating sites" who will accept the review and approval of the sIRB.

A summary of requirements and responsibilities for sites performing as a Single IRB and those sites who will rely on an sIRB as participating sites is available at:

Requisites for Single IRB

NIH Policy on the Use of a Single IRB (sIRB)