University of Southern California

Human Subjects Protection Program (HSPP)

Policies and Procedures

Office for the Protection of Research Subjects (OPRS)

Health Sciences Institutional Review Board (HSIRB)

University Park Institutional Review Board (UPIRB)

2016

Message from the USC Institutional Official

Institutions are charged with establishing policies and procedures for the protection of human research subjects according to federal policy. As the Institutional Official named in the University of Southern California (USC) Federalwide Assurances, it is my responsibility to provide and oversee these policies and procedures. These policies are regularly updated as practices and regulatory changes dictate.

The USC Human Subject Protection Policy and Procedures are designed to facilitate the protection of human subjects involved in research conducted under the auspices of the University. Investigators, IRB members and staff are encouraged to familiarize themselves with the policies and procedures and utilize them during the submission, review, and conduct of human subjects research.

Protecting the rights and welfare of human subjects is an important responsibility that can best be met through education of all parties involved in the conduct of human subject's research and implementation of practices designed to minimize risks and maximize benefits associated with these activities.

Thank you for your cooperation in our joint effort to protect the human subjects involved in our research studies.

Randolph W. Hall, Ph.D.

Vice President of Research

Statement of the University of Southern California

CODE OF ETHICS
OF THE UNIVERSITY OF SOUTHERN CALIFORNIA

At the University of Southern California, ethical behavior is predicated on two main pillars: a commitment to discharging our obligations to others in a fair and honest manner, and a commitment to respecting the rights and dignity of all persons. As faculty, staff, students, and trustees, we each bear responsibility not only for the ethics of our own behavior, but also for building USC's stature as an ethical institution.

We recognize that the fundamental relationships upon which our university is based are those between individual students and individual professors; thus, such relationships are especially sacred and deserve special care that they not be prostituted or exploited for base motives or personal gain.

When we make promises as an institution, or as individuals who are authorized to speak on behalf of USC, we keep those promises, including especially the promises expressed and implied in our Role and Mission Statement. We try to do what is right even if no one is watching us or compelling us to do the right thing.

We promptly and openly identify and disclose conflicts of interest on the part of faculty, staff, students, trustees, and the institution as a whole, and we take appropriate steps to either eliminate such conflicts or insure that they do not compromise the integrity of the individuals involved or that of the university.

We nurture an environment of mutual respect and tolerance. As members of the USC community, we treat everyone with respect and dignity, even when the values, beliefs, behavior, or background of a person or group is repugnant to us. This last is one of the bedrocks of ethical behavior at USC and the basis of civil discourse within our academic community. Because we are responsible not only for ourselves but also for others, we speak out against hatred and bigotry whenever and wherever we find them.

We do not harass, mistreat, belittle, harm, or take unfair advantage of anyone. We do not tolerate plagiarism, lying, deliberate misrepresentation, theft, scientific fraud, cheating, invidious discrimination, or ill use of our fellow human beings – whether such persons be volunteer subjects of scientific research, peers, patients, superiors, subordinates, students, professors, trustees, parents, alumni, donors, or members of the public.

We do not misappropriate the university's resources, or resources belonging to others which are entrusted to our care, nor do we permit any such misappropriation to go unchallenged.

We are careful to distinguish between legal behavior on the one hand and ethical behavior on the other, knowing that, while the two overlap in many areas, they are at bottom quite distinct from each other. While we follow legal requirements, we must never lose sight of ethical considerations.

Because of the special bonds that bind us together as members of the Trojan Family, we have a familial duty as well as a fiduciary duty to one another. Our faculty and staff are attentive to the well-being of students and others who are entrusted to our care or who are especially vulnerable, including patients, volunteer subjects of research, and the children in our daycare and community outreach programs.

By respecting the rights and dignity of others, and by striving for fairness and honesty in our dealings with others, we create an ethical university of which we can all be proud, and which will serve as a bright beacon for all peoples in our day and in the centuries to come.

Adopted by the Board of Trustees of the University of Southern California, March 28, 2004

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PREFACE

Commitment of USC to Human Subjects Protection

At USC, protection of research subjects is a university-wide function that merits and receives the highest level of institutional support, commitment, visibility, and rigor. A vast and successful research enterprise is a catalyst for societal benefits and economic well-being. Thus, maintaining public trust in USC's academic research is a critical goal. An excellent Human Subjects Protection Program (HSPP) is a vital part of retaining this trust and assuring that priority is given to the rights and welfare of those who participate in research.

The policies, procedures, and commitment established by this document reflect the practices, expectations and standards to which this Institution adheres.

Chapter 1:

USC Human Subjects Protection Program

Chapter Contents

Chapter 1
USC Human Subjects Protection Program

This chapter describes the purpose and composition of the USC Human Subjects Protection Program (HSPP). It also addresses how the Program protects human subjects and how USC involves the community in research. Lastly, this chapter introduces the USC Flexibility Policy.

1.1 Human Subjects Protection Program (HSPP)

The University of Southern California (USC) Human Subjects Protection Program (HSPP) oversees all research involving human subjects at USC. At USC, the HSPP program has the full support of the upper levels of the administration including the Board of Trustees, the President, the Provost and the Provost's staff. The members of the program include the Vice President of Research, Executive Director and staff of the Office for the Protection of Research Subjects (OPRS), and staff, Chairs, members of the Institutional Review Boards (IRBs) for the University Park (UPIRB) and Health Sciences (HSIRB).

The HSPP team is supplemented by faculty from both campuses and the Office of Compliance for guidance and issue resolution. The primary responsibility of the HSPP is to assure the protection of subjects participating in USC research and continuing to meet and exceed accreditation standards. For studies involving USC neighboring communities, USC involves the community in planning, designing and participating in the conduct of research.

The University of Southern California is committed to conduct biomedical and behavioral research involving human subjects following the ethical principles embodied in *The Belmont Report: Ethical Principles and Guidelines for the Human Subjects of Research* found in the Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

The USC IRBs have been established in compliance with existing regulations of the federal government under U.S. Department of Health and Human Services (DHHS) regulations in 45 CFR 46, the Food and Drug Administration (FDA) regulations in 21

CFR 50, 56 as well as other applicable federal regulations and state and local laws. **USC complies with requirements stipulated by other federal agencies when they serve as sponsors or have oversight of research conducted at USC.** For a list of applicable federal regulations, refer to Appendix M.

The IRBs are in compliance with International Conference on Harmonization Good Clinical Practice Consolidated Guidelines insofar as those guidelines are consistent with the FDA and DHHS regulations pertaining to the protection of human subjects in research.

The USC IRBs operate with a Federalwide Assurance issued by the DHHS, Office for Human Research Protections (OHRP). The USC IRB's are registered in the OHRP/FDA IRB database.

USC has chosen to limit the scope of its Federalwide Assurance (FWA) to federally funded research (by "unchecking the box"), the terms of which allow an appropriate level of flexibility for research involving no greater than minimal risk. This provides an appropriate level of administrative flexibility without compromising subject protections. Subject protections remain equivalent for all studies whether funded or not. For research involving no greater than minimal risk and receiving no federal funds, USC has created an innovative flexibility policy adapted by other Institutions nationwide.

ALL human subject research projects at USC must be reviewed and approved by an IRB before research can begin. While the principal investigator has primary responsibility for the conduct of the study, the USC IRBs are responsible for protecting the rights and welfare of study subjects under Federal Wide Assurances (FWAs) granted by DHHS (http://www.hhs.gov/ohrp/assurances/assurances/index.html) to the University Park Campus and the Health Science Campus. This fundamental commitment to the protection of human subjects applies to all USC research involving human subjects regardless of whether the research is funded through government, non-profit or industry sponsors, through University funds, or not funded at all, and regardless of the location of the research.

The University and its researchers adhere to federal, California, and local regulations and laws as appropriate. USC will comply with requirements stipulated by other federal agencies when they serve as sponsors of research conducted at USC. Ethical and procedural guidelines by recognized organizations are also used for achieving best practices.

The OPRS oversees university wide human subjects' protections through program oversight, education, policy setting, and outreach.

The IRBs at USC are delegated the authority to review all human subjects research proposals - funded or not - that are conducted by USC faculty, staff, graduate, and undergraduate students.

USC IRBs review, approve, and monitor all research involving human subjects under the jurisdiction of their FWAs. Each IRB office provides administrative support to the IRB committees, provides assistance to investigators who are preparing IRB applications, and maintains records of IRB reviews and approvals for investigators.

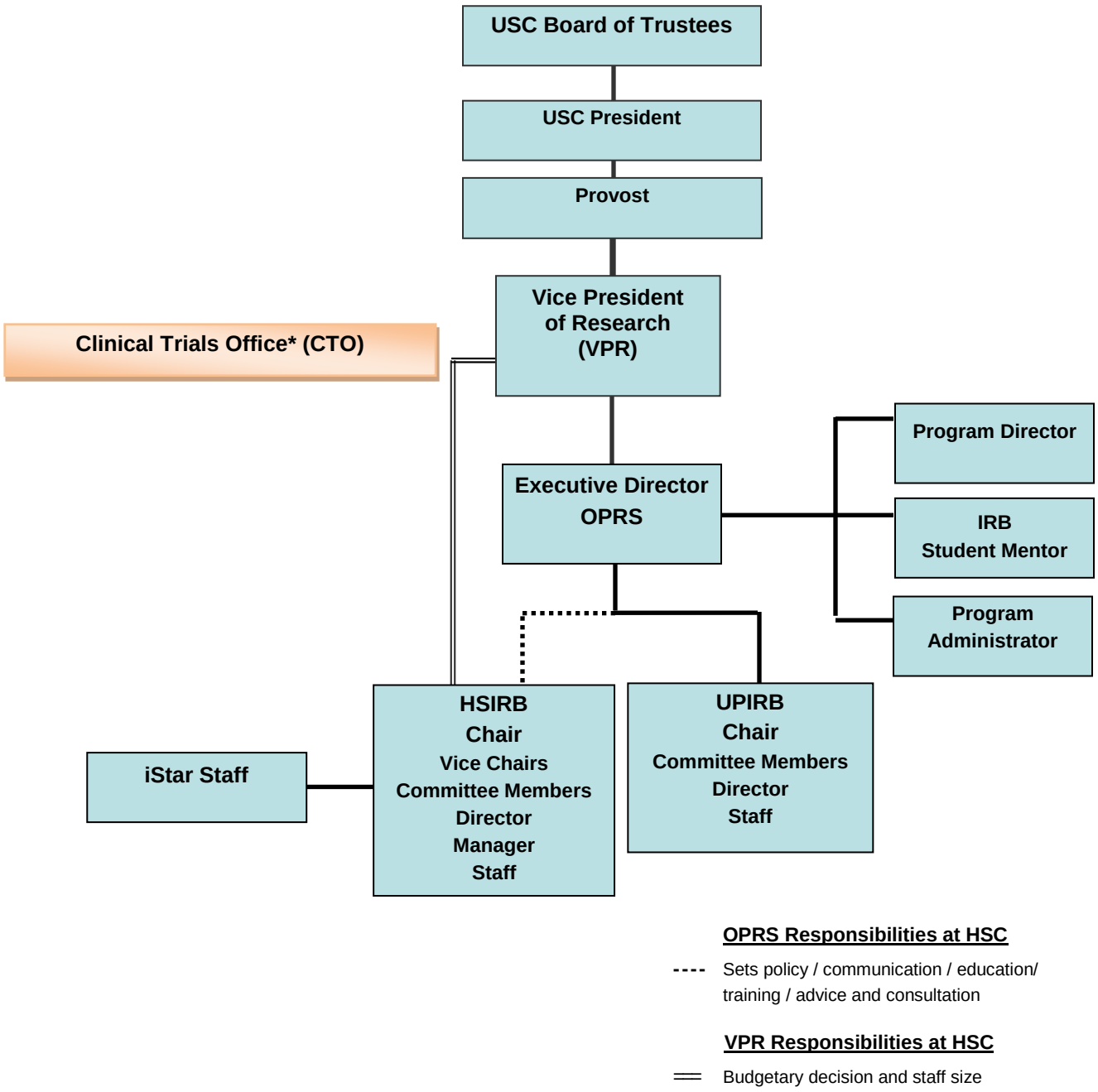
The University Park IRB is responsible for the review of research proposals conducted by the faculty, staff, and students of the USC University Park Campus, other than those in the Health Sciences Campus. The UPIRB is generally responsible for review of social and University-wide behavioral research. Student studies that administer medication will not be allowed at UPC.

The Health Sciences IRBs are responsible for review of Health Science research and all research conducted on the Health Sciences Campus. There are three HSIRBs: 2 review initial study submissions and 1 continuing review submissions. The HSIRBs are generally responsible for biomedical research, social and behavioral research conducted on the Health Sciences Campus, and research conducted by investigators in the schools of pharmacy and medicine. However, at the discretion of the Chairs, either IRB may defer to the other campus's IRB based upon recruitment site, expertise required, or other special circumstances.

The Office of Compliance and/or the Office of General Counsel are available for assistance and legal counsel in applying laws to research involving human subjects.

Note: the terms "subject" and "participant" are used interchangeably throughout the Policies & Procedures

Human Subjects Protection Program (HSPP) Organizational Chart



1.2 Human Subjects Protection Program Components

Institutional Official/Human Subjects Research

Vice President of Research
University of Southern California
3720 South Flower Street, 3rd Floor
Los Angeles, CA 90089-4019
TEL: (213) 740-6709 FAX: (213) 740-8919

Office for the Protection of Research Subjects

Executive Director
Program Director
Program Administrator
Graduate Assistant/IRB Student Mentor
University of Southern California
3720 South Flower Street, 3rd Floor
Los Angeles, CA 90089-1146
TEL: (213) 821-1154 FAX: (213) 740-9299
E-mail: oprs@usc.edu
Web: https://oprs.usc.edu/

University Park Institutional Review Board (UPIRB)

Chair
IRB Director
Credit Union Building (CUB) Third Floor 310, MC 0702
Los Angeles, CA 90089-0702
TEL: (213) 821.5272 FAX: (213) 821-5276
E-mail: upirb@usc.edu
Website: https://oprs.usc.edu/upirb/

Health Sciences Campus Institutional Review Board (HSIRB)

Chair
Vice-Chairs
IRB Director
IRB Manager
General Hospital (GNH), Fourth Floor, Suite 4700
1200 North State Street
Los Angeles, CA 90033
TEL: (323) 223-2340 FAX: (323) 224-8389
E-mail: irb@usc.edu
Website: https://oprs.usc.edu/hsirb/

iStar/Electronic Submission

General Hospital (GNH), Fourth Floor, Suite 4700
1200 North State Street
Los Angeles, CA 90033
TEL: (323) 223-2340 FAX: (323) 224-8389
E-mail: istar@usc.edu
Web: https://istar.usc.edu

Clinical Trials Office (CTO)

Director
2011 N. Soto Street
Los Angeles, CA 90032
TEL: (323) 442-7218 FAX: (213) 342-0947
Web: https://research.usc.edu/clinical-trials-at-usc/

1.3 How the Organization Works Together to Protect Subjects

The Human Subjects Protection Program oversees the ethical and regulatory affairs related to the protection of research subjects. The Program consists of the Vice President of Research, the Office for the Protection of Research Subjects (OPRS), four Institutional Review Boards, and the Department of Contracts and Grants. USC faculty, staff, and students are also participants in the HSPP. All these groups carry out their individual functions and endeavor to work together where their responsibilities intersect in human subjects protection.

The University's commitment to ethical and compliant human subjects research is embodied in the USC Code of Ethics, Faculty Handbook, and the HSPP Policies and Procedures.

Office for the Protection of Research Subjects

Responsible for: promoting excellence in human subjects research programs across the University, overseeing the IRB, providing human subjects education, seeking out and adopting best practices, advising the Vice President of Research, maintaining accreditation, and providing a national voice and presence in human subjects protections.

Accountability within the HSPP is expected of all levels of responsibility. Communication is routinely shared among all components of the HSPP. IRB members are encouraged to directly contact the IRB staff, Directors, Chairs and Vice Chairs or OPRS with questions, concerns, or suggestions. Regulatory and IRB policy changes are provided to the members and staff via email, through the OPRS listserv, and at IRB meetings. Education sessions are held for members and staff at the meetings, and for researchers special education sessions are given on an as-needed basis.

Human Subjects Working Group

Human Subjects Working Group consisting of OPRS, IRB Chairs and Directors meet regularly on monthly phone calls to discuss best practices, address and solve issues, and share news or concerns that affect the HSPP. Any IRB related issues taking place on either campus can be discussed at that time.

Other meetings and phone calls take place, as necessary, to deal with any problems, issues, concerns. These calls or meetings can be initiated by any member of the HSPP team.

OPRS/IRB Websites

OPRS/IRB websites receive thousands of visits per month, and provide a wealth of information to all stakeholders in human subjects research. Not only is there guidance for investigators and IRB staff, there is also information for research participants/subjects. The websites are continually updated with the most recent human subjects research policies, regulations, guidance, and news.

Human Subjects Research Listserv

Human Subjects Research Listserv is used by OPRS to communicate with IRB staff and members, as well as USC faculty, staff and students conducting human subjects research. This listserv includes the most recent information on federal and state regulations, IRB education opportunities at USC, human subjects news, legislation, and other pertinent human subjects research information that the USC community should be aware of.

Program Communication

IRBs have weekly staff meetings to ensure that issues within that IRB can be addressed and that all staff are made aware of any new regulations or guidance that may be available. Staff problems or concerns are also addressed at this time, or can be done on an individual basis. Issues that can benefit or educate others in the HSPP are forwarded to the OPRS for discussion and distribution to the entire HSPP team.

The Executive Director of the Office for the Protection of Research Subjects and Vice President of Research meet as needed. In these meetings, issues pertaining to the HSPP are addressed as are new suggestions or decisions, needing input at the Provost level.

1.4 Research Involving the Community

USC promotes the involvement of community members, when appropriate, in the design and implementation of research and the dissemination of results. Community involvement builds public awareness and trust in research. Additionally, the more involved the community is, the more likely it is to benefit from research discoveries.

Researchers have flexibility to develop their own approach to engagement, in keeping with the needs of a particular community. However, the approach must be rooted in ethical considerations – respect for persons, equitable selection of subjects, and beneficence – and should emphasize community outreach, consultation, involvement and collaboration.

At USC, the preponderance of community-engaged research occurs in Preventive Medicine at HSC and in the School of Social Work at UPC. When appropriate, the researcher will promote the involvement of community member in the design and implementation of research and the dissemination of results.

Several initiatives have been established by the Southern California Clinical Translation Science Institute (SC-CTSI) that provide guidance for conducting community-engaged research as outlined in A Quick Start Guide to Conducting Community-Engaged Research. For example, some research studies fund community activities that open the dialogue to USC research in general while also providing study-specific information. From such collaborations, researchers can identify community research needs and community members can identify research risks not known to researchers.

In addition to CTSI resources, the Office for the Protection of Research Subjects (OPRS) website provides information for prospective research participants about types of research being offered at USC, questions to consider before participation, and contact information for reporting research complaints and concerns. Brochures are available in English and Spanish to inform individuals in the community about what to know before participating in a research study. For additional information see references below.

Helpful Links

- OPRS Community Engaged Research webpage
  http://oprs.usc.edu/initiatives/cm/
- OPRS Participating in Research webpage
  http://oprs.usc.edu/about/participating/
- SC CTSI website
  http://sc-ctsi.org/
- SC CTSI Community Engagement Partners
  http://sc-ctsi.org/index.php/community/community_engagement_partners

1.5 Flexibility Policy and Coalition

Flexibility Policy

The University of Southern California IRBs operate with a Federalwide Assurance issued by the DHHS, Office for Human Research Protections (OHRP). The USC IRB's are registered in the OHRP/FDA IRB database. USC has chosen to limit the scope of its Federalwide Assurance (FWA) to federally funded research (by "unchecking the box"), the terms of which allow an appropriate level of flexibility for research involving no greater than minimal risk. This provides an appropriate level of administrative flexibility without compromising subject protections. Subject protections remain equivalent for all studies whether funded or not. For research involving no greater than minimal risk and receiving no federal funds, USC has created an innovative flexibility policy adapted by other Institutions nationwide.

The Flexibility policy is limited to unfunded studies involving no greater than minimal risk. Should the funding status of a study reviewed under this policy change, it is the responsibility of the Principal Investigator to notify the IRB. Under no circumstances will federally funded or FDA regulated research be reviewed under this policy.

The IRB may make exceptions to the funding exclusion when the funding is not federal funding.

All human subjects research projects conducted or supported at USC remain subject to USC IRB policies and review, whether they qualify for this policy or not. When questions of applicability arise, studies will be reviewed on a case by case basis.

Inclusion/exclusion of any research project will be at the discretion of the USC Institutional Review Boards (IRBs).

This Flex policy creates exempt categories not found in the federal regulations, (for projects that do not directly conform to a specific exempt category in 45 CFR 46). These projects will be reviewed using an approval process identical to that used for exempt research categories 1-6 under 45 CFR 46.101(b).

This policy also provides up to three-year approvals for nonexempt unfunded projects that are not FDA regulated involving no greater than minimal risk. These projects will be processed under expedited review according to 45 CFR 46.110 but approval will be valid for up to three years, rather than one year as required in 45 CFR 46.109(e).

Research projects that meet the federal definition for human subject research and exceed minimal risk are subject to the criteria for approval articulated in the regulations at 45 CFR 46 and/or FDA regulations as applicable and do not qualify for review under the flexibility policy.

For additional details about the Flexibility Policy, refer to Appendix H.

Flexibility Coalition

A Flexibility Coalition was established by the University of Southern California to disseminate flexibility policies and encourage similar programs at academic Institutions across the United States. Currently, the Flexibility Coalition consists of more than 75 Institutions from across the nation that have achieved a more flexible approach to increasingly problematic federal requirements, by finding simpler ways of reviewing studies. The freedom to be compliant yet flexible, is permitted for Institutions which have opted to "uncheck the box" on the Federalwide Assurance for the Protection of Human Subjects. Unchecking the box limits HHS oversight to projects funded and regulated by OHRP. The coalition goals are to identify additional areas of flexibility that can be implemented without diminishing the protection of human subjects, and benefit from the knowledge and experience of members. This Coalition has been a major success for USC.

Chapter 2:

Ethics

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