AAHRPP Site Visit
USC IRB Staff:
Prepare to be Interviewed!

As IRB Staff, you are an integral part of the Human Subject Protection Program (HSPP) at USC. USC is on the cusp of achieving accreditation for its HSPP. Reaccreditation is a goal the HSPP has worked long and hard to accomplish. Achieving accreditation will publicly affirm USC as a top-tier academic institution in its ethical and regulatory conduct of human subjects research. AAHRPP accreditation is a gold standard that will contribute to increased interest in the research being performed at USC. President Nikias and Provost Garet strongly support this effort and expect the HSPP to achieve reaccreditation.

USC’s HSPP accreditation largely depends on these interviews. We are counting on the commitment you make to review quality research and solicit your help in this endeavor. To obtain reaccreditation, all interviews must be successful.

We have created materials to help you succeed and OPRS staff is also available for single or group prep sessions. The following guidance is not intended to be memorized; it is intended to focus your thinking as you prepare for the interview. In addition to using your study sheet resource, the following items have been identified by other institutions as likely areas of focus by the site review team:

- Know your role(s) in the Human Subjects Protection Program and the roles of other members of the HSPP (e.g. IRBs, OPRS, Office of Compliance)
- Know where to obtain answers for ethical/regulatory behaviors expected of you in conducting research duties (e.g. IRB reviewer checklists, human subjects policies and procedures, HSPP website—oprsl.usc.edu)
- Know how to access HSPP Policies and Procedures oprsl.usc.edu/rules
- Know how to report trouble, non-compliance, adverse events, unanticipated events, etc.
- Know where to go for advice (e.g. IRB Chair, IRB Director, IRB Staff, IRB Members).
- Compliant research records and documentation, and justification for decisions is expected
- Focus on philosophical aspects of your role first, then know the regulatory details (e.g. what you are reviewing/performing is sound, purposeful, and has value, before the nuts and bolts of compliance assessment)
- Understand what constitutes a conflict of interest at all levels (e.g. staff, IRB, institution, administration).
- Familiarize yourself with the terminology/jargon contained in the IRB Reviewer Guidelines
  - HSIRB: http://oprsl.usc.edu/hsirb/hsirb-forms/
  - UPIRB: http://oprsl.usc.edu/upirb/upirb-forms/
- Describe the Human Subjects Education you’ve had and how you utilize it in your research
- Know the ethics of recruitment and inclusion/exclusion criteria

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1. **What is AAHRPP accreditation and why is it important to USC?**

   AAHRPP accreditation is a gold standard recognizing adherence to a rigorous set of human subjects protection standards that surpass state and federal requirements. The accreditation process involves an evaluation of the USC Human Subjects Protection Program (HSPP) and a site visit focused on interviews with critical members of the HSPP, including IRB members. Accreditation largely depends on these interviews which involve tough questions about research policies, process, and training.

   AAHRPP accreditation also:
   - Improves human research protection programs
   - Improves research quality
   - Builds public trust
   - Assures regulatory compliance
   - Reduces burden from government and industry inspection
   - Leads to better risk management programs
   - Gauges over-interpretation of regulations
   - Makes USC program more competitive for funding
   - Helps in recruiting participants
   - Attracts high-quality investigators
   - Increases efficiency and reduces costs
   - Fosters alliances with accredited organizations

2. **What is the guiding philosophy of human subjects protection in research?**

   This fundamental commitment to the protection of human participants applies to all University of Southern California research involving human participants regardless of whether the research is funded through Government, non-profit or industry sponsors or through University funds and regardless of the location of the research.

   The University of Southern California conducts its biomedical and behavioral research involving human subjects under rigorous ethical principles. All human subjects research at USC is reviewed by one of the four Institutional Review Boards (IRBs). USC is in compliance with the Federal Policy for the Protection of Human Rights (45 CFR 46-The Common Rule), the Food and Drug Administration (FDA) regulations (21 CFR 50, 56), and with the Federalwide Assurance granted by the H.H.S. Office of Human Research Protections (OHRP). The University has also agreed to adhere to the statements of ethical principles as described in *The Nuremberg Code, The Belmont Report: Ethical Principles and Guidelines for the Human Subjects of Research*, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
3. What is your involvement/role/responsibilities in USC’s Human Subjects protection Program (HSPP)/IRB

The main mission of the Institutional Review Boards at USC is to protect the rights, safety and welfare of research subjects. The IRBs review and approve research in accordance with Department of Health and Human Services (HHS) regulations in 45 CFR 46. For studies involving products regulated by the Food and Drug Administration (FDA), the IRBs review research according to the requirements in 21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 812. The IRBs also comply with HIPAA and the regulations in 45CFR 160 and 164.

As an IRB staff member, your are expected to review IRB applications and informed consent forms for research proposals, pre-review and complete a written critique of research proposals after reviewing the application and all supporting documents such as clinical protocol, grant application, questionnaires, advertisements, Investigator’s Drug Brochure and Informed Consent.

4. What education have you taken that qualifies you for staff reviewer?

The answer is person-specific but can include CITI Human Subjects Protection course, Good Clinical Practices, Responsible Conduct of Research, HIPAA training, Certified IRB Professional training, as applicable. Additional sources of ongoing education include: PRIM&R conferences (or equivalent professional meetings), monthly IRB member education during IRB meetings and additional educational opportunities offered at USC (Office of Research, Office of Compliance, IRB/OPRS).

5. Describe how and when you communicate with researchers? With students? With IRB members? With the IRB chair?

Communication is primarily through emails. In addition, phone conversations and in person conversations are also done. Furthermore, researchers often contact IRB staff just for questions about research and the function of the IRB in regards to getting study approval. Communication occurs during the review of a study, after the review, after an IRB meeting, etc.

6. How do you review a study?

Discuss how you do it, refer to any checklists you use, education/training you have received, and activities you conduct in ISTAR.

IRB staff receives studies in their inbox via ISTAR. When ownership of the study is taken by the IRBA, the current status of the application is changed to “Under Staff Review”. IRBA ensures that the study meets approval criteria and ethical standards. If more information is

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needed to make a determination, the IRBA will contact the PI. IRB staff determines the level of review. Unless a project is Expedited or Full Board, the IRBA has the authority to approve the project and create the approval letter. Full Board and Expedited levels are address by the IRB Chair or IRB.

On the Health Science Campus, only one or two IRB staff are designated to review Expedited and Exempt.

7. What is The Belmont Report? the “Common rule”?

In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research presented The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. The Report sets forth three basic ethical principles: respect for persons, beneficence, and justice. These principles are now accepted as the three quintessential requirements for the ethical conduct of research involving human subjects.

The Common rule is (46 CFR Part 46) the protection of all human subjects research through the Office for Human Research Protections (OHRP). The common rule establishes approval criteria, created IRBs, and additional protections for vulnerable populations.

The University has also agreed to adhere to the statements of ethical principles as described in The Belmont Report: Ethical Principles and Guidelines for the Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (Justice, Beneficence, and Autonomy are the concepts in the Belmont Report)

8. What is OHRP, FDA, HIPAA?

OHRP
The Office for Human Research Protections (OHRP) is the federal office overseeing the system that protects the rights, welfare, and well-being of subjects involved in research and helping to ensure that research is carried out in accordance with Department of Health and Human Services (DHHS) regulations.

FDA
The Food and Drug Administration is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, US food supply, cosmetics, and products that emit radiation. FDA regulations for research with drugs, devices, and biologics are contained in Title 21 Parts 50 and 56 of the Code of Federal Regulations. Additional FDA regulations that are relevant to IRB review of research are Parts 312 (Investigational New Drug Application), 812 (Investigational Device Exemptions) and 860 (Medical Device Classification Procedures).
HIPAA
The Health Insurance Portability and Accountability Act (HIPAA), also known as the “Privacy Rule” (effective April 14, 2003), establishes minimum Federal standards for safeguarding the privacy of individual’s identifiable health information. The law generally prohibits health care providers such as health care practitioners, hospitals, nursing facilities and clinics from using or disclosing “protected health information” without written authorization from the individual.

9. What does the IRB do?

There are four Institutional Review Boards at the University of Southern California (one on the University Park Campus, and three on the Health Sciences Campus). These IRBs review and approve research in accordance with Department of Health and Human Services (DHHS) regulations in 45 CFR 46. In addition, for studies involving products regulated by the Food and Drug Administration (FDA), the University of Southern California IRBs review research and comply with the requirements set forth in 21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 812. In addition, the IRBs comply with HIPAA and its Regulations set forth in 45CFR 160 and 164.

10. Does IRB receive upper administration support?

Yes, see organizational chart in the policies and procedures. The VPR, the Provost, and the President of USC, strongly support the IRBS and the goal to remain accredited.

11. Do you have written checklists? Written guidance? Do you use them?

We have checklists for the review categories, vulnerable subjects, and informed consent. Experienced staff may not always use the checklist, but they are available if questions arise.

12. What are and when are expedited or exempted categories used?

Exempt Human Subjects Research

The USC IRBs will review all human subjects research activities under its jurisdiction to determine whether the research meets one or more of the exemption categories described in the Federal regulations and that it complies with USC’s ethical standards.

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

**Expedited Review**

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the
(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children², considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncanulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

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Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:
   (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   (b) where no subjects have been enrolled and no additional risks have been identified; or
   (c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting
that the research involves no greater than minimal risk and no additional risks have been identified.

13. Does collection of highly sensitive information alter the level of risk? Why?

Yes

Sensitive information must be protected especially if it is collected with identifiers attached. If there are no identifiers and it is anonymous, it can qualify for a minimal risk determination.

Really sensitive information includes: but is not limited to, information relating to sexual attitudes, preferences, or practices; information relating to the use of alcohol, drugs, or other addictive products; information pertaining to illegal conduct; information, that if released, might be damaging to an individual’s financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination; information pertaining to an individual’s psychological well-being or mental health; and genetic information. These categories have special conditions in the regs because of their sensitivity and thus increased risk.

14. What is the difference between exempt human subjects research and not-human subjects research?

See answer above (#14) which explains the regulatory category exempt. One is a regulatory category, NHSR is not a category. NHSR refers to activities that do not meet the definitions of both human subjects and research. In addition, there are categories that are traditionally excluded from the jurisdiction of the IRB.

Among these are:

1. Data collection for internal departmental, school, or other University administrative purposes.
   Examples: teaching evaluations, “customer service” surveys.

2. Surveys issued or completed by University personnel for the intent and purposes of improving services and programs of the University or for developing new services or programs for students, employees, or alumni.

3. Fact-collecting interviews of individuals where questions focus on things, products, or policies, rather than on people or their opinions. Example: canvassing librarians about inter-library loan policies or rising journal costs.

4. Course-related activities designed specifically for educational or teaching purposes, where data is collected from and about human subjects as part of a class exercise or assignment that is not intended for use outside of the classroom;

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Example: instruction on research methods
Instructors of research courses are encouraged to consult with IRB staff.

5. Searches of existing literature
6. Quality Improvement
   In general, quality improvement projects are not considered research unless there is a clear intent to use the data derived from the project to improve the quality of patient care or efficiency of a healthcare operation and also contribute to generalizable knowledge via publication in professional journals and/or presentation at national or regional meetings. Any individual who is unsure whether or not a proposed quality improvement project should be classified as research should contact the IRB for guidance.

7. Case Studies
   Case histories which are published and/or presented at national or regional meetings are not considered research if the case is limited to a description of the clinical features and/or outcome of a single patient.

15. What ongoing professional meetings/trainings do you have?
   Attended any AAHRPP/PRIM&R meeting during IRB education/meetings? None?
   Complete CITI re-certification?
   Attended any AAHRPP/PRIM&R meeting during IRB education/meetings
   IRB Staff Educational Lunch two times a year (entire staff/both campuses)
   Listserv

16. What is a serious adverse events? An unanticipated problem?
   A serious adverse event (SAE) is an adverse event (untoward or unfavorable event that occurs during a study, whether or not it is related to participation in the study) that involves one of the following:
   - Inpatient hospitalization or prolongation of hospitalization
   - Life-threatening reactions
   - Persistent or significant disability/incapacity or permanent harm or disability (either physical or psychological)
   - A congenital anomaly/birth defect in the offspring of the subject
   - Jeopardizes the subject’s health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition
   - A breach of confidentiality that may have a negative consequence
   - Results in death or places subject in immediate risk of death

   Serious adverse events that are unexpected, related or possibly related must be reported to the IRB as soon as possible but no later than 10 working days after the investigator becomes
An unanticipated problem involving risk to subjects or others (UPX) is an incident, experience or outcome that was unexpected (e.g., not described in the protocol, study or consent document), related or possibly related to participation in the research and suggests that research places subjects or others at a greater risk of harm than was previously known or recognized. UPX must be reported to the IRB as soon as possible but no later than 10 working days after the investigator becomes aware of the event.

Not all serious adverse events are unanticipated problems involving risks to subjects or others.

17. What is noncompliance and when is it considered serious and/or continuing?

Noncompliance is the failure to follow regulations that govern human research, IRB requirements/recommendations or institutional policies. Noncompliance is considered serious when an action or omission that any reasonable individual would have foreseen as compromising the rights or welfare of subjects and/or others. Continuing noncompliance involves a pattern of repeated actions or omissions that indicate a pattern of deficiency or unwillingness to comply with federal regulations, IRB requirements or institutional policies.

18. What are your primary concerns when reviewing a consent form?

The informed consent must contain all the essential elements, be clear and well written, state the purpose, contact info, compensation, and explain that the activity is research and not treatment/therapy. Additionally, the consent must be written in a level/language understandable by the subject.

19. What are your primary concerns when reviewing a protocol?

The IRB approval criteria must be met and the risk-benefit ratio must be acceptable. The PI may need to be contacted regarding missing items, controversial issues, and vulnerable subjects. The protocol should describe the research in understandable terms. Any concerns/potential issues should be pointed out to the IRB members to be resolved with the PI.

20. What is the difference between noncompliance and an adverse event?

Noncompliance is failure to follow the regulations governing human research, requirements or determinations of the IRB, or institutional policies. This definition may include action of any University employee or agent, such as investigators, research staff, IRB members, IRB staff, employees or institutional officials.

The FDA defines adverse event as “any untoward medical occurrence associated with the...
use of a drug in humans, whether or not considered drug related” in the Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans.

OHRP defines adverse events as “any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research in the “Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events”.

21. What constitutes a continuing review and why is it done?

The IRB is required to review all non-exempt research projects at intervals appropriate to the degree of risk, but not less than once a year (45 CFR 46.109(e)). This is called “continuing review.” If a project initially received expedited review and risks to subjects remain minimal, the continuing review may be expedited (reviewed by the chair, Vice Chair or designated IRB member, generally within two weeks of receipt in the IRB Office). If a project initially received full board review, the project generally requires full board continuing review.

Continuing review requires IRB review of a written progress report from the clinical investigator. Generally the Continuing Review Form may be used. All items must be completed. The investigator must submit a copy of the currently approved informed consent form document. The informed consent form document will be returned to the investigator with an updated IRB stamp of continued approval.

The purpose of continuing review is to evaluate whether any changes have occurred in the past year or if subjects have withdrawn or results indicate an increase or decrease in risk. Continuing review is expected to be as thorough as initial review.

22. What is minimal risk and how is it evaluated?

According to the federal regulations, “minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” Risk includes not only physical risk, but also psychological, emotional, legal, social, and financial. The definition of minimal risk serves as the starting point for the IRB chair’s determination of the category of review. If a project meets the definition of minimal risk, and falls into an exempt or expedited category as described below, the Chair alone, Vice Chair, or designated IRB member may review and approve the project. The designated person may be an IRBA.
23. What are the kinds and levels of risk?

A risk is a potential harm or injury associated with the research that a reasonable person in the subject's position would likely be considered injurious. Risks can be categorized as physical, psychological, sociological, economic, and legal. Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects and to the importance of knowledge that may reasonably be expected to result from the research.

“Minimal Risk” means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily activities or during the performance of routine physical or psychological examinations or tests.”

“Greater than minimal risk” is a determination made by the IRB for studies which do not meet the definition of minimal risk.

24. To whom do you go to for help on review issues, be they regulatory or ethical?

Person dependent, could be the IRB Director, IRB Chair, colleagues, OPRS, OHRP, FDA, etc.

25. What is the difference between privacy and confidentiality?

An issue of primary importance in the protection of human research subjects is the protection of privacy and confidentiality.

Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

IRB review of privacy and confidentiality protections is required under the Common Rule and the FDA regulations as well as state and local statutes. Protections to be reviewed by the IRB include promises to subjects on informed consents, protections during recruitment and follow-up, and methods to be employed to protect data and samples during storage, and use, and eventual data destruction (if promised). The IRB must receive this information with the protocol submission documents. Sponsor access and any legally authorized access to subject information must be divulged in the consent form. Studies that obtain particularly sensitive information (e.g. HIV status, drug abuse) may be required.
to obtain a certificate of confidentiality (see below).

Coded information, de-identified information and cultural differences in value systems must be understood by the IRB for study approval.

The investigator must describe sound plans to protect the subject’s identity as well as the confidentiality of the research records. Care should be taken to explain the mechanisms that have been devised, for example, the use of numbering or code systems or safely locked files in private offices. Furthermore, the investigator should describe who has access to the data and under what circumstances a code system may be broken. Without appropriate safeguards, problems may arise from long-term retention of records. In special circumstances requiring additional safeguards to prevent potential criminal prosecution of the participating human subject, the IRB may require the destruction of all data that can identify the subjects. Subjects should be informed whether the data collected will be retained, and if so, for what purpose, what period of time, or whether and when data will be de-identified and destroyed.

A special situation arises for video or taped data and photographs since these media provide additional potential means for subject identification. Investigators must secure subject consent explicitly mentioning these practices. They should also explain plans for final disposition or destruction of such records.

A. NIH Certificate of Confidentiality
(from NIH Office of Extramural Research web site)

A Certificate of Confidentiality is a document issued by the National Institutes of Health (NIH) to protect the privacy of research subjects by protecting investigators and institutions from being compelled to release information that could be used to identify subjects in a research project. Certificates of Confidentiality are issued to institutions or universities where the research is conducted. They allow the investigator and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

Identifying information is broadly defined as any item or combination of items in the research data that could lead directly or indirectly to the identification of a research subject.

By protecting researchers and institutions from being compelled to disclose information that would identify research participants, Certificates of Confidentiality help the researcher achieve the research objectives and promote participation in studies by assuring privacy to subjects.
Certificates can be used for biomedical, behavioral, clinical or other types of “sensitive research”. Sensitive means that disclosure of identifying information could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation.

Examples of sensitive research activities include but are not limited to the following:

- Collecting genetic information;
- Collecting information on psychological well-being of subjects;
- Collecting information on subjects' sexual attitudes, preferences or practices;
- Collecting data on substance abuse or other illegal risk behaviors;
- Studies where subjects may be involved in litigation related to exposures under study (e.g., breast implants, environmental or occupational exposures).

A Certificate of Confidentiality (http://grants1.nih.gov/grants/policy/coc/index.htm) protects personally identifiable information about subjects in the research project while the Certificate is in effect. Generally, Certificates are effective on the date of issuance or upon commencement of the research project if that occurs after the date of issuance. The expiration date should correspond to the completion of the study. The Certificate will state the date upon which it becomes effective and the date upon which it expires. A Certificate of Confidentiality protects all information identifiable to any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during any time the Certificate is in effect. An extension of coverage must be requested if the research extends beyond the expiration date of the original Certificate. However, the protection afforded by the Certificate is permanent. All personally identifiable information maintained about subjects in the project while the Certificate is in effect is protected in perpetuity.

While Certificates protect against involuntary disclosure, investigators should note that research subjects might voluntarily disclose their research data or information. Subjects may disclose information to physicians or other third parties. They may also authorize in writing the investigator to release the information to insurers, employers, or other third parties. In such cases, researchers may not use the Certificate to refuse disclosure. Moreover, researchers are not prevented from the voluntary disclosure of matters such as child abuse, reportable communicable diseases (http://grants2.nih.gov/grants/policy/coc/cd_policy.htm) or subject's threatened violence to self or others. However, if the researcher intends to make any voluntary disclosures, the consent form must specify such disclosure.

In the Informed Consent Form, investigators should tell research subjects that a Certificate is in effect. Subjects should be given a fair and clear explanation of the protection that Office for the Protection of Research Subjects (OPRS) oprs.usc.edu
it affords, including the limitations and exceptions noted above.

The investigator may choose to apply for a Certificate of Confidentiality on his or her own, or the IRB may require that an investigator obtain a Certificate prior to conducting the research. Investigators who intend to apply for a Certificate of Confidentiality should contact the IRB Office regarding procedural steps for IRB approval and communicating with NIH. Complete information is available on the NIH Office of Extramural Research web site.

26. What is the difference between waivers of consent and waiver of documentation of consent? What justifies each?

Waiver of Documentation of Consent
In some situations, the IRB may waive the requirement for obtaining a signed informed consent document (45 CFR 46.117(c)). Waiver of signed consent is allowed if:

- The only record linking the subject and the research would be the consent document and potential harm may result from a breach of confidentiality (the subjects would be placed at risk by documents linking them with an illegal or stigmatizing characteristic or behavior). For example, survey or interview studies that contain highly sensitive (e.g., criminal behavior, sexual behavior) questions.

or

- The research presents no more than minimal risk of harm to the subjects and involves no procedures for which written consent is normally required outside of the research context. For example, online surveys about topics that could not reasonably damage a participant's reputation or employability or be otherwise stigmatizing.

In cases where the documentation requirement is waived the IRB may require the investigator to provide subjects with a written statement regarding the research (the documentation may also be referred to as an info, fact sheet or similar title).

Waiver of consent or elements of consent
Some research projects would not be possible if informed consent were required. The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent, or may waive the requirements to obtain informed consent (45 CFR 46.116(d)). The regulations state that informed consent may be waived in full or in part if the IRB determines that:

- the research involves no more than minimal risk to the subjects; and
- the waiver or alteration will not adversely affect the rights and welfare of the subjects; and

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• the research could not practicably be carried out without the waiver or alteration; and
• whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Examples of types of studies in which all of the elements of consent have been waived include retrospective chart reviews. If the study can be classified as minimal risk and adequate provisions for protecting data confidentiality are in place, the IRB chair generally finds that obtaining consent is not impracticable (not possible). Examples of types of studies in which some of the elements of consent have been waived include certain types of ethnographic research or studies that require deception. Studies involving deception require a debriefing statement that would be provided to the subjects (written and oral) at the conclusion of the study procedures. If the investigator seeks a waiver of any or all of the elements of consent, the IRB application should justify the request by showing the research could not be conducted without the waiver.

27. Are there additional requirements for DOD-sponsored studies/other agencies?

Additional regulations are required for DOD-sponsored studies. USC has provided policies to assure adherence to additional regulations for DOD studies in the form of a DOD Checklist (medical monitor, injury statement and scientific review). Other agencies such as NSF and DOE have their own regulations which do not significantly differ from the “Common Rule” but if there are differences we will adhere to those before a project funded by those agencies is approved.

28. What does not require IRB review?

Activities that do not meet the federal definition of “human Subjects” and “research” do not require IRB review, examples include classroom studies or research with autopsy materials.