AAHRPP Accreditation: A "Thumbs Up" Process

Table of Contents to Supplementary Documents:

For easy navigation, click on the titles below or use the "Bookmarks" tab located to the left.

Susan L. Rose, PhD
OPRS Executive Director,
University of Southern California
Web: http://www.usc.edu/admin/provost/oprs
Email: oprs@usc.edu

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)

November 2007

TABLE OF CONTENTS

http://www.usc.edu/admin/provost/oprs

University of Southern California

Protection of Research Subjects

USC

CONTENTS

QUICK LINKS

» iStar (IRB Application System)
» CITI (Human Subjects Edu.)
» HIPAA(Privacy Rule)

OTHER RESOURCES

» Research Related Committees
» FWAs and Delegation Memos
» Research at USC
» Health Research Association

Search »

Association for the Accreditation of Human Research Protection Programs, Inc. — Full AAHRPP Accreditation

Welcome to the Office for the Protection of Research Subjects

a commitment to respecting the rights and dignity of all persons

OPRS
About Us
AAHRPP (Accrediting Body for Human Subjects Research)
UPC/HSC Schedule for Human Subjects Education Sessions
Library of Human Subjects Research Brochures

For the General Public
Research Subjects
Clinical Trials Search
Should I Participate in Research? (English) (PDF)
¿Debería participar en una investigación? (Espanol)(PDF)

News and Events
University Park Human Subjects Education Session on 10/11
Health Sciences Human Subjects Education Session on 10/18
Reminder of Human Subjects Education Requirement (8/27/07)
iStar Changes Being Implemented on 7/12
USC Gets Human Research Accreditation (6/26/07)
HSPP Policies and Procedures Available Online
Human Subjects Newsletter
Human Subjects News

Complaints, Concerns, or Reports of Violations
Click here for info to report a complaint, concern, or violation

INSTITUTIONAL REVIEW BOARDS

UPIRB
University Park Institutional Review Board

HSIRB
Health Sciences Institutional Review Board

UPIRB How To:
Submit a New Proposal...
Submit a Claim of Exemption...
Submit a Continuing Review...
Submit an Amendment...
Why is IRB Submission Required?
iStar Application at a Glance...
Model IRB Applications

HSIRB How To:
Submit a New Proposal...
Submit a Continuing Review...
Submit an Amendment...
Why is IRB Submission Required?
iStar Application at a Glance...

Done

http://www.usc.edu/admin/provost/oprs/upirb

University of Southern California

Protection of Research Subjects

USC

CONTENTS

QUICK LINKS

» iStar (IRB Application System)
» CITI (Human Subjects Edu.)
» HIPAA (Privacy Rule)

OTHER RESOURCES

» Research Related Committees
» FWAs and Delegation Memos
» Research at USC
» Health Research Association

Search »

Association for the Accreditation of Human Research Protection Programs, Inc. — Full AAHRPP Accreditation

UPIRB University Park Institutional Review Board

HOW TO...

How To Submit a New Proposal...
How To Submit a Claim of Exemption...
How To Submit a Continuing Review...
How to Submit an Amendment to a Previously Approved Protocol...
Why? IRB Application and Review
iStar Application at a Glance...
IRB Application Templates/Examples

SEE ALSO:

HSIRB
Health Sciences Institutional Review Board

OPRS
Protection of Research Subjects

NEWS & ANNOUNCEMENTS

» University Park Human Subjects Education Session 10/11/07
» iStar Changes Being Implemented on 7/12
» Reminder of Human Subjects Education Requirement (8/27)
» New Student Researcher Page
» 2007-08 Meeting Schedule Available
» Human Subjects Research Brochures Posted Online
» Compliance and Monitoring Adherence
» UPIRB Office Hours
» Additional UPIRB Human Subjects Information Available

http://www.usc.edu/admin/provost/oprs/hsirb

University of Southern California

Protection of Research Subjects

USC

CONTENTS

QUICK LINKS

» iStar (IRB Application System)
» CITI (Human Subjects Edu.)
» HIPAA (Privacy Rule)

OTHER RESOURCES

» Research Related Committees
» FWAs and Delegation Memos
» Research at USC
» Health Research Association

Search »

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HSIRB Health Sciences Institutional Review Board

HOW TO...

How To Submit a New Proposal...
How To Submit a Continuing Review...
How to Submit an Amendment to a Previously Approved Protocol...
Why? IRB Application and Review
iStar Application at a Glance...

SEE ALSO:

UPIRB
University Park Institutional Review Board

OPRS
Protection of Research Subjects

NEWS & ANNOUNCEMENTS

» Health Sciences Human Subjects Education Session on 10/18
» Reminder of Human Subjects Education Requirement (8/27)
» iStar Changes Being Implemented on 7/12
» USC Gets Human Research Accreditation

CITI (Human Subjects Education Program)

How do I access the CITI course?
NOTE: You will need to input your iStar username during the registration process so that CITI certification can be automatically uploaded into your iStar account. If you do not already have an iStar username, visit the iStar website at http://istar-chla.usc.edu

To access the CITI course, follow these instructions…

1. Go to the "CITI Login and Registration Page": http://www.citiprogram.org (opens in new window for easy toggle)
2. If you already registered for CITI, enter your username and password (iStar username and password will NOT work unless you register). If you have not registered for CITI, proceed below.
3. Click on the red hyperlink “Register Here”. It is located in the "New Users" section.
4. Under the “Participating Institutions” drop down menu, locate University of Southern California and highlight. Click the “submit” button
5. Choose a unique username and password (username DOES NOT have to be your iStar username). Click the “submit” button.
6. Enter your name and email address in the appropriate fields.
7. Fill in the required fields in the "Member Information" page. (This is the section where you will input your iStar username). Only asterisked fields are required. Click the “submit information” button.
8. Select a group appropriate to your research activities. If you are unsure of what user group applies to you, contact the CITI helpdesk.
9. For the question, "Do you need to take training for more than one institution?", select "No" unless you are certain you need to take for another institution.
10. You can begin the course from the "Learner's Menu" page. Click on the red hyperlink "Enter", located under the "Status" header.

11. You must complete the modules in sequential order (except for elective modules), and obtain a cumulative score of at least 80% to pass. You can retake any quiz as many time as you would like to improve your score.
12. Log in as many times as necessary to complete the course. Once you have completed the course, a certificate will be issued and stored in your CITI account. Your certificate validity dates will be automatically uploaded into iStar.
13. Contact the CITI help desk at (213) 821-5272 or citi@usc.edu if you have questions.

What is CITI?
CITI (Collaborative IRB Training Initiative) is the premiere online human subjects education program. It is currently used at more than 800 institutions. It was created, developed, and is maintained by experts from the human subjects research community.

The CITI program offers...

- Dynamic organization committed to providing quality instructional resources to the research community.
- Comprehensive content.
- Institutionally driven course curriculum.
- Economy of time for the user.
- The course is available 24/7/365 from nearly anywhere
- A “user friendly” presentation model & Assessment tools.
- Help Desk for users and administrators.

How does CITI work?
The CITI program provides key personnel the opportunity to complete education modules and quizzes relevant to their research and discipline. A pool of modules is offered from which key personnel elect which ones to complete. A cumulative score of at least 80% is required for a completion certificate to be issued. The certificate is automatically uploaded into iStar, so there are no additional steps needed once you complete the program.

Who needs to take CITI?
All “key personnel” listed on the IRB application will be required to complete human subjects education before a study is approved by the IRB.

Who are “key personnel”?
“Key Personnel” are any individuals responsible for the protocol development or design, conduct, or reporting of research. These include but are not limited to: Principal Investigators (PIs), Co-PIs, faculty advisors, study coordinators, recruitment staff, and anyone else performing study procedures or interventions. If you are unsure whether or not you or someone on your study team needs to take CITI, please contact the OPRS at (213) 821-1154 or oprs@usc.edu

Who are NOT considered "key personnel"?
Individuals who are not considered “key personnel” includes technical staff such as: coders, statisticians, data entry personnel, IT support, and others. Adminstrative staff including secrectarial support, and logistics coordinators, and others types of administrative staff are also not considered “key personnel”. Although, these folks are not considered “key personnel” for the purpose of human subjects education they may be required to complete the HIPAA education program. Please see the Office of Compliance website:
http://ooc.usc.edu/PrivacySecurity/HippaPrivacy/EduProgram.cfm

Why do I need to take CITI?
Mandatory CITI education fulfills USC's committment to promote ethical conduct towards human subjects in all research projects, funded or unfunded. An IRB application, with key personnel listed who do not receive CITI certification, WILL NOT BE APPROVED BY THE IRB.

Do I need to take CITI if a project is "exempt"?
Yes, even if a projects is exempt all key personnel are still required to take CITI. A special user group is available for key personnel listed on "exempt" applications.

Do I need to take CITI if a project was determined to be "not human subjects research"?

NO, if a project was determined to be "not human subjects research" (e.g.this applies whether coded specimen/data or not meeting the federal definition) key personnel do not need to take the CITI course.

Do I need to take CITI if I already completed HIPAA and Contracts Management training?
Yes, you must complete CITI training even if you completed both HIPAA and the Contracts Management training. CITI is human subjects education while HIPAA and Contract Management training are not.

Do I need to take CITI for amendments to a previously approved IRB application?
Amendments for adding "key personnel" on a study require that the added individual(s) complete CITI before the amendment is approved. All other types of amendments to a previously approved IRB application do not require CITI certification although we strongly recommend key personnel take it anyways.

How is the new human subjects education policy different from the old policy?
The new policy requires USC key personnel (whether faculty, staff, or students) listed on ALL human subjects studies to complete human subjects education no matter which campus they are from (HSC or UPC). Previously, only key personnel listed on NIH funded studies were required to complete human subjects education.

Do I need CITI certification to have my IRB application approved?
YES!! And so do all key personnel listed on the IRB application. However, if you completed a human subjects education program at another institution, please send documentation of this to the OPRS.

How long will it take to complete the course?
Each CITI module has text to read and a quiz to complete. The average learner spends approximately 4.5 hrs in the Basic Course site and uses approximately 5 logins to complete the course.

How often do I need to take human subjects education?
Key personnel listed on IRB applications are required to complete the CITI program or equivalent every three (3) years. Confirmation of educational certification will be required prior to the approval of research projects submitted to the IRB.

I already have human subjects certification from the Office of Compliance.
The CITI program will replaced the education program offered by the USC Office of Compliance. However, current human subjects education certification from the Office of Compliance are valid until the certification expires. At that time, it will be necessary to complete the CITI program.

I already have certification from an outside institution?
Valid human subjects education certification accepted by other institutions such as NIH (National Institute of Health), Childrens Hospital Los Angeles (CHLA) or Rancho Los Amigos Rehabilitation Center will be accepted in lieu of CITI certification. Please upload a copy of this certification into iStar.

How do I upload my certificate from an outside institution into iStar?

1. Log in to iStar at http://istar-chla.usc.edu
2. Click on your name in the top right. This will take you to your personal profile.
3. Below the "Properties" tab, there is a "Select View" and a drop down box. Select "Edit User Profile" in the drop down box.
4. Once the screen refreshes, scroll down and attach the certificate using the "Add" button in the Human Subjects Certification area.
5. To save your profile, click the "Apply" button all the way at the bottom right.

Which user-group should I select?
The user-group you select depends on:
A) which IRB you will submit to;
B) what your role is in human subjects research (PI, IRB member, student investigator, etc); and
C) the type of research you are doing: biomedical, social & behavioral, or level of IRB review (Exempt or Expedited/Full Board) .

The different user-groups are listed below:

- **Health Sciences Investigators, Key Personnel, and HSIRB Members/Staff**
- **Health Sciences Investigators and Key Personnel Conducting Exempt Research****
- **University Park Student Investigators, Investigators/Key Personnel Conducting Exempt Research**, and Faculty Advisors on Student Research Projects**
- **University Park Faculty/Staff Investigators, Key Personnel, and UPIRB Members/Staff**

**Exempt research (e.g. de-identified data analysis, retrospective chart reviews, case reports, or key personnel listed for authorship purposes only). This course is NOT intended for studies involving vulnerable populations (e.g. children, pregnant women), or for Expedited or Full Board studies.

How do I check my certification expiration date?
To check the expiration date of your human subjects education certificate do the following:

1. Log into iStar http://istar-chla.usc.edu
2. Click on your name in the upper right-hand corner to bring up your profile.
3. Scroll down the profile page to the “certifications” section.
4. Your certification expiration date will be listed there.

How do I print a copy of my certification?
To print a copy of the CITI certificate do the following:

1. Log in into CITI (How do I access the CITI course?)
2. From the "Learners Menu" page, click on the "Completion Reports" link
3. The "Completion Reports" page will list all the CITI courses you have completed
4. Click on the completion report you want to print

To print a copy of the USC Office of Compliance certificate do the following:

1. Click on the following link https://ais-troy.usc.edu/cechsep-index-ssl.html
2. Log in
3. From the main menu you can print a copy of your certificate.

Questions or comments
USC CITI Help Desk
(213)-821-5272
citi@usc.edu

Technical questions or help:
For technical questions or help, please contact CITI at:
(305) 243-7970 or
citisupport@med.miami.edu

CITI FAQs
To see FAQs provided by CITI please click on the following link—
http://www.citiprogram.org/citidocuments/faq.htm

Whom at USC do I contact for human subjects research info, or to voice a concern or complaint?

USC Complaints, Concerns, or Reports of Violations Website
This website provides info on how to report a complaint, concern, or violation (anonymously if you prefer). You can also contact the offices listed below.
www.usc.edu/admin/provost/oprs/contact/complaints

Office for the Protection of Research Subjects (OPRS)
Susan L. Rose, Ph.D., Executive Director
3720 South Flower Street 325
Los Angeles, CA 90089-0706
Tel: (213)-821-1154 Fax: (213)-740-9299
E-mail: oprs@usc.edu
http://www.usc.edu/admin/provost/oprs

Health Sciences Institutional Review Board
Darcy Spicer, M.D., Chair
Sandra Jean, CIP, IRB Director
IRD Building, 2020 Zonal Ave, Room 425
Los Angeles, CA 90033
Tel: (323)-223-2340 Fax: (323)-224-8389
E-mail: irb@usc.edu
http://www.usc.edu/admin/provost/oprs/hsirb

University Park Institutional Review Board
Richard John, Ph.D., Chair
Kristin J. Craun, MPH, CIP, Director
Stonier Hall, Room 224a
Los Angeles, CA 90089-1146
Tel: (213)-821-5272 Fax: (213)-821-5276
E-mail: upirb@usc.edu
http://www.usc.edu/admin/provost/oprs/upirb

For copies of this brochure contact the oprs@usc.edu

Adapted from the Department of Veterans Affairs' Office of Research Compliance & Assurance "I'm a veteran. Should I participate in research?", and the University of Iowa Human Subjects Office "So you're thinking about being in a research study." http://research.uiowa.edu/hso/docs/brochureforpublic.pdf

Should I participate in research?

Some things you NEED to know before deciding to participate in research…

USC UNIVERSITY OF SOUTHERN CALIFORNIA

LAC+USC Healthcare Network

What is research?
Research is the collecting and analyzing of data that is done to answer a question. Some other words for research are clinical trial, protocol, survey, or experiment.

What is a human subject?
A subject is someone who volunteers to participate in research.

Who can be a subject in a research study?
Most research studies have certain requirements that must be met in order for a subject to participate. These requirements are designed to ensure the safety of the subjects and the usefulness of the research. Some studies have broad requirements such as being over 18. Other studies have a more focused requirement such as having a certain disease.

Do I have to participate?
NO! Participating in a research study is voluntary. A subject can drop out of a study at any time. Refusing to participate in a study will not result in a penalty or loss of any benefits to which you are entitled.

Are there risks to being in a research study?
Research may involve different types of risk. A study that asks you to fill out a survey has only minor risks, such as questions that may make you uneasy. For other studies, such as taking an experimental drug, the risks can be much greater (e.g. having a bad reaction to the drug). The research team is required to explain to you the foreseeable risks of being in the study before you decide whether or not to participate.

Are there benefits to being in a research study?
Not everyone who participates in a research study will benefit personally. Sometimes, your participation in the research study will be of benefit to society by helping researchers to learn more about a certain disease or condition. In some studies, however, you may personally benefit from medication that aids in your recovery or from any needed counseling.

Who leads a research study?
The Principal Investigator (PI) leads the research study. The PI is responsible for the overall conduct of the research study. The PI is also responsible for assuring the safety of the subjects. PIs are often faculty, physicians, or students.

Who else is involved in research studies?
Principal Investigators often rely on a research team to assist them in their study. The research team can be made up of research assistants, research nurses, data coordinators, statisticians, and other people with special skills needed for the study.

Who reviews a study?

At the University of Southern California, all studies that involve human subjects are reviewed by an Institutional Review Board (IRB) before they are allowed to begin.

What is an IRB?

An IRB is a committee of scientists and non-scientists who review projects submitted by researchers. The University of Southern California has four IRBs; one on the University Park Campus, and three on the Health Sciences Campus. The IRB's purpose is to protect the rights and welfare of the research subjects in a study.

Who will see my records?

Like your medical record, the information in your research record will be confidential. Information will be given only to the researchers who carry out the study or to those who make sure the study is safe and carried out the way it was planned.

Are there any special rules to help protect certain subjects?

Children, pregnant women, and prisoners can all be participants in research studies, but are considered potentially "vulnerable populations." There are special rules to protect participants who fall into one of these groups.

What kinds of procedures are involved?

Research studies can involve a wide variety of procedures, ranging from filling out surveys and questionnaires to taking experimental medicines or using experimental devices. Some research studies last only a few minutes, while others last for several years. The research team will describe to you all of the procedures that you will be asked to undergo before you agree to be in the study.

What is informed consent?

Informed consent is the process of learning the key facts about a research study before you decide whether or not to volunteer. Your agreement to volunteer should be based upon a clear understanding of what will take place in the study and how it might affect you. The consent process begins when the research staff explains the facts about the research study to you. The research staff will assist you with the "informed consent form" that goes over these facts so you can decide whether or not you want to take part in the study. These facts include details about the study, tests, or procedures you may receive, the benefits and risks that could result, alternatives available should you decided not to participate, and your rights as a research volunteer.

What questions should I ask before I agree to take part in a research study?

Before you decide to volunteer for a research study, you need to know as much as possible about it. If there are any issues that concern you, be sure to ask questions. The following is a list of important questions. **Not every question applies to every study, but you have every right for answers to all you ask.**

- ☐ Will I benefit from this study?
- ☐ Who is doing this study and what question might it answer?
- ☐ Will this research help me to understand my condition? If so, how?
- ☐ Will I miss out on any "normal care" by participating in this study?
- ☐ What tests or procedures will be done?
- ☐ What alternatives are available if I decide not to participate in the study?
- ☐ Is it possible that I will receive only a placebo (inactive substance)?
- ☐ What could happen to me, good or bad, if I take part in the study?
- ☐ How long will the study last?
- ☐ What will happen to specimens I give?
- ☐ Who has reviewed/approved this study?
- ☐ If I have a condition, could it get worse during the study?
- ☐ Will I be charged anything or paid anything to be in this study?
- ☐ If I decide to participate in this study, how will it affect my daily life?
- ☐ What will happen to me at the end of the study?
- ☐ Will I be told the results of the study?
- ☐ Who will find out that I am taking part in this study?
- ☐ How do I end my participation in this study if I change my mind?
- ☐ Whom do I contact for questions and information about the study?
- ☐ What risks are involved in this study?

Where can I find reliable health and research information?

USC Human Subjects Information
Provides links to research and health info for subjects. www.usc.edu/admin/provost/oprs/public

American Heart Association
Features an online heart and stroke encyclopedia. www.americanheart.org

ClinicalTrials.Gov
Provides info about federally and privately supported clinical research. www.clinicaltrials.gov

Family Doctor
Health info from the American Academy of Family Physicians. www.familydoctor.org

Healthfinder
A health library available in English and Spanish. www.healthfinder.gov

Medem
A partnership among medical societies to foster doctor patient-communications; includes an online medical library. www.medem.com

Medline Plus
The National Library of Medicine's complete health info portal. http://medlineplus.gov

National Cancer Institute
Provides clinical details about every type of cancer and the latest treatments. www.cancer.gov

IS YOUR PROJECT HUMAN SUBJECTS RESEARCH?

A Guide for Investigators

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CALIFORNIA

Office for the Protection of Research Subjects

Office of the Provost

This booklet, prepared by the Office for the Protection of Research Subjects (OPRS), provides guidance to USC investigators who may be uncertain if their study meets the definitions of human subjects research stated in the federal regulations (45CFR46.102). The OPRS recognizes that the definition may not always provide a straightforward answer. Is Your Project Human Subjects? A Guide for Investigators offers investigators an explanation of the definitions as well as examples of studies that do or do not qualify as human subjects research. For further information, please refer to the *Resources* section in the back of this booklet.

HUMAN SUBJECTS RESEARCH

Research projects involving human subjects require review and approval by an Institutional Review Board. An IRB is an ethics committee composed of scientists and non-scientists who serve as advocates for human subjects involved in research. The IRB is charged with the responsibility of reviewing and overseeing human subjects research conducted under the aegis of USC. The first question a researcher should consider with respect to IRB review is whether the research project fits the definition of human subjects research. In light of the mission to protect human subjects, and the potential regulatory consequences of not obtaining IRB review and approval, **the investigator should choose to err on the side of caution and consult the IRB or the IRB Designee when he/she is uncertain whether the study is human subjects research or not.**

DEFINING RESEARCH

Federal Regulations define **research** as **"a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge[1]"** (45CFR46.102(d)). As described in the Belmont Report[2] "...the term 'research' designates an activity designed to test a hypothesis [and] permit conclusions to be drawn... Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective."

"Research" generally does **not** include operational activities such as defined practice activities in public health, medicine, psychology, and social work (e.g., routine outbreak investigations and disease monitoring) and studies for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits, marketing studies or contracted-for services. It generally does not include journalism or political polls. However, some of these activities may include or constitute research in circumstances where there is a clear intent to contribute to generalizable knowledge.

[1] "Generalizable knowledge" is information where the intended use of the research findings can be applied to populations or situations beyond that studied.

[2] The Belmont Report is a statement of ethical principles (including beneficence, justice, and autonomy) for human subjects research by the U.S. Department of Health, Education, and Welfare.

DEFINING HUMAN SUBJECTS

A **human subject** is defined by Federal Regulations as **"a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."** (45 CFR 46.102(f)(1),(2))

Living individual – The specimen(s)/data/information must be collected from live subjects. Cadavers, autopsy specimens or specimens/ information from subjects now deceased is not human subjects.

"About whom" – a human subject research project requires the data received from the living individual to be **about** the person.

Intervention includes physical procedures, manipulations of the subject, or manipulations of the subject's environment for research purposes. **Interaction** includes communication between the investigator and the subject. This includes face-to-face, mail, and phone interaction as well as other modes of communication.

Identifiable private information[3] "includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place," (such as a public restroom) "and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a health care record)." (45 CFR 46.102(f)(2)) **"Identifiable" means the information contains one or more data elements that can be combined with other reasonably available information to identify an individual** (e.g. Social Security #).

Observational studies of public behavior (including television and internet chat rooms) do **not** involve human subjects as defined when there is no intervention or interaction with the subjects and the behavior is not private. Also, studies based on data collected for non-research purposes may **not** constitute human subjects research if individuals are not identifiable (e.g. data such as service statistics, school attendance data, crime statistics, or election returns).

Studies based on data that are individually identifiable but are also publicly available may **not** constitute human subjects research. However, the term "publicly available" is intended to refer to record sets that are truly readily available to the broad public, such as census data, or federal health, labor, or educational statistics. An investigator should **not** assume information qualifies as "publicly available" merely because it has been posted on an electronic website and can be accessed without authorization.

[3] Researchers must take caution since disclosure of private information may place the subjects at risk of criminal or civil liability and/or damage their financial standing, employability, or reputation.

IDENTIFYING HUMAN RESEARCH STUDIES

Certain studies may have the characteristics of human subjects research but may not meet the regulatory definition. Studies which meet the definition require IRB review. There are three categories to be considered:

- **studies that <u>are</u> human subjects research**
- **studies that <u>may be</u> considered human subjects research (gray area)**
- **studies that <u>do not</u> qualify as human subjects research**

Any investigator who is unsure of whether his/her proposal constitutes "human subjects research" should contact the IRB office or submit an online "Request for Human Subjects Research Determination" through iStar (http://istar-chla.usc.edu). The IRB staff, Chair and/or designee will determine if the study is human subjects research. Federal regulations do not allow investigators to make this determination themselves.

If a study does not qualify as human subjects research, the IRB can issue a letter stating that the project does not require IRB review or approval. When a "Request for Human Subjects Determination" is submitted through iStar, a decision letter will be sent to the investigator via email. NOTE: Grant offices, faculty advisors, or publications may require a determination letter from the IRB/designee.

STUDIES THAT ARE <u>NOT</u> HUMAN SUBJECTS RESEARCH

Studies that fit any of the categories below <u>do not</u> need IRB review.

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

2. **Service 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, as long as the privacy of the subjects is protected, the confidentiality of individual responses are maintained, and survey participation is voluntary. This would include surveys by professional societies or University consortia. *Note: If at a future date, an opportunity arose to contribute previously collected identifiable or coded survey data to a new study producing generalizable knowledge, IRB review may be required before the data could be released to the new project.*

3. **Information-gathering interviews** where questions focus on things, products, or policies rather than people or their thoughts regarding themselves. 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, but are **not** intended for use outside of the classroom. Example: instruction on research methods and techniques. *Note: The IRB is only required to review studies that meet the Federal definitions of research and human subject[4], or "engaged in research"[5].*

5. **Biography or oral history** research involving a living individual that is not generalizable beyond that individual.

6. **Independent contract for procedures** carried out for an external agency. Examples: personnel studies, cost-benefit analyses, customer satisfaction studies, biological sample processing (for a fee and not authorship or other credit), public park usage, IT usage, and software development.

7. **Research involving cadavers,** autopsy material or bio-specimens from now deceased individuals. *Note: Some research in this category, such as genetic studies providing private or medical information about live relatives, may need IRB review. Please contact the IRB for further information.*

8. **Innovative therapies** except when they involve "research" as defined by the above criteria. (An innovative clinical practice is an intervention designed solely to enhance the well being of an individual patient or client. The purpose of an innovative clinical practice is to provide diagnosis, preventative treatment, or therapy to particular individuals.) *Note: When innovative therapies differ significantly from routine practice it should be viewed and treated as such with appropriate safeguards in place to protect the rights and welfare of the patients.*

9. **Quality improvement** projects are generally **not** considered research unless there is a clear intent to contribute to generalizable knowledge ***and*** use the data derived from the project to improve or alter the quality of care or the efficiency of an institutional practice. Any individual who is unsure whether or not a proposed quality improvement project should be classified as research should contact the IRB for guidance. If the data is re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application must be submitted to the IRB.

10. **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

[4] http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
[5] http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm

and/or outcome of a single patient and do not contribute to generalizable knowledge.

11. **Publicly available data** do **not** require IRB review. Examples: census data, labor statistics. *Note: Investigators should contact the IRB if they are uncertain as to whether the data qualifies as "publicly available".*

12. **Coded private information or biological specimens** that were **not** collected for the currently proposed projects do not need IRB review as long as the investigator cannot link the coded data/specimens back to individual subjects. If the data/specimen provider has access to the identity of the subjects (e.g. subjects' names, addresses, etc.), the investigator must enter into an agreement with the data/specimen provider that states under no circumstances will the identity of the subjects be released to the investigator. *Note: Investigators are not allowed to make this determination. These projects require verification from the IRB or the IRB liaison/designee.* (http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf)

13. Some examples of **Non-Engagement in Research** include: when an institution's employees or agents act as consultants on research but at no time obtain, receive, or possess identifiable private information, perform commercial services for the investigators, or inform prospective subjects about the availability of research. *Note: the examples above are not an all inclusive listing.* (http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm)

STUDIES THAT ARE HUMAN SUBJECTS RESEARCH

1. Studies that utilize test subjects for new devices, products, drugs, or materials.

2. Studies that collect data through intervention or interaction with individuals. Examples of this type of research include drug trials, internet surveys about alcohol consumption, studies that involve deception, research involving risky behaviors or attitudes, and open-ended interviews with minors that contribute to generalizable knowledge.

3. Studies using private information that can be readily identified with individuals, even if the information was not collected specifically for the study in question.

4. Studies that use bodily materials such as cells, blood, urine, tissues, organs, hair, or nail clippings, even if one did not collect these materials for the study. However, such research may be considered exempt or not human subjects research if the materials/data are coded and the investigator does not have access to the coding systems. Guidance on research involving coded private information or biological specimens is available on the web at: (http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf.)

5. Studies that produce generalizable knowledge about categories or classes of subjects from individually identifiable information.

6. Studies that use human beings to evaluate environmental alterations, for example, weatherization options or habitat modifications to their living or working space or test chamber.

RESOURCES

- United States Department of Health & Human Services: Office for Human Research Protections (OHRP) http://www.hhs.gov/ohrp/

- US HHS Office of Human Research Protections (OHRP) **Decision chart to assist in determining whether a project is human subjects research.** www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm select: *Chart 1: Is an Activity Research Involving Human Subjects?*

- US HHS Office for Human Research Protections (OHRP) **Engagement of Institutions in Research** http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm

- United States Food and Drug Administration
  http://www.fda.gov/

- Federal Policy for the Protection of Human Subjects **(Common Rule)**
  http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

- **Guidance on Research Involving Coded Private Information or Biological Specimens**
  http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf

- **The Belmont Report**
  http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm

- Pritchard, Ivor A. **Searching for "Research Involving Human Subjects": What is Examined? What is Exempt? What is Exasperating**; *IRB: Ethics and Human Research* 23, no.3 (2001), 5-12

- University of Southern California: Office for the Protection of Research Subjects website
  http://www.usc.edu/admin/provost/oprs/

- University of Southern California: Institutional Review Board website
  http://www.usc.edu/admin/provost/oprs/upirb/

- University of Southern California: **IRB Submission Tracking and Review System (iStar) website**.
  http://istar-chla.usc.edu/
  Note: To access the Request for Human Subjects Determination application, you must login to iStar and click the "request information" button located under "Should I Submit My Project to HSIRB or UPIRB?".

WHOM TO CONTACT

Office for the Protection of Research Subjects (OPRS)
3720 South Flower Street
Credit Union Buidling 325
Los Angeles, CA 90089-0706
Tel: (213) 821-1154
Fax: (213) 740-9299
E-mail: oprs@usc.edu
http://www.usc.edu/admin/provost/oprs/upirb/

Health Sciences Institutional Review Board
2020 Zonal Avenue
IRD Building, Room 425
Los Angeles, CA 90033
Tel: (323) 223-2340
Fax: (323) 224-8389
E-mail: irb@usc.edu
http://www.usc.edu/admin/provost/oprs/hsirb/

University Park Institutional Review Board
837 Downey Way
Stonier Hall, Room 224a
Los Angeles, CA 90089-1146
Tel: (213) 821-5272
Fax: (213) 821-5276
E-mail: upirb@usc.edu
http://www.usc.edu/admin/provost/oprs/upirb/

Office of Compliance
3500 Figueroa Street
University Gardens Building, Room 105
Los Angeles, CA 90089-8007
Tel: (323) 740-8258
Fax: (213) 740-9657
E-mail: complian@usc.edu
http://www.usc.edu/admin/compliance/

1. Project Identification Information

1.1. * **Type of Submission**:

- (●) Research Protocol/Study/Class Project Only
- ( ) Grant/Contract Only
- ( ) Facilitated Review (CIRB)

1.2. **Full Title of Research Protocol**
A Study of Thriving

1.3. * **Short Title**
A Study of Thriving

1.3.1. **If there is a sponsor protocol number associated with this file, specify it here:**

1.4. * **Please indicate which IRBs you are requesting review from (check all that apply):**

- [ ] USC - Health Sciences IRB (HSIRB)
- [x] USC - University Park IRB (UPIRB)
- [ ] CHLA - Committee on Clinical Investigations (CCI)

1.4.1. **If there are any individual collaborators from other institutions, check here:** [x]

iStar ID: Application Version Date:5/7/2006 Version:1.0

2. Study Personnel (for a study already submitted to the IRB)

This screen indicates the active study team once the proposal has been submitted. This screen is not required during presubmission and should be left blank.

2.1. * **Principal Investigator (PI):**

2.2. **Study Coordinator or Contact Person:**

2.3. **Co-Investigators:**

Last	First	Organization

There are no items to display.

2.4. Other Study Personnel who will be able to edit this online application and study materials:

Last	First	Organization

There are no items to display.

2.5. * Is the Principal Investigator a student, resident, trainee, or visiting scholar?

○ Yes ◉ **No**

2.6. If yes, please designate a Faculty Advisor:

2.7. Guests (Other registered users who will have read-only access to this IRB submission):

Last Name	First Name	Organization

There are no items to display.

iStar ID:	Application Version Date:5/7/2006 Version:1.0

3. Required Department Approvals (for a study already submitted to the IRB)

This screen indicates the division/department approvals received once the proposal has been submitted. This screen is not required during presubmission and should be left blank.

3.1. Pending Division/Department Approvals:

Name	Division/Department	Parent Campus

There are no items to display.

3.2. Received Division/Department Approvals:

Name	Division/Department	Parent Campus

There are no items to display.

3a.3. (HSC Only) Other Health Science campus committees that will need to review and approve this protocol:

Committee Name	Committee Chair	Approval Memo

There are no items to display.

3c.3. (CHLA Only) Other CHLA hospital committees that will need to review and approve this protocol:

Committee Name	Committee Chair	Approval Memo

There are no items to display.

3c.4. (CHLA Only) Are you planning to submit this study to the GCRC for review?

○ Yes ○ No

iStar ID	Application Version Date:5/7/2006 Version:1.0

2d. Collaborators from other institutions

This screen is required if there are collaborators from other institutions (Question 1.4.1.)

Collaborators from other institutions:

Last Name	First Name	Institution	Role

iStar ID: Application Version Date:5/7/2006 Version:1.0

4. Study Location(s)

4.1. Indicate the locations where this study will be conducted by the USC/CHLA investigator(s) (check all that apply):

Location	
HSC - Health Sciences Associated Locations	☐
UPC - University Park Associated Locations	☐
CHLA	☐
Other Sites/Institutions (In the US)	☑
Other Sites/Institutions (Outside the US)	☐

4.2. Is this a multi-site study?

◉ **Yes** ○ No

iStar ID: Application Version Date:5/7/2006 Version:1.0

5c. Other Sites/Institutions

This screen is required if you indicated Other Sites/Institutions inside or outside the US (Question 4.1.)

5c.1. Other Sites/Institutions (In the United States): List all of the non-USC/CHLA sites at which the Principal Investigator will conduct the study.

Site Name	Address

5c.2. Other Sites/Institutions (Outside the United States): List the institution(s) and country(ies) at which the Principal Investigator will conduct the study.

Site Name	Address	Country

There are no items to display.

iStar ID: Application Version Date:5/7/2006 Version:1.0

6. Information For Multi-Site Study

This screen is required if you indicated this is a multi-site study (Question 4.2.)

6.1. Is the coordinating center at HSC, UPC, or CHLA?

◉ **Yes** ○ No

If yes, describe how the information relevant to protecting participants, such as reporting of

6.1.1. If yes, describe how the information relevant to protecting participants, such as reporting of unexpected problems, protocol modifications, and interim results are managed.
This is a simple web-based survey in which data will be stored by the Principal Investigator, Christine Porath. Participants will be able to contact the Principal Investigator at any time to report any unexpected problems.

6.2. If no, what is the location of the coordinating site? (If there is no coordinating site, indicate N/A).

iStar ID:	Application Version Date:5/7/2006 Version:1.0

7. Funding Information

7.1. Are you or the institution receiving any financial support for the conduct of this study?

○ Yes ◉ **No**

iStar ID:	Application Version Date:5/7/2006 Version:1.0

8. Type of Study Review

8.1. Please indicate the type of review that you are requesting for this study:
Exempt Review

8.2. Attach the Protocol(s) or Proposal(s) below if applicable. Also attach the sponsor's informed consent template and summary of protocol changes if they are separate documents. DO NOT ATTACH OLD VERSIONS OF THE IRB APPLICATION (AKA SECTION II) AS A PROTOCOL.

name	Version	Modified
Thriving Survey	0.01	5/6/2006 6:29 AM

iStar ID:	Application Version Date:5/7/2006 Version:1.0

8b. Type of Study Review - Application for Exempt Status

This screen is required if you are requesting a claim of exemption for this study (Question 8.1.)

WARNING: A Claim of Exemption is not allowed for any research involving prisoners or minors (except for research involving observations of public behavior of minors when the investigator(s) do not participate in the activities being observed). In these cases, you must request Expedited Review.

8.1. Please indicate the type of review that you are requesting for this study:
Exempt Review

8b. If you checked that your study meets the qualifications for exempt status, please choose the applicable category from the list and attach your data collection forms below. (Note: these exemptions do not apply to research involving prisoners. For children, all exemption categories apply except for (2) unless it is simply observation of public behavior and the investigator does not interact with the children.) Click on the abbreviated category to receive the full description:

	Short Description (click for full desciption)
☐	(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices...
☑	(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior...
☐	(3) Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section...

- [ ] (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens...
- [ ] (6) Taste and food quality evaluation and consumer acceptance studies...
- [ ] (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...

Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review. To request this category of exempt research, contact the IRB office to obtain the requisite forms and information.

8b.1. If you checked that your study meets the qualifications for exempt status, please attach a copy of the forms you will be using to collect data, if applicable. In addition, include any applicable data use agreements:

name	Version	Modified
Thriving Survey	0.01	5/6/2006 6:31 AM

9. Methods and Procedures - Selected Descriptors

Note: The items listed below ARE NOT an all inclusive list of methods and procedures available to investigators. The list only includes items that will trigger additional questions specific to areas of research or are necessary for the review process.

9.1. * Social-Behavioral Procedures (check any or all that apply):

Specific Descriptor

- [ ] Behavioral Observations and/or Behavioral Experimentation
- [ ] Behavioral Interventions
- [ ] Deception
- [ ] Interview/Focus Groups
- [ ] Population-based Field Study
- [ ] Psychophysiological Testing
- [x] Surveys/Questionnaires/Psychometric Testing
- [ ] Other Social-Behavioral Procedures
- [ ] None of the above Social-Behaivoral Procedures apply to this study.

9.2. * Medical Procedures/Considerations (check any or all that apply):

Specific Descriptor

- [ ] Biohazardous Substances
- [ ] Controlled Substances
- [ ] Emergency Treatment
- [ ] Gene Transfer Study
- [ ] Stem Cell Research
- [ ] Magnetic Resonance Imaging (MRI)
- [ ] Investigational/Approved Drugs and Biologics
- [ ] Investigational/Approved Devices

- [ ] Radiation exposure other than clinically indicated tests and/or therapy
- [ ] Radionuclides
- [ ] Substance Abuse Treatment (with medication)
- [ ] Surgery
- [ ] Venipuncture
- [ ] Other Medical Procedures/Considerations
- [x] None of the above Medical Procedures/Considerations apply to this study.

9.3. * **Data Collection Types (check any or all that apply):**

Specific Descriptor

- [ ] Banking of Specimens/Data (Creation of a repository)
- [ ] Prospective Collection of Specimens/Data
- [ ] Genetic Specimens
- [ ] Audio/Video Recordings or Photographs
- [x] None of the above Data Collection Types apply to this study.

9.4. * **Does this study involve the use of existing/retrospective data/specimens?**

○ Yes ◉ **No**

10. Characteristics of the Study Subject Population

10.1. **What is the maximum number of subjects you plan to recruit for this site? (Integer values only)**

50

10.1.1. **If this is a multi-site study, indicate the projected total subject accrual. (Integer values only)**

250

10.2. **Indicate the inclusion criteria for enrollment. (HSC: *refer to specific sections of the protocol/grant, if applicable*)**

Organizations will need to agree to participate in this web-based survey. XXXXXX plans to contact clients to solicit interest in participation.

10.2.a. **If needed, copy-and-paste any tables here and reference in the question above. Tables**

10.3. **Indicate the exclusion criteria for enrollment. (HSC: *refer to specific sections of the protocol/grant, if applicable*)**

NA

10.3.a. **If needed, copy-and-paste any tables here and reference in the question above. Tables**

10.3.1. **If there are any age, ethnic, language, or gender-based exclusion criteria, please provide justification.**

NA

11. Study Summary

11.1. Abstract: Provide a brief (1 to 2 paragraph) description of the study in LAY LANGUAGE. This should not be a scientific abstract.

Recently, there has been more of an emphasis on focusing on people's strengths and creating a context in which people can thrive. Thriving is defined as growth in a positive capacity, manifested in greater learning as well as enhanced vitality/energy (Spreitzer, Sutcliffe, Dutton, Sonenshein, & Grant, 2005). It is presumed that those who are thriving enjoy many benefits, including better performance and well-being. In this study, we focus on the organizational conditions and individual behaviors that enable thriving at work. Very little is known about the positive role that organizations can play in enabling thriving, and how individuals can affect human growth. We hope to better understand how organizations can create an environment in which people can thrive, and what individual actions facilitate this state. We also hope to show that people in a thriving state are more likely to perform better over time.

11.2. Research objectives and background

11.2.1. Describe the specific objectives or aims of the study and hypotheses or research questions. (HSC: *refer to specific sections of the protocol/grant, if applicable*)

Test whether a culture of incivility is negative related to individual thriving (and positively related to stress).

Test whether the communication climate of the organization is related to individual thriving.

Test whether individual thriving is associated with leader effectiveness and better performance (and negatively associated with stress or burnout).

11.2.2. Provide a summary of the background of the study, and explain how this research will contribute to existing knowledge. Describe previous work that provides a basis to show that the proposed research can be carried out without undue risk to human subjects. Include relevant citations. (HSC: *refer to specific sections of the protocol/grant, if applicable*)

Recently, there has been more of an emphasis on focusing on people's strengths and creating a context in which people can thrive. This is part of the Positive Organizational Scholarship (POS) movement. A recent theoretical article defines thriving as growth in a positive capacity, manifested in greater learning as well as enhanced vitality/energy (Spreitzer, Sutcliffe, Dutton, Sonenshein, & Grant, 2005). It is presumed that those who are thriving enjoy many benefits, including better performance and well-being. However, there have been no empirical studies to date. In this study, we focus on the organizational conditions and individual behaviors that enable thriving at work. We also hope to establish that this thriving state enables leadership effectiveness and performance (over time).

iStar ID: Application Version Date:5/7/2006
Version:1.0

12. Methods and Procedures - Prospective Studies

12.1. Describe in detail the design and methodology of the study. If applicable, include information on stratification or randomization plans. Identify and distinguish between those procedures that are standard of care and those that are experimental. Include the frequency and duration of each activity and the total length of subject participation. (HSC: *refer to specific sections of the protocol/grant, if applicable*)

This proposed study is a simple survey. The survey will contain validated items which measure individual thriving, the organizational culture, attitudes, and job/organizational characteristics.

The survey will be web-based.

12.1.a. If needed, copy-and-paste any tables here and reference in the question above.
Tables

12.2. Provide a detailed description of the planned data collection, specific outcomes, and criteria for evaluation and endpoint definition. (HSC: *refer to specific sections of the protocol/grant, if applicable*)
Once respondents answer the web-based survey, they will have completed the study. The sponsor organization will provide data about the respondent's performance.

12.2.a. If needed, copy-and-paste any tables here and reference in the question above.
Tables

12.3. Describe the statistical considerations for the study, how the sample size was determined, and how the results will be analyzed, if applicable. (HSC: *refer to specific sections of the protocol/grant, if applicable*)
Results of this study will be analyzed using SPSS. Regression analyses will be employed.

12.3.a. If needed, copy-and-paste any tables here and reference in the question above.
Tables

21. Methods and Procedures - Surveys/Questionnaires/Psychometric Testing

This screen is required if you indicated the use of Surveys, Questionnaires, or Psychometric Testing under social-behavioral procedures (Question 9.1.)

21.1. List all of the measures/instruments that will be used for this study and attach copies below.
Please see attached survey.

21.1.1. Attach copies of all measures/instruments that will be used for this study here.

name	Version	Modified
Thriving Survey	0.01	5/7/2006 6:03 AM

21.2. Indicate the member(s) of the study team who will use these measures/instruments and any necessary qualifications such as special training or licenses.
XXXXXX designed the survey and will be conducting analyses.
XXXXXXX will create the web-based design
so that participants can complete this survey on-line with all the web-based precautions necessary (such as firewalls in place).

22. Special Subject Populations

22.1. Special Subject Populations (Check all that apply).

Population	
Normal Volunteers	☐
Employees	☑
Students	☐

- [ ] Adults not Competent to Consent
- [ ] Non-English Speaking Populations
- [ ] Minors (subjects under 18 years of age)
- [ ] Pregnant Women, Human Fetuses, or Neonates
- [ ] Prisoners/Detainees
- [ ] Wards
- [ ] None of the above

iStar ID:	Application Version Date:5/7/2006 Version:1.0

22b. Special Subject Populations - Employees/Students

This screen is required if you indicated Employees or Students as a special subject population (Question 22.1.)

22b. If you selected Employees or Students, please indicate how you will minimize the potential for them to feel coerced to participate. Discuss how the potential confusion in roles will be addressed.
Participants have no external pressure to participate. Researchers will make it clear to employees that participation is voluntary. With the web-based design, there is little pressure or coercion to participate.

iStar ID:	Application Version Date:5/7/2006 Version:1.0

23. Subject Identification and Study Resources

23.1. Describe the method(s) by which subjects will be identified, eligibility will be determined, and by whom.
The sponsor organization will provide e-mail addresses for those who are eligible to participate.

23.2. Describe the time the investigators have available to conduct and complete the research and justify that it is sufficient.
Surveys will be web-based. Investigators will conduct and complete analyses of the project in a timely manner.

23.3. Describe the staff and justify they are adequate in number and qualifications.
Not applicable.

23.4. Describe the study facilities and justify they are adequate.
Not applicable.

23.5. Describe how the investigators will ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions.
Not applicable.

iStar ID:	Application Version Date:5/7/2006 Version:1.0

24. Subject Recruitment

24.1. Recruitment Tools (Check all that apply):

Tool

- [ ] E-mail
- [ ] Flyers
- [ ] Letters
- [ ] Newspaper/Magazine Advertisements
- [ ] Radio/Television Announcements
- [ ] Subject or Participant Pool
- [ ] Telephone Scripts
- [ ] Verbal (Personal Solicitation)
- [ ] Website
- [ ] Other
- [x] None of the above

24.1.1. If Other Recruitment Tool, please specify:

24.2. Attach copies of all recruitment tools indicated above.

name Version Modified

There are no items to display.

24.3. Describe in detail all recruitment strategies for each participant group involved in this study. Explain how you will have access to a population that will allow recruitment of the required number of participants. Explain who will approach the participants, how and when the participants will be approached, and what will be said.

Not applicable. The e-mail with the web survey link will introduce the study to all eligible participants. These participants will be those identified by client organizations that have agreed to participate in this study of thriving. Once organizations agree that they are interested, they will supply us with the e-mails of eligible participants. These employees will then receive an e-mail with the survey-link.

24.4. What measures will be taken during the recruitment and consent process to safeguard against potential coercion or the appearance of coercion?

Employees will be reminded that participation is voluntary.

25. Financial Obligation and Compensation

25.1. Financial Obligation: Describe any financial obligations that the subject may incur as a result of participating in the study. Indicate which costs will be covered by the study.

There are no financial obligations that subjects will incur and no costs provided by this study.

25.2. Payment for Participation: Describe how much, if any, financial or other form of compensation will be provided to the subject/family. Describe the requisite conditions that must be fulfilled to receive full or partial compensation. Descibe the proposed method of timing and disbursement. If children are involved, please specifically address how the compensation will be distributed to children.

There is no compensation provided for participation in this study.

25.3. Emergency Care, Injury and Compensation for Injury: If participants were to require care, medical or psychological services as a consequence of the research, how will they be made available? If applicable, describe how the financial liability for research-related injuries would be handled.
Not applicable.

26. Data Privacy and Confidentiality

26.1. How will the data for this study be collected and recorded? Describe the provisions to protect the privacy of the individual.
Data will be recorded onto a server which will be saved by the principal investigator.

26.2. How will the data be recorded to protect personal privacy (select one)?
Coded (Data will be linked to subjects with a code)

26.2.1. If Other is selected, please specify.

26.3. Where will the research data be stored? Please specify the physical location and how it will be secured to protect confidentiality.
Any information that is obtained in connection with this study and that can be identified with participants will remain confidential and will be disclosed only with participant permission or as required by law. All paper responses will be kept in a locked office. Research data will be coded and stored with the principal investigator and research collaborator password-protected computers. Specific consent for access or knowledge about the data will be solicited formally (e.g., for research purposes). Individual responses to survey questionnaires will be kept for at least three years (and until published in academic journals). Participant's names will not be attached to this data.

When the results of the research are published or discussed in conferences, no information will be included that would reveal participant identity.

26.4. Who, other than the specified study team, will have access to the study records or data? Specify their name, role and affiliation. Do not list study personnel already listed on screen 2.

Name	Role	Affiliation

26.5. If coded or identified data will be released, specify the persons, agencies to whom the information will be released. Please also indicate the provisions that will be taken to assure that the transmission of the data will maintain confidentiality.
Not applicable. The codes are for our use only so that a measure of performance can be matched to the participant.

26.6. Describe what will happen to the data or data set, when the study is completed. Please indicate your plans for destruction of identifiers at the earliest opportunity consistent with the conduct of the research and/or clinical needs, if applicable.
Individual responses to survey questionnaires will be kept for at least three years (and until published in academic journals). Participant's names will not be attached to this data.

When the results of the research are published or discussed in conferences, no information will be included that would reveal participant identity.

Will a Certificate of Confidentiality be obtained for this study?

26.7. Will a Certificate of Confidentiality be obtained for this study?

○ Yes ◉ **No**

26.7.1. If yes, please attach the Certificate of Confidentiality if applicable.

26.8. If audio/video recordings or photographs will be used, specify your plans for deidentifying or anonymizing the material and when it will be destroyed.
Not applicable.

27. Risk/Benefit Assessment - Risks

27.1. Risk classification for this study (select one).
Minimal Risk

27.2. Risks, Discomforts and Potential Harms: Describe the risks associated with each intervention. Include consideration of physical, psychological, social, and other factors. If data is available, estimate the probability that a given harm may occur and the potential reversibility. (HSC: *refer to specific sections of the protocol/grant, if applicable*)
Participants may withdraw (without penalty) at any time during the study. They may also skip questions that make them feel uncomfortable.

27.2.a. If needed, copy-and-paste any tables here and reference in the question above.
Tables

27.3. Describe the safety precautions that will be taken to minimize risks/harms. (HSC: *refer to specific sections of the protocol/grant, if applicable*)
None. Participants may quit the survey at any time.

27.3.a. If needed, copy-and-paste any tables here and reference in the question above.
Tables

27.4. Data Safety Monitoring Plan: Describe how the studies are monitored for the safety of the participants and for the validity and integrity of the data. (If a DSMB is involved with this study, please describe the composition, plans for monitoring and distributing information to the local IRBs.)
Not applicable.

27.4.1. (CHLA Only) Attach the CHLA DSMP form.

28. Risk/Benefit Analysis - Potential Benefits and Alternatives

28.1. Describe any potential for direct benefits to participants in the study. There may be no direct benefits.
We believe this study will provide valuable information to managers, organizations, and scholars about the conditions and behaviors that promote thriving, and that thriving may lead to better leadership effectiveness and performance. Our hope is that these participants learn from our findings and can adjust behaviors, and enjoy a thriving state more often.

28.2. Describe any potential benefits to society.
We believe this study will provide valuable information to managers, organizations, and scholars about the conditions and behaviors that promote thriving, and that thriving may lead to better leadership effectiveness and performance. Our hope is that people learn from our findings and can adjust behaviors, and enjoy a thriving state more often. Ideally, managers and organizations can use our findings to create an environment which is liekly to promote thriving states.

28.3. Alternatives to Participation: If applicable, describe alternatives (research or non-research) that are available to subjects if they choose not to participate in this study. This could include not participating in the study.
Not applicable (people can choose not to participate).

28.4. Risk/Benefit Analysis: Describe the risk to benefit relationship of participation in the research (relative to non-participation and/or alternatives).
We believe the risks to participants are minimal (that there are no direct risks to participants). We believe this study will provide valuable information to managers, organizations, and scholars about thriving and how it affects leadership effectiveness and performance.

29. Informed Consent and Waivers

29.1. * Indicate the types of consent that will be involved in this study (check all that apply):

Consent Type	
Written/signed consent by the subject	☐
Written/signed consent by a legally authorized representative (for an adult)	☐
Written/signed permission for a minor by a parent or legal guardian	☐
Written/signed assent by a minor	☐
Verbal consent or written information sheet (Requires waiver of written or signed consent below)	☐
Consent will not be obtained for this study	☑

29.1.1. Attach copies of all of the informed consent/assent, information sheet, and verbal script documents that will be used for this study
name Version Modified
There are no items to display.

29.2. * Waivers: If you are applying for any waivers of consent (check all that apply).

Waiver Type	
Waiver of consent	☑
Waiver of assent	☐
Waiver of parental permission	☐
Waiver of written or signed consent (i.e., information sheets, telephone consent, verbal script)	☐
I am not applying for a waiver	☐

Note: Waivers of consent are not applicable if the research is subject to FDA regulations, except the following.

FDA Exception from general requirements:

1. **Waivers of Informed Consent in FDA-regulated studies are permissible in case of life-threatening situations, inability to communicate, not sufficient time and no alternative method, even if research presents more than minimal risk [21CFR50.23];**
2. **If the study satisfies the requirements under 21CFR50.24 "Exception from Informed Consent Requirements for Emergency Research."**

31. Waiver of Consent

This screen is required if you indicated you are requesting a Waiver of Consent (Question 29.2.)

If you are applying for a waiver of informed consent, per 45 CFR 46.116 (d) provide the following information:

31.1. Explain why the research involves no more than minimal risk to the subjects.
This research involves a survey of individual perceptions about their behaviors and feelings, and the organizational culture. Participation is completely voluntary, and participants can withdraw or choose not to answer any question(s).

31.2. Explain why the waiver or alteration will not adversely affect the rights and welfare of the subjects.
The e-mail with the web-based survey link will explain that participation is voluntary. As noted in 31.1, participants can also withdraw at any point, and choose not to answer any questions.

31.3. Explain why the research could not practicably be carried out without the waiver or alteration.
It will be made very clear about the voluntary nature of this study. Participants are leaders in Fortune 1000 organizations and we are trying to make this as simple as time effective as possible. The participating organizations that normally work with are not used to completing any waiver in studies with them. We are complying with these norms since we see no risks to participation and because we see no pressure to participate.

31.4. Explain how whenever appropriate, the subjects will be provided with additional pertinent information after participation. (e.g., an information sheet).
We will provide information for participants who would like to know about our findings, and the implications of our findings.

35. Is the HIPAA Privacy Rule Applicable?

35.1. Do you intend to access, use or disclose protected health information (PHI) in order to abstract medical record data (even if you are de-identifying the data abstracted), identify potential participants or to conduct your research?

○ Yes ◉ **No**

35.2. If Yes, do you intend to use data that contains any of the 18 elements defined by HIPAA as identifiers (listed below), in your research?

○ Yes ◉ **No**

The HIPAA Privacy Rule regulations [45 CFR 164.514(b)] lists 18 specific elements that are considered to be personal identifiers. The list includes:

- Name/Initials
- Street address, city, county, precinct, zip code, or equivalent geocodes
- All elements of dates (except year) directly
- Health plan identification number
- Account number
- Certificate/license number
- Vehicle identifiers and serial numbers,

related to an individual (date of birth, admission date, discharge date, date of death)
- Elements of date, including year, for persons 90 or older
- Telephone number
- Fax number
- Electronic mail address
- Social Security Number
- Medical record number

including license plate number
- Device identifiers and serial number
- Web addresses (URLs); Internet IP addresses
- Biometric identifiers, including finger and voice print
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic or code

39. Conflict of Interest Information

39.1. Do any of the participating study investigators or other research personnel (or their immediate family/significant other) have a financial and/or intellectual property interest in the sponsor or products used with this project.

○ Yes ◉ **No**

39.2. If yes, attach a completed Financial and Intellectual Interest Disclosure Form for each person who has a potential conflict to be managed.

name	Version	Modified

There are no items to display.

40. Additional Supporting Documents

40.1. Attach any other documents that have not been specifically specified in previous questions, but are needed for IRB Review. For additional documentation that may be required for HSIRB Submissions, please consult the HSIRB Checklist.

name	Version	Modified

There are no items to display.

40.2. If there is any additional information that you wish to communicate about the study please include it below. Please note, this section should not be used in lieu of or instead of the standard application items.

99. Instructions for Study Submission

Congratulations! You have completed the application for a new protocol. When you are sure of the content, the following steps may be taken to submit your study for review.

For HSIRB Submissions, please consult the HSIRB Checklist found here.

For UPIRB Submissions, please consult the UPIRB Checklist found here.

1. **Click the "Finish" button on the top or bottom application navigator bar to return to the study folderspace.**
2. **Use the SmartForm Progress Calculator to determine that all sections of the application are filled out correctly.**
3. **Use the "Send Study Ready Notification" activity to send an email to the Principal Investigator and Co-Investigator's with instructions for reviewing and submitting the application.**

iStar ID:	Application Version Date:2/28/2006 Version:0.1
Date: Thursday, May 04, 2006 8:01:08 AM	Print Close

1. Project Identification Information

1.1. * **Type of Submission**:

- (•) Research Protocol/Study/Class Project Only
- ( ) Grant/Contract Only
- ( ) Facilitated Review (CIRB)

1.2. **Full Title of Research Protocol**
Teaching and Learning with Multimedia

1.3. * **Short Title**
Teaching and Learning with Multimedia

1.3.1. **If there is a sponsor protocol number associated with this file, specify it here:**

1.4. * **Please indicate which IRBs you are requesting review from (check all that apply):**

- [ ] USC - Health Sciences IRB (HSIRB)
- [x] USC - University Park IRB (UPIRB)
- [ ] CHLA - Committee on Clinical Investigations (CCI)

1.4.1. **If there are any individual collaborators from other institutions, check here:** [ ]

Version:0.1

2. Study Personnel (for a study already submitted to the IRB)

This screen indicates the active study team once the proposal has been submitted. This screen is not required during presubmission and should be left blank.

2.1. * **Principal Investigator (PI):**

2.2. **Study Coordinator or Contact Person:**

2.3. **Co-Investigators:**

Last	First	Organization

2.4. Other Study Personnel who will be able to edit this online application and study materials:

Last First Organization

2.5. * Is the Principal Investigator a student, resident, trainee, or visiting scholar?

Yes **No**

2.6. If yes, please designate a Faculty Advisor:

2.7. Guests (Other registered users who will have read-only access to this IRB submission):

Last Name	First Name	Organization

There are no items to display.

iStar ID: Application Version Date:2/28/2006 Version:0.1

3. Required Department Approvals (for a study already submitted to the IRB)

This screen indicates the division/department approvals received once the proposal has been submitted. This screen is not required during presubmission and should be left blank.

3.1. Pending Division/Department Approvals:

Name	Division/Department	Parent Campus

There are no items to display.

3.2. Received Division/Department Approvals:

Name	Division/Department	Parent Campus

There are no items to display.

3a.3. (HSC Only) Other Health Science campus committees that will need to review and approve this protocol:

Committee Name	Committee Chair	Approval Memo

There are no items to display.

3c.3. (CHLA Only) Other CHLA hospital committees that will need to review and approve this protocol:

Committee Name	Committee Chair	Approval Memo

There are no items to display.

3c.4. (CHLA Only) Are you planning to submit this study to the GCRC for review?

Yes No

iStar ID: Application Version Date:2/28/2006 Version:0.1

4. Study Location(s)

Indicate the locations where this study will be conducted by the USC/CHLA investigator(s) (check all

4.1. Indicate the locations where this study will be conducted by the USC/CHLA investigator(s) (check all that apply):

Location
☐ HSC - Health Sciences Associated Locations
☑ UPC - University Park Associated Locations
☐ CHLA
☑ Other Sites/Institutions (In the US)
☐ Other Sites/Institutions (Outside the US)

4.2. Is this a multi-site study?

◉ **Yes** ○ No

iStar ID:	Application Version Date:2/28/2006 Version:0.1

5b. UPC Location(s)

This screen is required if you indicated UPC - University Park Associated Locations (Question 4.1.)

5b.1. UPC Locations (check all that apply and provide room numbers or location where indicated):

Location
☐ Faculty office
☐ Campus location
☑ Off-campus location

5b.2. If campus location, please specify:

5b.3. If off-campus location, please specify:
Institute for XXXXXXXXXXXX

iStar ID:	Application Version Date:2/28/2006 Version:0.1

5c. Other Sites/Institutions

This screen is required if you indicated Other Sites/Institutions inside or outside the US (Question 4.1.)

5c.1. Other Sites/Institutions (In the United States): List all of the non-USC/CHLA sites at which the Principal Investigator will conduct the study.

Site Name	Address

5c.2. Other Sites/Institutions (Outside the United States): List the institution(s) and country(ies) at which the Principal Investigator will conduct the study.

Site Name	Address	Country

There are no items to display.

iStar ID:	Application Version Date:2/28/2006 Version:0.1

6. Information For Multi-Site Study

This screen is required if you indicated this is a multi-site study (Question 4.2.)

6.1. Is the coordinating center at HSC, UPC, or CHLA?

(●) **Yes** ( ) No

6.1.1. If yes, describe how the information relevant to protecting participants, such as reporting of unexpected problems, protocol modifications, and interim results are managed.

Each member of the research team working on this study is responsible for uploading and archiving the data they collect to a non-networked, password protected database that is located in a locked office at the XXXXXX. All members of the research team have access to the data.

Provides an adequate plan to address unanticipated issues or problems

The research team meets twice a month to address study coordination issues and discuss interim findings. Unexpected problems and protocol modifications can also be identified and addressed with the whole team in these meetings, if applicable.

Two of the researchers involved in the study that have almost weekly contact with the various research sites. Should any unexpected problems or protocol modifications arise, they can communicate these directly to the administrators, teachers, and when applicable, students involved in the study.

6.2. If no, what is the location of the coordinating site? (If there is no coordinating site, indicate N/A).

iStar ID:	Application Version Date:2/28/2006 Version:0.1

7. Funding Information

7.1. Are you or the institution receiving any financial support for the conduct of this study?

(●) **Yes** ( ) No

iStar ID:	Application Version Date:2/28/2006 Version:0.1

7a. Funding Information - Details

This screen is required if you indicated you or the institution are receiving financial support for this study (Question 7.1.)

7.2. If the funding source has undergone separate review by the IRB (i.e., cooperative group grants, umbrella grants, multi-project/program grants, center grants), please try to select it from the list using the "Add" button. If the funding source is not displayed in the list, enter the information in question 7.3.

Grant # Principal Investigator Grant Title

There are no items to display.

7.2.1. If the grants selected in question 7.2 fund multiple studies, please attach the specific pages of the grant that are relevant to THIS study.

name Version Modified

There are no items to display.

7.3. Please specify any funding source that is not listed in question 7.2. You will need to use the "Add" button for each funding source for this study.

Sponsor	Principal Investigator	Type of Funding
XXXXXXXXXXXXXX		

iStar ID: Application Version Date:2/28/2006 Version:0.1

8. Type of Study Review

8.1. Please indicate the type of review that you are requesting for this study:
Expedited Review

8.2. Attach the Protocol(s) or Proposal(s) below if applicable. Also attach the sponsor's informed consent template and summary of protocol changes if they are separate documents. DO NOT ATTACH OLD VERSIONS OF THE IRB APPLICATION (AKA SECTION II) AS A PROTOCOL.

name		Version	Modified
xxxxxxxx	Initiative Proposal	0.02	7/21/2005 4:10 PM

iStar ID: Application Version Date:2/28/2006 Version:0.1

8a. Type of Study Review - Expedited Review

This screen is required if you are requesting an expedited review for this study (Questi

Appropriate level of review and corresponding categories

8.1. Please indicate the type of review that you are requesting for this study:
Expedited Review

8a. If you checked expedited review, please choose the applicable category from the list and attach your data collection forms below (click on the abbreviated category to receive the full description):

	Short Description (click for full desciption)
☑	(6) Collection of data from voice, video, digital, or image recordings made for research purposes.
☐	(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met...
☐	(4) Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves...
☑	(7) Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies...
☐	(5) Research involving materials that have been collected, or will be collected solely for nonresearch purposes...
☐	(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture...
☐	(3) Prospective collection of biological specimens for research purposes by noninvasive means...

8a.1. If you checked expedited review, please attach a copy of the forms you will be using to collect data, if applicable:

name	Version	Modified
There are no items to display.		

iStar I Application Version Date:2/28/2006

iStar ID: Application Version Date:2/28/2006 Version:0.1

9. Methods and Procedures - Selected Descriptors

Note: The items listed below ARE NOT an all inclusive list of methods and procedures available to investigators. The list only includes items that will trigger additional questions specific to areas of research or are necessary for the review process.

9.1. * **Social-Behavioral Procedures (check any or all that apply):**

Specific Descriptor
☑ Behavioral Observations and/or Behavioral Experimentation
☐ Behavioral Interventions
☐ Deception
☑ Interview/Focus Groups
☐ Population-based Field Study
☐ Psychophysiological Testing
☑ Surveys/Questionnaires/Psychometric Testing
☐ Other Social-Behavioral Procedures
☐ None of the above Social-Behaivoral Procedures apply to this study.

9.2. * **Medical Procedures/Considerations (check any or all that apply):**

Specific Descriptor
☐ Biohazardous Substances
☐ Controlled Substances
☐ Emergency Treatment
☐ Gene Transfer Study
☐ Stem Cell Research
☐ Magnetic Resonance Imaging (MRI)
☐ Investigational/Approved Drugs and Biologics
☐ Investigational/Approved Devices
☐ Radiation exposure other than clinically indicated tests and/or therapy
☐ Radionuclides
☐ Substance Abuse Treatment (with medication)
☐ Surgery
☐ Venipuncture
☐ Other Medical Procedures/Considerations
☑ None of the above Medical Procedures/Considerations apply to this study.

9.3. * **Data Collection Types (check any or all that apply):**

Specific Descriptor
☐ Banking of Specimens/Data (Creation of a repository)
☐ Prospective Collection of Specimens/Data

- [ ] Genetic Specimens
- [x] Audio/Video Recordings or Photographs
- [ ] None of the above Data Collection Types apply to this study.

9.4. * **Does this study involve the use of existing/retrospective data/specimens?**

○ Yes ◉ **No**

10. Characteristics of the Study Subject Population

10.1. **What is the maximum number of subjects you plan to recruit for this site? (Integer values only)**
600

10.1.1. **If this is a multi-site study, indicate the projected total subject accrual. (Integer values only)**
3000

10.2. **Indicate the inclusion criteria for enrollment. (HSC: *refer to specific sections of the protocol/grant, if applicable*)**
Subjects will include education professionals from the XXXXXX area and middle school students from middle schools.

1. Education professionals
Initially, subjects in this category will be recruited from the pool of education professionals participating in the XXX Initiative, which includes 20 teachers, 5 administrators, and 7 coaches (experienced media educators). As the research progresses, other education professionals within the schools who are using multimedia in their classrooms, after-school clubs, etc., may be identified by researchers conducting participant observation, and will be verbally invited to participate by researchers. Education professionals will complete a consent form in order to participate in the study.

Detailed and thorough explanations

2. Students
Student subjects will be middle school students (grades 6-8) from one of five middle schools involved with the 2005-06 xxxxxx Initiative. Initially, students will be invited to participate if they are in one of the classes taught by teachers participating in XXXX. As researchers become involved in additional school activities involving media and technology, such as after-school computer clubs, they may invite students involved in these activities to participate in the study. Any student who volunteers to participate and returns a signed parent/guardian consent form and a completed assent form will be included in the study.

10.2.a. **If needed, copy-and-paste any tables here and reference in the question above.**
Tables

10.3. **Indicate the exclusion criteria for enrollment. (HSC: *refer to specific sections of the protocol/grant, if applicable*)**
We will be excluding participants who do not speak either Spanish or English as well as participants who do not return the required consent and assent forms.

10.3.a. **If needed, copy-and-paste any tables here and reference in the question above.**
Tables

10.3.1. **If there are any age, ethnic, language, or gender-based exclusion criteria, please provide justification.**
The language exclusion is based on the language competency of our research team. We cannot support documents and interviews conducted in languages other than Spanish and English.

iStar ID: Application Version Date:2/28/2006
Version:0.1

11. Study Summary

11.1. Abstract: Provide a brief (1 to 2 paragraph) description of the study in LAY LANGUAGE. This should not be a scientific abstract.

Easily understood, no technical language used

The XXXXXX Initiative is a professional development program in multimedia literacy that provides training for teachers, administrators, and coaches. This research study examines how teachers implement multimedia teaching methods in practice and how students respond to them. We are interested in learning how multimedia may be used to enhance teaching and learning, and how new computer and media technologies are providing challenges and opportunities for young people to learn and express themselves. The research questions in this study can be divided roughly into three areas, with significant overlap between the three areas: 1) program evaluation and participant outcomes; 2) theoretical and practical insights from xxxx for the fields of media education and critical literacy; and 3) the relationship between informal learning with digital media and in-school teaching and learning.

11.2. Research objectives and background

11.2.1. Describe the specific objectives or aims of the study and hypotheses or research questions. (HSC: *refer to specific sections of the protocol/grant, if applicable*)

Excellent explanation

The goal of the project is to develop grounded qualitative descriptions and case studies to inform the development of educational programs, particularly those involving media education. The study will directly contribute to the goals of the Institute for Multimedia Literacy and the xxxxxxxxx School District, xxxx Education Branch, to evaluate and improve their educational activities in curriculum development and professional development. The study will also contribute to the broader goal of building capacity, expertise, and models for media education in U.S. schools. Finally, the study will contribute to primary research about the role of media and technology in the lives of young people, and the relationship between formal and informal learning.

Research questions:
Please see the xxxxxx Initiative Evaluation Plan (attached in section 40) for a more comprehensive list of research questions, methods, and data sources. The following is a general overview of the types of research questions we plan to ask.

Program Evaluation and Program Outcomes:
- Were the xxxx activities implemented as planned?
- What were the mediating factors that affected implementation?
- What was the value, quality, and utility of the implementation of the xxxx activities?
- In what ways did teachers increase their understanding and skill of multimedia pedagogy (including facilitating student knowledge, production, etc.) and assessment of student learning?
- In what ways were teachers able to incorporate their knowledge of multimedia literacy into the development and implementation of a standards-based instructional unit?
- How does participating in the xxxx program influence students (e.g., interest, motivation, engagement, learning)?
- In what ways will xxxxxx be able to sustain the work of providing training in multimedia literacy for teachers in district schools K-12?

Insights and implications for teaching and learning
- What can be learned from xxxx about multimedia literacy professional development?
- What can be learned from xxxx about multimedia literacy pedagogy and standards-based curricula development?

Relationship to informal learning
- What background knowledge and prior experiences do xxxx students have related to media and technology?
- What role does students' background knowledge of media and technology play in their learning, motivation, and interest in school?
- What can be learned about the relationship between kids' informal learning with media and technology and learning in school?

11.2.2. Provide a summary of the background of the study, and explain how this research will contribute to existing knowledge. Describe previous work that provides a basis to show that the proposed research can be carried out without undue risk to human subjects. Include relevant citations. (HSC: *refer to specific sections of the protocol/grant, if applicable*)

Complete background summary, backed up with literature, includes citations.

While media education remains under-documented and under-researched, case study analyses have demonstrated that it can play a powerful role in promoting literacy skills and learning on a wide range of topics (Fisherkeller 2002; Goldfarb 2002; Goodman 2003; Tyner 1998, 2003). As many have argued, media education can also play an important role in helping students come to have a more empowered relationship to mass media and popular culture, and encourage them to be more actively involved in media criticism as well as the production and distribution of their own media representations (Buckingham 2000, 2003; others listed above). To date, schools are not systematically taking advantage of this potential; particularly urban schools which have the highest concentrations of poverty, the highest concentrations of ethnically marginalized students, and the highest concentrations of academic failure. We also know that urban students of color spend more time outside of school engaged with media than their counterparts from other demographic groups (Goodman, 2003; Nielson Media Research, 2000). Clearly, if media education is to be more widely developed as an academic and critical enterprise, it will need to be thoughtfully incorporated into curriculum and professional development activities. What's more, empirical research is needed to document such activities and to draw theoretical and practical insights from their successes and challenges. This study draws on this background and aims to provide such empirically grounded research.

Based on the previous work of educational researchers, such as many of those listed above, as well as the experience of the co-investigators of this study, we believe the proposed work can be carried out without undue risk to human subjects. Both co-investigators have several years of experience involved in research that balances participant observation and interviews with adults and children with other roles in a research setting, such as classroom helper or after-school mentor (see Ito and Tripp citations below). Each is experienced at supporting the learning goals of teachers and students, interacting in a friendly and helpful way with diverse "school agents" and youth without excluding or alienating anyone, and collecting meaningful observational and interview data at the same time. They have also supervised undergraduate and/or graduate students in learning and using similar methods in a range of research projects, and are confident in their ability to direct and supervise the current research team. For example, was a researcher, and sometimes instructor, for approximately ten years in a research and education project at the University of xxxxx , "xxxxxx" and "xxxxxxx," that trained hundreds of undergraduates in these kinds of research methods with children. During her ten years affiliated with the research project, and often supervising the research sites, there were no reports or complaints of undue risk from any participating children, parents, teachers, or undergraduate students.

Selected citations :

"Technologies of the Childhood Imagination: Yugioh, Media Mixes, and Otaku." Presentation at: Digital Generations: Children, Young People and New Media, organized by the Centre for the Study of Children, Youth and Media, University of London, 2004.

Interactive Media for Play: Kids, Computer Games, and the Productions of Everyday Life. Dissertation. Stanford University School of Education. 1998.

"Using ethnographic methods to study learning with media production." Presentation at Youth Media Evaluation Institute, Department of Radio-Televsion-Film, The University of Texas at Austin, 2004.

Trying to Bend the Bars of the Iron Cage: A Case Study of a K-16 Partnership. Dissertation. University of California, San Diego. 2002.

Additional relevant citations:

Alvermann, D. E., J. S. Moon, et al. (1999). Popular culture in the classroom: teaching and researching critical media literacy. Newark, Del.; Chicago, Ill.: International Reading Association; National Reading Conference.

Buckingam, D. (1995). Cultural Studies Goes to School: Reading and Teaching Popular Media (Critical Perspectives on Literacy and Education). New York, London, UK: Taylor & Francis Group.

Buckingham, D. (2000). After the death of childhood: growing up in the age of electronic media. Cambridge, UK: Polity Press; Blackwell.

Buckingham, D. (2003). Media Education: literacy, learning, and contemporary culture. Cambridge, UK: Polity Press.

Dyson, A. H. (1994). The Ninjas, the X-Men, and the ladies: playing with power and identity in an urban primary school. Teachers College Record 96(2): 219-239.

Dyson, A. H. (1997). Writing superheroes: Contemporary childhood, popular culture, and classroom literacy. New York: Teachers College Press.

Dyson, A. H. (2003). The brothers and sisters learn to write: Popular literacies in childhood and school cultures. New York: Teachers College Press.

Fisherkeller, J. (2002). Growing up with television: Everyday learning among young adolescents. Philadelphia: Temple University Press.

Goldfarb, B. (2002). Visual pedagogy: media cultures in and beyond the classroom. Durham, NC: Duke University Press.

Goodman, S. (2003). Teaching youth media: a critical guide to literacy, video production & social change. New York: Teachers College Press.

Luke, C. (2004). “Re-crafting Media and ICT Literacies,” in D. Alvermann (ed.) Adolescents and Literacies in a Digital World. New York: Peter Lang.

Morrell, E. (2004). Linking literacy and popular culture: Finding connections for lifelong learning. Christopher-Gordon Pub.

Tyner, K. (1998). Literacy in a digital world: Teaching and Learning in the Age of Information. New Jersey: Lawrence Earlbaum Associates.

Tyner, K. (ed). (2003). A Closer look: Case studies from NAMAC’s youth media initiative. San Francisco: National Alliance for Media Arts and Culture.

12. Methods and Procedures - Prospective Studies

12.1. Describe in detail the design and methodology of the study. If applicable, include information on stratification or randomization plans. Identify and distinguish between those procedures that are standard of care and those that are experimental. Include the frequency and duration of each activity and the total length of subject participation. (HSC: *refer to specific sections of the protocol/grant, if applicable*)

Detailed explanation of all study procedures

This research study incorporates a mix of qualitative methods conducted at school sites to construct a rich picture of the implementation and reception of multimedia pedagogy at the middle school level. Through the analysis of this data, researchers will work to theorize the broader role of multimedia in teaching and learning. Data collection and subject participation will take place over the course of the 2005-2006 school year (approximately 10 months, September 2005 through June 2006). The subject population includes education professionals and middle school students from five schools participating in the xxxxxxxx Initiative, as well as a few other education professionals affiliated with the Initiative.

At some sites, student subjects will be recruited to participate in the research in two phases. Phase 1 will include the following research methods (described in greater detail below): participant observation, audio recording conversations, surveys, and the collection of multimedia coursework. Phase 2 will occur later in the school year, when a subset of the student population will be recruited for participation in additional research. This phase will include the following research methods (described in greater detail below): photographing and videotaping classroom activities and participating in a focus group.

At other sites, student subjects will be recruited to participate in the research only once during the school year, and their consent/assent forms will ask for their consent/assent to participate in all of the research methods (described in Phase 1 and 2, above). For the sake of clarity in managing our protocols for the various sites, we will refer to this as Phase 3 of the research. Sites will be selected to participate in Phase 3 of the research if subject recruitment at that site has begun late in the school year, such that the methods originally addressed in "Phase 2" consent forms are already appropriate for these sites.

The research team for this study includes co-investigators , as well as graduate student xxxxxxx, postdoctoral research associate evaluation consultants that will assist with data collection and program evaluation, xxxxxxx, and xxxxxxxx. Additional staff involved in running the xxxxxxxxxx.

Methods

Participant Observation and Audio Recordings:
Researchers will engage in participant observation in school sites in order to try to understand the school context and research topics from the perspectives of the subject population. Participant observation is different from the passive or evaluative observations often conducted in classrooms, as participant observers often take on an active role in the observational context. For this study, participant observers will act as classroom aides and assist students during class activities. The exact role of the researcher will differ depending on the needs and desires of the schools, classroom teachers, and students. Researchers and teachers together will decide how active the researcher will be in class activities. Researchers acting as classroom aides will assist all students, not only those who have agreed to participate in the study. A member of the research team will visit each of the five sites as a participant observer a minimum of once a month for the duration of the study. At some sites, or for the duration of particular school activities, a member of the research team may conduct more frequent visits and participant observations, possibly including several visits in a given week. At first, participant observation activities will center on the classrooms of teachers. As members of the research team get to know other teachers or learn of other school activities involving media and technology, they may make arrangements to visit and participant observe additional classrooms and activities.

Detailed explanation of all study procedures

Because participant observers will become part of the class community, they will be able to speak to the students informally while working on projects. This will help give researchers a better understanding of the student experience in a class setting that utilizes multimedia. Researchers will record their observations in the form of written field notes. While conducting an observation, these notes will typically consist of very brief notes that the researchers can use as a reference for later typing up in greater detail. Researchers will also use audio recorders to tape occasional brief, informal conversations with students who have received parental consent and have agreed to be recorded. If at any time students are present who do not have consent (or assent) for audiotaping, the researchers will not record any conversations. Audiotaped conversations may later be transcribed for inclusion in publications and presentations. If external transcription companies are used, a confidentiality agreement will be signed with those companies. In written transcripts and reports of audio data, all student names will be replaced with pseudonyms. In audio excerpts of the data used for presentations or publications, with parental/child consent/assent, first names of students may occasionally be audible.

Surveys:
Survey data will be collected from education professionals and students when they join the study. This information will provide baseline data about participants' background, experience, and interest with various media and technologies. Education professionals will also complete formative evaluation surveys of each of the five professional development workshops held throughout the year. This data will be used for program evaluation and contribute to the assessment of program outcomes.

Coursework Examples:
Researchers will collect samples of multimedia projects created by education professionals and students. Researchers will also collect copies of teachers' lesson plans and instructional materials to document the methods used in their multimedia pedagogy. These materials will provide evidence and examples of outcomes for students and education professionals.

Videotaped Classroom Activities:
Later in the school year, when teachers begin implementing multimedia lessons, the research team may select their class for additional research including videotaping classroom activities. Should a class be selected for videotaping, this taping will last approximately 1-10 hours over the course of 1-3 weeks. Teachers will help administer parental consent and student assent forms specific to this second phase of the research. They will also be asked to assist researchers in identifying students who have not given consent/assent to be videotaped so that videographers can avoid recording them. Videographers who work with the Institute for Multimedia Literacy are trained professionals and can adjust camera position and framing, and/or shoot video selectively, so that children who don't have permission to be recorded can be excluded from the video without being asked to move. To accomplish this, they will use two modes of videotaping: 1) when they videotape a teacher delivering instruction, they will film the teacher only; 2) when they videotape students, they will only film students while they are working in small groups on a classroom project. They will only film a small group if everyone in the group has provided consent/assent. The research

team believes this arrangement will allow videographers to capture as much of the instruction as possible while still respecting the privacy of students who have not provided consent/assent or who do not wish to be videotaped.

Interviews and Focus Groups:
Individual interviews will be conducted with school administrators to gather data on the role of the administrator in supporting multimedia education. Additionally, focus groups will be conducted with teachers, coaches (experienced media educators acting as mentors to the teachers and administrators participating in the 2005-2006 Initiative), and students. Additional education professionals, such as speakers at the Institute's professional development workshops held over the course of the year and other school staff may be interviewed with their consent at the discretion of the research team. The use of focus groups allows participants to voice opinions within a group of peers, and allows researchers to observe the coherence or dissimilarities of experiences of the community. For some participants, and for students in particular, the use of focus groups can afford a greater comfort level than individual interviews. Focus groups will, with consent from all members of the group, be videotaped to allow researchers to review the tapes, transcribe participants' discussion, and possibly observe non-verbal behaviors that supplement the discussion. If someone participating in the focus group does not want to be videotaped, or has not received parental consent (in the case of students), the focus group will not be recorded. Focus groups will be held at each school site in the spring and last approximately 1 hour each; members of the research team will meet separately with students and educational professionals. All educational professionals involved in the Initiative, and a subset of approximately 50 students will be invited to participate in the focus groups. Only those who have returned consent/assent forms for this phase of the study will be allowed to participate.

Consent to be Contacted for a Home Interview:
When parents first consent for their child to participate in this study, they will be asked if a member of the research team can contact them about participating in a home interview. This is a recruitment tool for a related study that this research team is conducting, entitled "Multimedia Literacy and Digital Kids." Should a parent agree to be contacted for this research, a member of the research team will contact him/her following the recruitment protocols and consent forms approved for that study. The Human Subjects Protocol for this study is being submitted separately for full board review.

12.1.a. If needed, copy-and-paste any tables here and reference in the question above.
Tables

12.2. Provide a detailed description of the planned data collection, specific outcomes, and criteria for evaluation and endpoint definition. (HSC: *refer to specific sections of the protocol/grant, if applicable*)
Please see the Evaluation Plan (Section 40) for complete outline of data collection and evaluation.

Education Professionals/Workshop Data Collection
- Participant observation of workshops (field notes, audio, video)
- Interviews and focus groups with educational professionals (notes, audio, video)
- Surveys with educational professionals (pre workshop & formative assessments)
- Examples of educators' projects and instructional resources (electronic copies)

Student/Classroom Data Collection
- Participant observation in classrooms (field notes, audio, video)
- Focus groups with students (notes, audio, video)
- Examples of student school work (electronic copies)

Data collection will finish at the end of the 2005-2006 school year (June 2006).

12.2.a. If needed, copy-and-paste any tables here and reference in the question above.
Tables

12.3. Describe the statistical considerations for the study, how the sample size was determined, and how the results will be analyzed, if applicable. (HSC: *refer to specific sections of the protocol/grant, if applicable*)
Since this study employs a case-based and descriptive ethnographic method, we do not seek statistically valid sampling measures. Sample size is determined by the number of students in each of the teachers' classes who return the consent forms.

12.3.a. If needed, copy-and-paste any tables here and reference in the question above.
Tables

iStar ID:	Application Version Date:2/28/2006 Version:0.1

19. Methods and Procedures - Interview/Focus Groups

This screen is required if you indicated the use of Interview or Focus Groups under social-behavioral procedures (Question 9.1.)

19.1. Attach copies of any scripts and/or questions that will be used to guide the interviews/groups.

Relevant documents attached

name	Version	Modified
Administrator Interview questions	0.01	7/27/2005 3:57 PM
Coach focus group questions	0.02	7/27/2005 3:57 PM
Student focus group questions	0.01	8/1/2005 3:54 PM
Teacher interview questions	0.02	7/27/2005 3:58 PM

19.2. Indicate the member(s) of the study team who will conduct the interviews/focus groups and any necessary qualifications such as special training.
All researchers will be supervised by xxxx and xxxx and have experience conducting research in schools or with children.

iStar ID:	Application Version Date:2/28/2006 Version:0.1

21. Methods and Procedures - Surveys/Questionnaires/Psychometric Testing

This screen is required if you indicated the use of Surveys, Questionnaires, or Psychometric Testing under social-behavioral procedures (Question 9.1.)

21.1. List all of the measures/instruments that will be used for this study and attach copies below.
Experience and Background Survey for Educational Professionals
Experience, Background, and Interest Survey for Students
Workshop Formative Evaluation Survey for Educational Professionals

21.1.1. Attach copies of all measures/instruments that will be used for this study here.

name	Version	Modified
Education Professional Survey	0.01	8/1/2005 4:22 PM
Student Survey	0.02	8/2/2005 3:18 PM
Workshop Formative Evaluation Survey for Educational Professionals	0.01	7/27/2005 4:01 PM

21.2. Indicate the member(s) of the study team who will use these measures/instruments and any necessary qualifications such as special training or licenses.
All researchers will be supervised by xxx and xxxxxx and have experience conducting research in schools or with children.

iStar ID:	Application Version Date:2/28/2006 Version:0.1

22. Special Subject Populations

22.1. Special Subject Populations (Check all that apply).

Population

All applicable populations selected

- [ ] Normal Volunteers
- [x] Employees
- [x] Students
- [ ] Adults not Competent to Consent
- [x] Non-English Speaking Populations
- [x] Minors (subjects under 18 years of age)
- [ ] Pregnant Women, Human Fetuses, or Neonates
- [ ] Prisoners/Detainees
- [ ] Wards
- [ ] None of the above

iStar ID	Application Version Date:2/28/2006 Version:0.1

22b. Special Subject Populations - Employees/Students

This screen is required if you indicated Employees or Students as a special subject population (Question 22.1.)

22b. If you selected Employees or Students, please indicate how you will minimize the potential for them to feel coerced to participate. Discuss how the potential confusion in roles will be addressed.

Answers the question thoroughly, provides details

For students, there is wording in the recruitment letter and all consent and assent forms that makes it clear that participation in the study is voluntary and will not have any effect on student assessment or grades. Participant observation will take place within classes and student activities that are existing parts of students' schedules, and there is no compensation for participation, so it is unlikely that parents and students will feel coerced to participate in the study.

Teachers and administrators attending the 2005-06 Initiative have agreed to participate in basic program evaluation activities, including being observed in the classroom when they implement lessons. However, their participation in the research study is voluntary, and this distinction is explained in the consent form. For example, education professionals are free to choose whether or not they want researchers to use the data they collect for publication or other educational purposes. They may also choose not to be video or audiotaped, or not to have their instructional materials collected by the research team.

iStar ID:	Application Version Date:2/28/2006 Version:0.1

22d. Special Subject Populations - Minors

This screen is required if you indicated Minors (subjects under 18 years of age) as a special subject population (Question 22.1.)

22d. If you selected Minors, answer the questions below.

22d.1. Provide a justification for involving minors in this research.
This is a study specifically about middle school education and youth.

22d.2. Choose the proposed category of permissible research with children.

Category
(•) a. 46.404 - Research not involving greater than minimal risk.
( ) b. 46.405 - Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual.
( ) c. 46.406 - Research involving greater than minimal risk and no prospect of direct benefit to individual, but likely to yield generalizable knowledge about the subject's disorder or condition.
d. 46.407 - Research not otherwise approvable which presents an opportunity to understand,

- prevent or alleviate a serious problem affected the health or welfare of children.
- None of the above categores; Minors will not participate in this study.

iStar ID:	Application Version Date:2/28/2006 Version:0.1

23. Subject Identification and Study Resources

23.1. Describe the method(s) by which subjects will be identified, eligibility will be determined, and by whom.

Subjects will include education professionals from the XXXXXX area and middle school students from XXXXX middle schools.

1. Education Professionals
Initially, subjects in this category will be identified by their participation in the Initiative, which includes 20 teachers, 5 administrators, and 7 coaches (experienced media educators). These education professionals applied to participate in the Initiative for the 2005-06 academic year. Each educational professional's eligibility for participation in the study will be determined his/her agreement to participate indicated on the consent form. This eligibility will be determined by the research team. As the research progresses, other education professionals within the schools who are using multimedia in their classrooms, after-school clubs, etc., may be identified by researchers conducting participant observation, and will be asked to participate by a member of the research team. If they express interest in participating in the study, they will required to sign the consent form for education professionals. Again, eligibility will be determined by the research team.

2. Students
Student subjects will be selected from the 5 middle schools involved with the 2005-2006 .

Detailed and thorough

Some schools will recruit subjects in two phases, referred to as Phase 1 and Phase 2 of the study. In these cases, the subject pool will be identified through the use of a recruitment letter, which will be distributed by teachers. Students who return the attached consent/assent forms will be considered eligible for participation in the first phase of the study. As teachers begin implementing media lessons later in the year, the research team will choose some classes for a second phase of the research that includes photographing and/or videotaping classroom activities and conducting focus groups with students. Once a classroom is selected by the research team for this additional research, teachers in these classes will distribute consent/assent forms describing the additional research activities. Students who return the consent/assent forms will be considered eligible for participation in the second phase of the study.

Other schools will recruit subjects in one phase only, referred to as Phase 3 of the study. In these cases, the subject pool will be identified through the use of a recruitment letter, which will be distributed by teachers. Students who return the attached consent/assent forms will be considered eligible for participation in the study.

At various points in the school year, members of the research team may identify other potential student subjects through other school activities, such as after-school computer clubs. In these cases, the member of the research team will describe the study and give him/her parental consent and student assent forms. If the student expresses an interest in participating, he/she will be required to take the forms home and submit signed consent/assent forms. Eligibility to participate in the study will be determined on the basis of consent/assent to participate and will be determined by the research team.

23.2. Describe the time the investigators have available to conduct and complete the research and justify that it is sufficient.

The Principal Investigator and Co-Investigator working on this study have approximately 3-10 hours per week, between now and the end of June 2006, to

supervise, coordinate, and conduct research related to this study. The Postdoctoral Research Associate working on the project has 37.5 hours per week to work on three related research projects, which include this study. The Graduate Student Research Assistant working on the project has approximately 20 hours per week to work exclusively on this research project. External program evaluators affiliated with the xxxx , who are also listed as a part of the research team, have budgeted for approximately 60 days to work on research related to this study. This combination of investigators will provide adequate time to conduct and complete research at each of the sites that agree to participate in the study.

23.3. Describe the staff and justify they are adequate in number and qualifications.

The staff includes xxxxx as Co-Investigators for the study. xxxx has a Ph.D., and xxxx has a Ph.D. . Both have several years of experience involved in research that balances participant observation and interviews with adults and children with other roles in a research setting, such as classroom helper or after-school mentor.

Selected citations
"Technologies of the Childhood Imagination: Yugioh, Media Mixes, and Otaku." Presentation at: Digital Generations: Children, Young People and New Media, organized by the Centre for the Study of Children, Youth and Media, University of London, 2004.

Interactive Media for Play: Kids, Computer Games, and the Productions of Everyday Life. Dissertation. Stanford University School of Education. 1998.

Selected citations
"Using ethnographic methods to study learning with media production." Presentation at Youth Media Evaluation Institute, Department of Radio-Televsion-Film, The University of Texas at Austin, 2004.

Trying to Bend the Bars of the Iron Cage: A Case Study of a K-16 Partnership. Dissertation. University of California, San Diego. 2002.

The staff also includes Postdoctoral Research Associate,xxxxx, who has a Ph.D. in Communication and whose dissertation included similar research methods and subject populations as are included in this study.

The staff also includes Graduate Student Research Assistant, xxxxxxx who is pursuing a Ph.D. She has prior work experience as a school teacher and has taken research methods courses at xxxxxxx, both of which have provided her with useful experience for work on this study.

There are three external program evaluators who have been hired to conduct research for this study. All three have Ph.D.'s and have worked professionally as educational program evaluators for several years.

This staff is sufficient in number to be able to conduct an adequate number of observations, interviews, focus groups, etc., with the participating teachers and students in the study.

23.4. Describe the study facilities and justify they are adequate.

The study only requires office facilities for meetings and access to computers and media equipment for word processing, database entry and management, and audio/video storage. Investigators have offices at xxxxxxxxxxxxx and access to the necessary computers and media equipment. The rest of the data for the study is collected in the context of site-specific educational activities, which rely on middle school facilities, such as classrooms.

23.5. Describe how the investigators will ensure that all persons assisting with the research are adequately informed about the protocol and their research-related

duties and functions.
The research staff working on this study helped design the protocol and have discussed and clarified their research-related duties and functions with the investigators and the whole research team.

The external program evaluators working on the study have also reviewed the protocol and have clearly identified with the investigators what data they would be responsible for collecting and analyzing.

In cases when teachers assist with the research by handing out consent forms to students, our research staff will review and discuss the forms with the teachers prior to them handing out the forms. Also, this same member of the research staff will be present when the teachers hand out the consent forms in order to answer any questions that students may have about the study. Our research staff will also inform teachers to encourage parents and students to contact our staff directly if they have additional questions about the research.

iStar ID:	Application Version Date:2/28/2006 Version:0.1

24. Subject Recruitment

24.1. Recruitment Tools (Check all that apply):

Tool	
☐ E-mail	
☐ Flyers	
☑ Letters	Relevant documents for the selected items are attached below in section 24.2
☐ Newspaper/Magazine Advertisements	
☐ Radio/Television Announcements	
☐ Subject or Participant Pool	
☐ Telephone Scripts	
☑ Verbal (Personal Solicitation)	
☐ Website	
☐ Other	
☐ None of the above	

24.1.1. If Other Recruitment Tool, please specify:

24.2. Attach copies of all recruitment tools indicated above.

name	Version	Modified
Recruitment Letter Phase 3:	0.01	2/27/2006 9:44 PM
Recruitment Letter Phase 3:	0.01	2/27/2006 9:45 PM
Recruitment Letter Phase 3: 0.01		2/27/2006 9:45 PM
Recruitment letter:	0.01	8/1/2005 3:55 PM
Recruitment letter:	0.01	8/1/2005 3:55 PM
Recruitment letter:	0.01	8/1/2005 3:55 PM
Recruitment letter:	0.01	8/1/2005 3:56 PM
Recruitment letter:	0.01	8/1/2005 3:56 PM
recruitment script for educators	0.01	8/1/2005 4:02 PM

recruitment script for students 0.01 8/1/2005 4:02 PM

24.3. Describe in detail all recruitment strategies for each participant group involved in this study. Explain how you will have access to a population that will allow recruitment of the required number of participants. Explain who will approach the participants, how and when the participants will be approached, and what will be said.

Education Professionals:
The core group of education professionals will be recruited from participants in the 2005-06.
. Research team members will explain the study to these educators in person and present them with consent forms. Researchers will be available to answer any questions subjects may have, and will collect all completed consent forms. Education professionals from schools who are not attending the Initiative may be asked to participate in the research study later in the year. Again, a member of the research team will personally explain the study and administer consent forms.

Students:
A member of the research team or a xxxx teacher will briefly explain the research study to a class of students and give them an information packet about the study (including consent/assent forms) to take home to their parents.

Some schools will recruit subjects in two phases, referred to as Phase 1 and Phase 2 of the study. In these schools, the information packet will include the following: 1. Recruitment letter, 2. "Phase 1" parental consent form (2 copies), 3. "Phase 1" student assent form (2 copies), 4. Student survey (to be completed at home). As teachers begin implementing media lessons later in the year, the research team will choose some classes for a second phase of the research that includes photographing and/or videotaping classroom activities and conducting focus groups with students. Once a classroom is selected by the research team for this additional research, teachers or a member of the research team will distribute "Phase 2" consent/assent forms to be completed at home. All students that return completed consent/assent forms will be included in the study.

Other schools will recruit subjects in one phase only, referred to as Phase 3 of the study. In these schools, the initial information packet will include the following: 1. Recruitment letter, 2. "Phase 3" parental consent form (2 copies), 3. "Phase 3" student assent form (2 copies), 4. Student survey (to be completed at home).

All of the classes that are taught by education professionals involved in the xxxxxx Initiative will be eligible to participate in the study. The decision about which "phase" of the research to administer at which site will be based partly on the timing of when subject recruitment at that site will begin, and partly on discussions with the teachers about which method of recruitment will be most convenient for the teachers and their students.

In addition, during participant observation at each site, researchers may identify additional subjects appropriate for inclusion in the study (for example, students in an after-school club). Researchers may approach potential subjects to explain the research and ask them to participate, and at that time, give them an information packet.

Lastly, when parents first consent for their child to participate in this study, they will be asked in the consent form if a member of the research team can contact them about participating in a home interview. This is a recruitment tool for a related study that this research team is conducting, entitled “xxxxxxxxxx ” The protocol for this study is being submitted separately for full board review. Should a parent agree to be contacted for this research, a member of the research team will contact him/her following the recruitment protocols consent forms approved for that study.

Please see attached recruitment scripts.

24.4. What measures will be taken during the recruitment and consent process to safeguard against potential coercion or the appearance of coercion?

Education Professionals:
The education professionals involved in the study have agreed to participate in program evaluation as part of their acceptance to the xxxxx Initiative. Applying for the xxxxx Initiative is voluntary. Educators have the ability to opt out of the study by requesting through the consent form that information about them not be included in published research. We have included wording in the consent form for education professionals that emphasizes the educator’s right to decline being audiotaped, videotaped, and photographed without being excluded from the study. In addition, educators are informed that they may omit any interview questions they do not wish to answer and that they may discontinue participation in the study at any time without consequence.

Answer addresses the question of potential coercion.

Students:
All recruitment tools, including the initial recruitment flyer, parental consent form, and student assent form contain language emphasizing that participation in the study is voluntary and that participation in the study is not linked to performance assessment at school in any way. Students and parents are afforded the opportunity to decline being audiotaped, videotaped, and photographed without being excluded from the study. Students are not required to participate in any part of the study without their assent. This is a safeguard against parental mandate to participate. Students are also informed of their right to refuse to answer any question in interviews and to discontinue participation in the study at any time for any reason.

iStar ID:	Application Version Date:2/28/2006 Version:0.1

25. Financial Obligation and Compensation

25.1. Financial Obligation: Describe any financial obligations that the subject may incur as a result of participating in the study. Indicate which costs will be covered by the study.
The subjects will not incur any financial obligations as a result of the study.

25.2. Payment for Participation: Describe how much, if any, financial or other form of compensation will be provided to the subject/family. Describe the requisite conditions that must be fulfilled to receive full or partial compensation. Descibe the proposed method of timing and disbursement. If children are involved, please specifically address how the compensation will be distributed to children.
Subjects will not receive any payment for participating in the study.

25.3. Emergency Care, Injury and Compensation for Injury: If participants were to require care, medical or psychological services as a consequence of the research, how will they be made available? If applicable, describe how the financial liability for research-related injuries would be handled.
N/A

iStar ID:	Application Version Date:2/28/2006 Version:0.1

26. Data Privacy and Confidentiality

26.1. How will the data for this study be collected and recorded? Describe the provisions to protect the privacy of the individual.
Surveys of educational professionals and students will be collected via paper surveys or online through the website.

Interviews and focus groups with students who have agreed to be video taped will be recorded. If any member of a focus group declines to be videotaped, the session will not be taped. All interviews and focus groups will be recorded with written notes.

Observations will be recorded as handwritten notes and typed up into fieldnotes. The fieldworkers will also audiotape brief conversations with students who have given their assent (along with parental consent) to be audiotaped. Observations of specific class periods in which multimedia projects are the focus will be videotaped or photographed.

Class curriculum, lesson plans, and student work will be collected from the teachers. Students will provide parental consent and personal assent to collection and use of student work.

26.2. How will the data be recorded to protect personal privacy (select one)?
Coded (Data will be linked to subjects with a code)

26.2.1. If Other is selected, please specify.

26.3. Where will the research data be stored? Please specify the physical location and how it will be secured to protect confidentiality.
All video and audio tapes, photographs, field notes, transcripts, surveys, and work samples will be kept in a locked cabinet in a secured office in a University building. Electronic data will be stored in password protected files or on a secure computer or server. Only the research team will have access to data. The data will be kept indefinitely for future research purposes or reference.

26.4. Who, other than the specified study team, will have access to the study records or data? Specify their name, role and affiliation. Do not list study personnel already listed on screen 2.
Name Role Affiliation
There are no items to display.

26.5. If coded or identified data will be released, specify the persons, agencies to whom the information will be released. Please also indicate the provisions that will be taken to assure that the transmission of the data will maintain confidentiality.
Transcription of video and audio tapes will be performed by a member of the research team or a professional transcription service. If tapes are released, the research team will sign a confidentiality agreement with the transcription service.

26.6. Describe what will happen to the data or data set, when the study is completed. Please indicate your plans for destruction of identifiers at the earliest opportunity consistent with the conduct of the research and/or clinical needs, if applicable.
The data collected in this study will not be destroyed, but will be archived by the co-investigators.

26.7. Will a Certificate of Confidentiality be obtained for this study?
○ Yes ◉ **No**

26.7.1. If yes, please attach the Certificate of Confidentiality if applicable.

26.8. If audio/video recordings or photographs will be used, specify your plans for deidentifying or anonymizing the material and when it will be destroyed.
At the time of transcription remove any references to the subjects' last names and change the names of any subjects who requested a pseudonym be used in place of their real names. Materials will be archived indefinately and will not be destroyed.

27. Risk/Benefit Assessment - Risks

27.1. Risk classification for this study (select one).
Minimal Risk

27.2. Risks, Discomforts and Potential Harms: Describe the risks associated with each intervention. Include consideration of physical, psychological, social, and other factors. If data is available, estimate the probability that a given harm may occur and the potential reversibility. (HSC: *refer to specific sections of the protocol/grant, if applicable*)
The physical, psychological, social, and legal risks to the subjects are minimal. Subjects may feel uncomfortable with the presence of researchers or video cameras or answering certain questions in interviews or focus groups.

If needed, copy-and-paste any tables here and reference in the question above.

27.2.a. If needed, copy-and-paste any tables here and reference in the question above. Tables

27.3. Describe the safety precautions that will be taken to minimize risks/harms. (HSC: *refer to specific sections of the protocol/grant, if applicable*)
Subjects will be informed of their right to decline to be recorded, to decline to answer any question, or to withdraw from the study anytime without penalty. Only students' first names will be used in publications or presentations. Education Professionals are given the option to have their names replaced with a pseudonym in publications and presentations.

27.3.a. If needed, copy-and-paste any tables here and reference in the question above. Tables

27.4. Data Safety Monitoring Plan: Describe how the studies are monitored for the safety of the participants and for the validity and integrity of the data. (If a DSMB is involved with this study, please describe the composition, plans for monitoring and distributing information to the local IRBs.)
Data safety is discussed in item 26.

27.4.1. (CHLA Only) Attach the CHLA DSMP form.

28. Risk/Benefit Analysis - Potential Benefits and Alternatives

28.1. Describe any potential for direct benefits to participants in the study. There may be no direct benefits.
Through the xxxxxxxx, the educators are provided with human and technical resources to support their multimedia curriculum. In addition, the research will provide them an opportunity to reflect on their own practices and gain access to research results that are directly relevant to their pedagogy.

28.2. Describe any potential benefits to society.
The potential benefits to society include contributions to the growing body of work regarding multimedia literacy and pedagogy. The results of the study will be used in the development of a Media Literacy curriculum for xxxxxx. In addition, findings of this study have the potential to inform state and national educational policy by providing models for teaching and learning with multimedia.

28.3. Alternatives to Participation: If applicable, describe alternatives (research or non-research) that are available to subjects if they choose not to participate in this study. This could include not participating in the study.
All subjects may choose not to participate in the study, and still participate in ongoing classroom, teaching, and learning activities associated with the xxxxx Initiative.
All subjects are given the choice of declining to be audiotaped, videotaped, and/or photographed. Teachers who have agreed to participate in the xxxxxxxx Initiative are required to participate in basic program evaluation activities, but may choose not to be included in publications about the Initiative or in additional research.

28.4. Risk/Benefit Analysis: Describe the risk to benefit relationship of participation in the research (relative to non-participation and/or alternatives).
The benefits of participating in this research study outweigh the risk because of the access to resources for implementing a multimedia curriculum provided by the xxxxxxx Initiative. Risks are minimal and alternatives to participation are given to eliminate risk factors.

29. Informed Consent and Waivers

29.1. * **Indicate the types of consent that will be involved in this study (check all that apply):**

Consent Type
☑ Written/signed consent by the subject
☐ Written/signed consent by a legally authorized representative (for an adult)
☑ Written/signed permission for a minor by a parent or legal guardian
☑ Written/signed assent by a minor
☐ Verbal consent or written information sheet (Requires waiver of written or signed consent below)
☐ Consent will not be obtained for this study

29.1.1. **Attach copies of all of the informed consent/assent, information sheet, and verbal script documents that will be used for this study**

All relevant consent documents attached

name	Version	Modified
Appearance Release	0.01	8/1/2005 4:23 PM
Education Professional Consent Form_clean_revised	0.02	9/21/2005 12:14 PM
Education Professional Consent form_marked_revised	0.02	9/21/2005 12:09 PM
Parent Consent Form: Phase 1_clean_revised	0.02	9/21/2005 12:13 PM
Parent Consent Form: Phase 1_marked_revised	0.03	9/21/2005 12:10 PM
Parent Consent Form: Phase 2_clean_revised	0.02	9/21/2005 12:15 PM
Parent Consent Form: Phase 2_marked_revised	0.03	9/21/2005 12:11 PM
Parent Consent: Phase 3	0.01	2/27/2006 9:52 PM
Student Assent Form: Phase 1_clean_revised	0.02	9/21/2005 12:16 PM
Student Assent Form: Phase 1_marked_revised	0.03	9/21/2005 12:12 PM
Student Assent Form: Phase 2_clean_revised	0.04	9/21/2005 12:16 PM
Student Assent Form: Phase 2_marked_revised	0.03	9/21/2005 12:12 PM
Student Assent: Phase 3 (Marked)	0.01	2/27/2006 9:53 PM

29.2. * **Waivers: If you are applying for any waivers of consent (check all that apply).**

Waiver Type
☐ Waiver of consent
☐ Waiver of assent
☐ Waiver of parental permission
☐ Waiver of written or signed consent (i.e., information sheets, telephone consent, verbal script)
☑ I am not applying for a waiver

Note: Waivers of consent are not applicable if the research is subject to FDA regulations, except the following.

FDA Exception from general requirements:

1. **Waivers of Informed Consent in FDA-regulated studies are permissible in case of life-threatening situations, inability to communicate, not sufficient time and no alternative method, even if research presents more than minimal risk [21CFR50.23];**
2. **If the study satisfies the requirements under 21CFR50.24 "Exception from Informed Consent Requirements for Emergency Research."**

30. Description of Informed Consent Process

30.1. Personnel Obtaining Consent: indicate the names and qualifications of study personnel who will be involved in the informed consent process.

30.2. Describe the consent process. Discuss when and where the consent process will take place relative to the initiation of the study procedures, as well as, how opportunities will be made for possible participants/families to discuss their participation with others before signing the consent form. Describe the steps taken to provide the prospective participant sufficient opportunity to consider whether or not to participate in the study.

Education professionals will be asked to complete the Consent form for Education Professionals at the xxxxx Workshop held at the xxxxx in August 2005 or
in follow up visits by the research team to school sites. Research team members will present subjects with information and consent forms at the end of the event, and will ask for participation in the year-long study. Researchers will be available to answer any questions subjects may have, and will collect completed consent forms. Education professionals who are recruited after participant observations have begun will be given a consent form and asked to return the consent form to the researchers in person or by mailing it to the research team at the xxxxxxxxxxxxx.

Detailed description

At some sites, student subjects will be recruited to participate in the research in two phases. At such sites, students will first receive an information packet including the following: 1. recruitment letter, 2. parental consent form (2 copies), 3. student assent form (2 copies), 4. student survey. These packets will be distributed in class by the teacher in an envelope labeled with the student's name. Students will bring the packets home to review and discuss with parents/guardians, and will return one set of consent/assent forms and the student survey in the same envelope to their teachers before a specified deadline (approximately one week after distribution of the materials). The second set of consent and assent forms is for the student and parent to keep. All students will be asked to return the materials, even if they are not participating in the study, to help researchers track participation and to avoid students feeling embarrassed if they do not have anything to turn in.

If additional subjects are identified during participant observation, researchers may give subjects who agree to participate an information packet. Subjects will bring the packet home to discuss with parents and will return the packet to their teacher according to the process described above.

In the second phase of research, teachers of selected classes and activities will distribute a second set of consent and assent forms (2 copies of each) in an envelope labeled with the student's name. Students will again complete these forms at home to facilitate consultation with parents. Students will return one copy of the forms in the same envelope. The second copy is for the student and parent to keep. All students will be asked to return the materials, even if they are not participating in the study, to help researchers track participation and to avoid students feeling embarrassed if they do not have anything to turn in.

Again, if students who are not a part of the groups initially targeted for recruitment in the second phase of research are identified by researchers, those students will be given a set of consent forms to complete and return to their teacher in the manner described above.

At other sites, student subjects will be recruited to participate in the research only once during the school year, and their consent/assent forms will ask for their consent/assent to participate in all of the research methods (described in Phase 1 and 2, above). For the sake of clarity in managing our protocols for the various sites, we will refer to this as Phase 3 of the research. Sites will be selected to participate in Phase 3 of the research if subject recruitment at that site has begun late in the school year, such that the methods originally addressed in "Phase 2" consent forms are already appropriate for these sites.

30.3. Describe the steps that will be taken to assure that subjects (including children) fully understand the nature of their involvement in research.

Consent/Assent forms have been crafted to contain straightforward langauge and clear descriptions of the research. The assent form has been written to account for middle school students' reading abilities. Subjects are instructed to ask researchers any questions they have regarding the nature of their involvement in the research.

All forms and instruments will be available in English and Spanish.

30.4. Will you be recruiting non-English speaking subjects?

(●) **Yes** ( ) No

30.5. Describe how capacity for consent will be determined if some or all of the subjects have cognitive and/or language/hearing impairments.

Because we are recruiting from general education classrooms, we do not anticipate subjects having cognitive and/or language/hearing impediments that will impact their ability to consent.

30.5.1. If applicable, attach any instruments that will be used to determine the subject's capacity to consent.

name Version Modified

There are no items to display.

30.6. Describe the procedures for identifying a legally authorized representative/guardian for those unable to consent (adults) or for minors not accompanied by their parents, as applicable.

Consent forms will be sent home with students, most of whom will be living with a parent legal guardian. Researchers will request assistance from the school in identifying a legal guardian if such assistance is needed.

35. Is the HIPAA Privacy Rule Applicable?

35.1. Do you intend to access, use or disclose protected health information (PHI) in order to abstract medical record data (even if you are de-identifying the data abstracted), identify potential participants or to conduct your research?

( ) Yes (●) **No**

35.2. If Yes, do you intend to use data that contains any of the 18 elements defined by HIPAA as identifiers (listed below), in your research?

( ) Yes ( ) No

The HIPAA Privacy Rule regulations [45 CFR 164.514(b)] lists 18 specific elements that are considered to be personal identifiers. The list includes:

- Name/Initials
- Street address, city, county, precinct, zip code, or equivalent geocodes
- All elements of dates (except year) directly related to an individual (date of birth, admission date, discharge date, date of death)
- Elements of date, including year, for persons 90 or older
- Telephone number
- Fax number
- Electronic mail address
- Social Security Number
- Medical record number
- Health plan identification number
- Account number
- Certificate/license number
- Vehicle identifiers and serial numbers, including license plate number
- Device identifiers and serial number
- Web addresses (URLs); Internet IP addresses
- Biometric identifiers, including finger and voice print
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic or code

39. Conflict of Interest Information

39.1. Do any of the participating study investigators or other research personnel (or their immediate family/significant other) have a financial and/or intellectual property interest in the sponsor or products used with this project.

○ Yes ◉ **No**

39.2. If yes, attach a completed Financial and Intellectual Interest Disclosure Form for each person who has a potential conflict to be managed.

name	Version	Modified

There are no items to display.

iStar ID: Application Version Date:2/28/2006 Version:0.1

40. Additional Supporting Documents

40.1. Attach any other documents that have not been specifically specified in previous questions, but are needed for IRB Review. For additional documentation that may be required for HSIRB Submissions, please consult the HSIRB Checklist.

name	Version	Modified
Application	0.01	8/1/2005 4:17 PM
Evaluation Plan	0.01	8/1/2005 4:16 PM

40.2. If there is any additional information that you wish to communicate about the study please include it below. Please note, this section should not be used in lieu of or instead of the standard application items.

iStar ID: Application Version Date:2/28/2006 Version:0.1

41. Non-English Speaking Subjects

This screen is required if you indicated you will be recruiting non-English speaking subjects (Question 30.4.)

41.1. Describe the process of how you will explain the study and assure that the non-English speaking subjects understand the study and their participation in research. For example, the use of translators, translated informed consent documents, short forms, and any other methods that would be taken.

Subjects must speak English or Spanish. Several members of the research team are bilingual in English and Spanish and will conduct interviews and informal conversations in Spanish, if necessary. All parent consent and student assent forms will translated into Spanish and will be available in English and Spanish.

41.2. If the study will likely include subjects and families for whom Spanish is the primary language, the consent documents must be translated into Spanish. Please indicate the method of translation.

- ○ Request that the IRB office translate (HSIRB & CCI Only)
- ○ Request that the IRB office provide contact information of qualified translation services (translation agreements made by study team)
- ◉ Investigator will provide the IRB with a translation of the approved consent form

41.3. If the research will primarily include subjects who speak a language other than English or Spanish, the informed consent documents should be translated into that language. Please indicate the languages and method of translation.

Language	Translation Method

There are no items to display.

41.4. (CHLA Only) If the consent translation fee is in the contract for this study, please record the cost center to be charged. If there is no cost center, indicate "Not Applicable".

iStar ID:	Application Version Date:2/28/2006 Version:0.1

99. Instructions for Study Submission

Congratulations! You have completed the application for a new protocol. When you are sure of the content, the following steps may be taken to submit your study for review.

For HSIRB Submissions, please consult the HSIRB Checklist found here.

For UPIRB Submissions, please consult the UPIRB Checklist found here.

1. **Click the "Finish" button on the top or bottom application navigator bar to return to the study folderspace.**
2. **Use the SmartForm Progress Calculator to determine that all sections of the application are filled out correctly.**
3. **Use the "Send Study Ready Notification" activity to send an email to the Principal Investigator and Co-Investigator's with instructions for reviewing and submitting the application.**
4. **All listed Co-Investigators (Question 2a.3, 2b.3, or 2c.3.) must use the "Agree to Participate" activity and answer yes.**
5. **Once all the Co-Investigators have agreed to participate, the Principal Investigator (Question 2a.1, 2b.1, or 2c.1.) can submit the study by using the "Submit Application to ____", where ____ indicates the IRB you are submitting to.**
6. **The PI will have to check the PI endorsement box. The PI will also have to check the student endorsement box if it is applicable.**
7. **The study is submitted. The state indicator in the top left of the study folderspace will no longer display Pre Submission.**
8. **The PI and Study Coordinator will receive an email confirming the application has been submitted.**

iStar ID:	Application Version Date:2/28/2006 Version:0.1

5c.1. Other Site/Institution (In the United States)

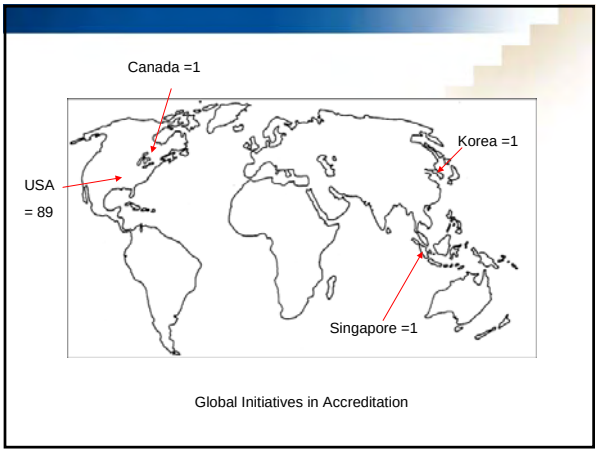
5c.1.1. * Site Name:
xxxxxxxxxxxx

5c.1.2. * Address:
xxxxxxxxxxxxxx

5c.1.3. * Will any of the personnel at this non-USC/CHLA institution carry out research activities such as obtaining consent or conducting study procedures?
◯ **Yes** ◯ No

5c.1.4. If yes, indicate under which category(ies) the institution is engaged, and attach a copy of the IRB approval from that site below.

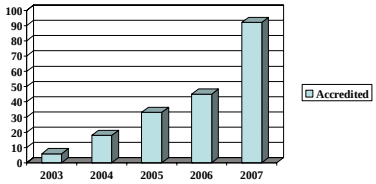
	Long Description
☐	(1) Institutions whose employees or agents intervene with living individuals by performing invasive or noninvasive procedures for research purposes (e.g., drawing blood; collecting other biological samples; dispensing drugs; administering other treatments; employing medical technologies; utilizing physical sensors; utilizing other measurement procedures).
☐	(2) Institutions whose employees or agents intervene with living individuals by manipulating the environment for research purposes (e.g., controlling environmental light, sound, or temperature; presenting sensory stimuli; orchestrating environmental events or social interactions; making voice,



Accredited organizations

- As of December 2007, 92 organizations representing a total of 367 entities:
  - Contract research organizations, hospitals, independent IRBs, research institutes, universities and government agencies
  - Small (fewer than 20 protocols) and large (greater than 6,000 protocols) institutions
  - Clinical and non-clinical research programs
  - International programs: Canada, Singapore, and South Korea

History of accreditations



Who's seeking accreditation – based on United States data

- 100% of VA medical centers
- 85% of research intensive universities
- 80% of independent IRBs
- 75% of academic medical centers
- 75% of NCI-funded cancer centers
- 30% independent teaching hospitals
- 27% independent children's hospitals
- 20% universities with only behavioral/social science programs
- First applications from research sites and pharmaceutical companies

2002 - 2007

- Major improvement in the quality of accreditation applications
  - Annual conference
  - Networks
  - Evaluation Instrument on Accreditation and Tip Sheets
  - Preliminary application
- More focus from AAHRPP on practice than on written documentation

Major accreditation findings

- Of the 77 elements, 21 pose challenges
  - Domain I
  - Domain II
  - Domains III - V

Accreditation findings – Domain I

- Elements I.3.C, I.3.D, I.3.F
  - Definition of research involving human subjects (I.3.C)
    - Missing FDA definitions
    - Definitions inconsistent with federal regulations
  - Criteria for exemptions (I.3.D)
    - Do not take into account FDA regulations
    - Do not take into account OHRP guidance
  - Definitions of legally authorized representative, child, guardian (I.3.F)
    - Which individuals within your state meet the federal definitions

Accreditation findings – Domain I

- Elements I.3.G, I.3.I, I.3.J
  - Investigator conflict of interest (I.3.G)
    - Missing FDA and PHS disclosures
    - Missing a procedure that the IRB has the final authority to decide whether the research is approvable
  - Non-compliance (I.3.I)
    - Definitions, determinations, actions, reporting
  - Unanticipated problems involving risks to participants or others (I.3.J)
    - Process to determine whether a problem is an “unanticipated problem involving risks to participants or others”
    - Reporting

Accreditation findings – Domain I

- Elements I.5.A
  - Missing definitions of when IND or IDE are required
  - Missing process to verify that the IND or IDE is correct
  - Missing process to determine whether an investigator acting in the sponsor role is knowledgeable about the federal requirements for sponsors

Accreditation findings – Domain II

- Element II.1.D
  - Missing an evaluation process for the IRB chair and members
  - Missing a requirement to include someone on the IRB who represents the views of participants

Accreditation findings – Domain II

- Element II.2.B
  - Procedures for review using the expedited procedure
    - Missing applicability criteria
    - Missing definition of "minor"
- Element II.2.D
  - Continuing review
    - Missing a status report or status report is incomplete
- Element II.3.C
  - Missing documentation of required determinations

Accreditation findings – Domain II

- Element II.4.A
  - Evaluation of risks and potential benefits
    - Missing the three regulatory criteria
- Element II.4.B
  - Evaluation of data and safety monitoring plan
    - Missing an evaluation component
- Element II.4.D
  - Suspension and termination of IRB approval
    - Definitions of suspension and termination
    - Consider consequences of suspension or termination for enrolled participants
    - Reporting

Accreditation findings – Domain II

- Element II.6.A
  - Protection of privacy interests
    - Understanding the difference between privacy and confidentiality
    - Missing as a criterion for approval of research
- Elements II.7.A – F
  - Missing evaluation of the consent process
  - Missing required disclosure elements
  - Missing FDA requirements pertaining to consent
  - Confusion between waiver of the consent process and waiver of documentation of the consent process
  - Confusion of requirements for implementing the exception to obtain consent in emergency situations

High quality human research protection programs

- Elements met with distinction
  - I.1.A - strong integrated plan for human research protection
  - I.1.B - strong program for scientific review
  - I.1.C - strong and highly motivated organizational leader
  - I.2.A - program for review of resources for the HRPP
  - I.2.B - research specific IRBs
  - I.2.D - strong network of communication among units
  - I.3.H - policy and procedure to identify and manage organizational conflict of interest
  - I.3.L - strong quality improvement programs
  - I.4.A - strong education programs for researchers and staff
  - II.1.D - highly competent IRB chairs, members, or staff
  - V.2.A - impressive educational materials for the community

High quality human research protection programs

- Leadership, leadership, leadership
- Knowledgeable IRBs and researchers
- Respect gained from the faculty
- Communication among units involved in human research protection
- Emphasis on a program – not just the IRB
- Significant emphasis on accountability
- (Resources)

Leveraging Accreditation at the University of Southern California (USC)

Susan L. Rose, Ph.D.
OPRS Executive Director
oprs@usc.edu
http://www.usc.edu/admin/provost/oprs

USC UNIVERSITY OF SOUTHERN CALIFORNIA

2008 AAHRPP Annual Conference
Minneapolis, Minnesota
February 24 – 26, 2008

Definition

***leverage*:** "shamelessly exploit the system to one's advantage"—Alexander Wolff (196?-)

Using AAHRPP as a Stick Rather than a Carrot

Then

…"if you don't do this, we will not get accredited"

Leveraging at USC

Positives:	Negatives:
• Fiscal items • Using technology • Turning from an IRB into a program • Using the regulations appropriately • Attitudes	• Firing staff • Replacing IRB chairs/members • Stubbornness/conservative • Reluctance to change
Serendipity/Accidental:	**Failures:**
• Team players self identify • Diamonds in the rough • Visibility of the program	• Using accreditation to prevent off campus move • Online application system • Asymmetry between campus unchanged

Random Thoughts on USC Leveraging

- Take policies and procedures from accredited institutions and make practices fit
- Visit accredited institutions
- Unload bad IRB staff, bad IRB members, bad IRB chairs
- Find and hire good IRB staff, good IRB members, and good IR
- Do not put off anything, use immediacy to your advantage
- Reorganize staff and office physically and functionally
- Promotions and thank yous
- Student mentor
- Listserv and website
- Begin novel best practices
- Do what you need to do anyhow but call it accreditation
- Educate, educate, educate!!
- Network and shamelessly ask for help inside and outside of institution
- Eliminate unhelpful people from rolodex—get even!
- Independent space/enough space
- Meet higher-ups and VIP faculty one couldn't meet otherwise
- Create new rolodex with good guys
- Help other people getting accredited with your experience/paperwork
- Reap rewards, market your success

Using AAHRPP as a Stick Rather than a Carrot

Now

…"if you don't do this, we will not remain accredited"

T.th…th..that’s all folks!!!!

Available online— http://www.usc.edu/admin/provost/oprs/news/archives/index.html

VOLUME 4, ISSUE 2 MARCH 12, 2008

USC UNIVERSITY OF SOUTHERN CALIFORNIA Human Subjects Newsletter

Published by the Office for the Protection of Research Subjects (OPRS)
Susan L. Rose, PhD, Executive Director

2008 Annual IRB Survey: Your Chance to Review the IRB!

The annual IRB survey is open for participation until March 28th. The Office of Protection of Research Subjects (OPRS) uses this survey to evaluate and improve the Human Subjects Protection Program (HSPP). Your participation is voluntary and will remain anonymous. The brief survey is comprised of four sections and should take 10 minutes or less to complete.

To participate, click HERE

Grad Assistant Replacement Sought from the OPRS

The prize a former Student Mentor was awarded for her service.

The OPRS is searching for the next Grad Asst./IRB Student Mentor. The position is ideal for a first year Masters or PhD candidate who can commit at least two years to the appointment. The position includes all RA/TA position benefits: tuition remission, payment of mandatory fees, and a monthly stipend.

For more info visit: Grad Asst. Opportunity: IRB Student Mentor/Member

The IRB Student Mentor position has been a very successful program at USC and we want it to continue.

For anyone interested, please send a CV/Resume to the oprs@usc.edu

HSC Human Subjects Education Session: 3/20 (Thu) at 12:00

Are You Conducting Human Subjects Research for the First Time? Health Sciences Faculty, Staff, and Students… Come join us for an introductory education session on human subjects research and the IRB process.

When: **March 20, 2008**
Time: **12:00 – 1:00**
Location: **Health Sciences Campus, McKibben Hall 149 (MCH)**

RSVP to oprs@usc.edu
Flyer: http://www.usc.edu/admin/provost/oprs/private/docs/oprs/HSC_IRB_Ed_Session.pdf

Improvements to CITI (online human subjects education)

The CITI program was recently modified to streamline the enrollment process, and provide more flexibility in selecting modules most relevant/interesting to the participant.

Three different programs are available in CITI: the mandatory human subjects program, and two optional programs; the Responsible Conduct of Research, and Good Clinical Practice (GCP). All three programs are clearly identified in the enrollment process and participants can elect to complete one, two, or all three.

The human subjects program was downsized from ten to only four user-groups, and participants can elect which courses they wish to complete. The new user-groups are listed below.

CITI Human Subjects Program User-Groups:

- **Health Sciences Investigators, Key Personnel, and HSIRB Members/Staff**
- **Health Sciences Investigators and Key Personnel Conducting Exempt Research**
- **University Park Student Investigators, Investigators/Key Personnel Conducting Exempt Research, and Faculty Advisors on Student Research Projects**
- **University Park Faculty/Staff Investigators, Key Personnel, and UPIRB Members/Staff**

CITI: http://www.citiprogram.org/

News Articles

- **OHRP Concludes Case Regarding Johns Hopkins University Research on Hospital Infections,** (2/15/08) http://www.hhs.gov/ohrp/news/recentnews.html#20080312
- **F.D.A. Seeks to Broaden Range of Use for Drugs**, *NY Times* (2/16/08) http://www.nytimes.com/2008/02/16/business/16drug.html?ref=policy
- **Justices Shield Medical Devices From Lawsuits**, *NY Times* (2/21/08) http://www.nytimes.com/2008/02/21/washington/21device.html
- **F.D.A. Approves Drug's Use for Breast Cancer**, *NY Times* (2/22/08) http://www.nytimes.com/2008/02/22/business/apee-drug.html
- **Pfizer to End Lipitor Ads by Jarvik**, *NY Times* (2/26/08) http://www.nytimes.com/2008/02/26/business/26pfizer.html
- **Investigator attendance at review board reviews: hindrance or help?** *John Hopkins Univ.* (3/10/08) http://www.eurekalert.org/pub_releases/2008-03/jhmi-iaa031008.php

Contact Information

Office for the Protection of Research Subjects (OPRS)
Phone: (213) 821-1154 Email: oprs@usc.edu Web: http://www.usc.edu/ admin/provost/oprs