

Date: Thursday, February 27, 2014 9:54:20 AM

iStar ID: HS- -

Application Version Date: 8/5/2012

Version: 1. 0

1. Project Identification and Abstract

1.1. * Type of Submission:

[Guidance](#)

Research Protocol or Study on Human Subjects

Grant/Contract Only

Facilitated Review (NCI CIRB)

USC/CHLA Collaborative Review

Use of Humanitarian Use Device (Not Research)

Ceded Review (Utilize approval by an outside IRB)

1.2. * Full Title of Research Protocol

[Guidance](#)

Does a workshop on Handoffs improve student verbal and written Handoffs skills?

1.3. * Short Title

[Guidance](#)

Handoffs workshop and student skills

1.4. **Abstract: Provide a simple explanation of the study and briefly address (in 1 to 2 sentences) each of the following points: rationale; intervention; objectives or purpose; study population or sample characteristics; study methodology; description of study arms (if appropriate); study endpoints or outcomes; follow-up; statistics and plans for analysis.**

[Guidance](#)

Background and Rationale:

Handoffs are essential for the continuity of patient care. The Joint Commission in 2006 recommended standardizing patient handoff procedures and the use of “read-back” and “repeat-back” practices during transitions of care. In 2010 the Joint Commission incorporated the patient handoff into its Accreditation Standards. The Accreditation Council for Graduate Medical Education (ACGME) required that residents are competent in handoff communications. However, few trainees receive formal training in handoffs education. Since 2011, therefore, the Keck School of Medicine implemented handoffs training through a workshop in the Intersessions Course.

Objectives:

To determine whether medical students’ skills in handoffs communication improved after a training workshop.

Selection Criteria:

All third year medical students at the Keck School of Medicine, graduating in 2014.

Study Methodology:

Students will participate in an interactive workshop on communication skills required for effective handoffs during the Intersessions course. The students will then be assessed on their verbal and written handoffs skills with a resident or faculty serving as standardized receivers of the handoffs.

Study Outcomes:

Student improvement in preparedness for verbal and written handoffs.

Intervention and follow-up

As the students rotate through their Internal Medicine clerkship after Intersessions, they will be assessed by the residents as part of their curriculum in Internal Medicine.

Statistics and plans for analysis

Aggregate unpaired data will be analyzed using simple statistics and where appropriate for paired data, Wilcoxon test will be used

- 1.5. * Select which IRB you are requesting review from:
USC-Health Sciences (HSC)

[Guidance](#)

iStar ID: HS- -

Application Version Date: 8/5/2012

Version: 1. 0

2. Study Personnel

- 2.1. Study Personnel and their roles:

[Guidance](#)

| Last Name | First Name | Organization | Study Role | Certifications | Obtain Consent |
|----------------------|------------|---|------------------------|----------------|----------------|
| View | | MEDICAL EDUCATION | Principal Investigator | | yes |
| View | | GERIATRIC, HOSPITAL, PALLIATIVE, Co-& GENERAL INTERNAL MEDICINE | Investigator | | yes |
| View | | GERIATRIC, HOSPITAL, PALLIATIVE, Co-& GENERAL INTERNAL MEDICINE | Investigator | | yes |
| View | | GERIATRIC, HOSPITAL, PALLIATIVE, Co-& GENERAL INTERNAL MEDICINE | Investigator | | yes |
| View | | GERIATRIC, HOSPITAL, PALLIATIVE, Co-& GENERAL INTERNAL MEDICINE | Investigator | | yes |

- 2.2. Is the Principal Investigator a student, resident, fellow, other trainee, or visiting scholar at USC/CHLA?
Yes No

[Guidance](#)

- 2.3. If there are any individual collaborators from other institutions, check here:

[Guidance](#)

- 2.4. Does this study require Cancer Center Committee (CIC) approval?
Yes No

[Guidance](#)

- 2.4.1. Are Cancer Patients Involved? Yes No

- 2.5. Specify the group/organization who has reviewed this study for scientific merit:
Division of Medical Education Research Group

[Guidance](#)

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.

3.1. Pending Division/Department Approvals:

[Guidance](#)

Name Division/Department Parent Campus

There are no items to display

3.2. Received Division/Department Approvals:

[Guidance](#)

| Name | Division/Department | Parent Campus |
|--|---------------------|---------------------------|
| GERIATRIC, HOSPITAL, PALLIATIVE, & GENERAL INTERNAL MEDICINE | Division | USC-Health Sciences (HSC) |
| MEDICINE | Department | USC-Health Sciences (HSC) |
| MEDICAL EDUCATION | Division | USC-Health Sciences (HSC) |

3a.3. Other campus committees, services or departments that need to review and approve this protocol:

[Guidance](#)

Committee Name Committee Chair Approval Memo

There are no items to display

3a.4. Will the research be conducted through the CTU?

[Guidance](#)

Yes No

4. Funding Information

4.1. * What existing, planned, or pending support will be used for this study? (check all that apply)

[Guidance](#)

Cooperative Group (SWOG, COG, RTOG, etc.)

CTSI

Department of Defense (DOD) Funds

Departmental/Institutional Funds

Federal Grant/Contract

Foundation Grant/Contract

Industry

Intramural/Internal Grant

Residual Funds

State or Local Grant/Contract

Subcontract from another institution

No Funding

Other

5. Type of Study Review

5.1. Select the type of review that you are requesting for this study:

[Guidance](#)

Full Committee Review

Expedited Review

Exempt Review

Coded Specimens/Data

5.2. Attach the protocol here. For simple, investigator-initiated studies, a separate protocol may not be necessary. However, larger, complex, or multi-site studies require a fully developed protocol. If you have questions contact the IRB office to discuss.

[Guidance](#)

name Version Modified

There are no items to display

5.3. Attach the sponsor's template informed consent here.

[Guidance](#)

name Version Modified

There are no items to display

5.4. If any study documents are password protected, enter the passwords here.

[Guidance](#)

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

[Guidance](#)

iStar ID: HS- - -

Application Version Date: 8/5/2012

Version: 1. 0

5b. Type of Study Review - Application for Exempt Status

This screen is required if you are requesting a claim of exemption for this study (Question 5.1.) If this is the incorrect review type, please return to page 5 to make changes.

WARNING: A Claim of Exemption is not allowed for any research involving prisoners. In these cases, you must request Expedited Review.

5b. * Choose the applicable exemption categories from the list below. (Note: these exemptions do not apply to research involving prisoners. For children, all exemption categories may apply except for (2) unless it is simply observation of public behavior and the investigator does not interact with the children.)

[Guidance](#)

Short Description (click for full description)

(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...

(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...

(6) Taste and food quality evaluation and consumer acceptance studies...

6. Study Location(s)

6.1. **Select the locations where this study will be conducted by the USC/CHLA investigator(s) (check all that apply):** [Guidance](#)

HSC - Health Sciences Associated Locations

UPC - University Park Associated Locations

CHLA

6.2. **Are there other sites besides USC/CHLA involved in the research?** [Guidance](#)

Yes No

6a. HSC Location(s)

This screen is required if you indicated HSC - Health Sciences Associated Locations (Question 6.1.)

6a.1. **Locations that recruitment, consent, and/or study procedures will be performed: (check all that apply)** [Guidance](#)

Location

LAC+USC Medical Center

LAC+USC Emergency Dept

LAC+USC Outpatient Clinics

LAC+USC 5P21 Building

Keck Hospital of USC Facilities

USC Norris Comprehensive Cancer Center Facilities

Keck School of Medicine of USC

USC Eye Institute

USC Healthcare Consultation Center I or II

USC Center for Health Professions (CHP)

USC School of Dentistry

El Monte Comprehensive Health Center *

H. Claude Hudson Comprehensive Center *

Roybal Comprehensive Health Center *

Verdugo Hills Hospital

Other location (e.g., subjects home, community)

6a.2. **Describe other location(s):** [Guidance](#)

6a.3. **If you are conducting this research in an LAC+USC location, specify the room numbers:** [Guidance](#)

6a.4. **If you are conducting this research at a location marked with an asterisk "*", attach a letter of approval from the medical director.** [Guidance](#)

name Version Modified

There are no items to display

iStar ID: HS- -

Application Version Date: 8/5/2012

Version: 1. 0

9. Methods and Procedures - Selected Descriptors/Community Engaged Research

Note: The list of items below IS 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.

This study will involve: (check all that apply)

- Prospective collection of data/specimens
- Use of existing or retrospective data/specimens

[Guidance](#)9.2. **Study Procedures:** (check all that apply)[Guidance](#)

- Audio/Video Recordings or Photographs
- Behavioral Observations and/or Behavioral Experimentation
- Behavioral Interventions
- Deception
- Interview/Focus Groups
- Population-based Field Study
- Psychophysiological Testing
- Surveys/Questionnaires/Psychometric Testing
- Anatomic Pathology Specimens
- Approved/Investigational Devices
- Approved/Investigational Drugs and Biologics
- Biohazardous Substances
- Controlled Substances
- Creation of a Data or Tissue Repository
- Emergency Research (with exception from informed consent requirements)
- Gene Transfer Study
- Heritable Genetic Specimens or Germ Line
- Magnetic Resonance Imaging (MRI) or ultrasound other than clinically indicated
- Radiation Exposure Other Than Clinically Indicated Tests and/or Therapy (e.g. x-ray, CT, DEXA, radiation therapy, etc.)
- Stem Cell Research
- Substance Abuse Treatment (with medication)
- Venipuncture

9.4. **Will data from this study be submitted to the NIH Genome-Wide Association Studies (GWAS) data repository?**[Guidance](#)

Yes No

9.5. **Does your study involve community-engaged research (community-engaged research addresses community needs and involves the community in research plan, conduct of study, etc)?**[Guidance](#)

Yes No

11. Study Design and Methodology

- 11.1. 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.**

[Guidance](#)

The Internal Medicine clerkship is including Handoffs training in their curriculum.

Students in the first two rotations of the Internal Medicine clerkship will serve as the pre-intervention group, with the assessments by the residents on their handoff skills serving as their baseline. They will be trained and assessed together with the rest of the class. The scores they receive in the assessment during Intersessions will serve as their post-intervention scores. For the rest of the class, the assessment in Intersessions will serve as their baseline and when they rotate through the Internal Medicine clerkship, the assessment by the residents will serve as their post-intervention scores.

- 11.2. Provide a description of the study population.**

All third year medical students from the class of 2014

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

This screen is required if you indicated the use of Surveys, Questionnaires, or Psychometric Testing (Question 9.2.)

- 21.2. Attach copies of all measures/instruments that will be used for this study.**

[Guidance](#)

| name | Version | Modified |
|---|---------|-------------------|
| Handoff CEX History | 0.01 | 7/30/2012 3:04 PM |

22. Special Subject Populations

- 22.1. Indicate any vulnerable subject populations you intend or expect to enroll in the research: (check all that apply)**

[Guidance](#)

Normal Volunteers

Employees or Students

Adults not Competent to Consent (or likely to lose the capacity to consent during the study)

Non-English Speaking Populations

Minors (subjects under 18 years of age)

Pregnant Women / Human Fetuses

Neonates (infants under 30 days old)

Prisoners/Detainees

Wards

None of the above

24. Subject Recruitment and Informed Consent

24.1. Recruitment Tools that will be used by the local site (check a box only if your site will control the use or distribution of the recruitment tool): (check ALL that apply) *Guidance*

- E-mail/Electronic Mailing List
- Brochure
- Flyers
- Letters
- Newspaper/Magazine Advertisements
- Radio/Television Announcements
- Subject or Participant Pool
- Telephone Scripts
- Verbal (Personal Solicitation)
- Website / Social Media Outlets
- Other
- None of the above

24.1.1. Please specify: *Guidance*
 Part of the educational curriculum

24.2. Attach copies of all recruitment tools that will be used at the local site. (Do not attach any advertising or recruitment materials that are provided by a sponsor that cannot be modified by the local site.) *Guidance*

name Version Modified
 There are no items to display

24.3. Will you be obtaining informed consent, assent, parental permission, or be providing participants with information sheets? *Guidance*
 Yes No

24.4. Attach copies of the informed consent documents(s), information sheets, and any statements of new information/findings or consent addenda (as applicable) that will be used in this study. This set should also contain any assent or parental permission documents that will be used. *Guidance*

name Version Modified
[Handoffs_Info Sheet_8.20.12_clean.docx](#) | [History](#) 0.02 8/20/2012 11:31 AM

24.5. Personnel from section 2.1 obtaining consent/permission/assent: *Guidance*

| Last Name | First Name | Organization | Study Role | Certifications | Obtain Consent |
|-----------|------------|--|------------------------|----------------|----------------|
| | | MEDICAL EDUCATION | Principal Investigator | | yes |
| | | GERIATRIC, HOSPITAL, PALLIATIVE, & GENERAL INTERNAL MEDICINE | Co-Investigator | | yes |
| | | GERIATRIC, HOSPITAL, PALLIATIVE, & GENERAL INTERNAL MEDICINE | Co-Investigator | | yes |
| | | GERIATRIC, HOSPITAL, PALLIATIVE, & | Co- | | |

| | | | |
|--|--|-----------------|-----|
| | GENERAL INTERNAL MEDICINE | Investigator | yes |
| | GERIATRIC, HOSPITAL, PALLIATIVE, & GENERAL INTERNAL MEDICINE | Co-Investigator | yes |

If the above list is incomplete or incorrect, please navigate to item 2.1 and make your changes there.

24.6. Describe the circumstances and location of the process of recruitment/consent: (check all that apply) *Guidance*

- In a private area
- In a waiting room, open ward, group, or public setting
- Online, over the telephone, by mail, or via fax
- Other

24.6.1. If Other, please specify: *Guidance*

During orientation for the handoffs workshop during Intersessions, we will be racing the verbal consent form to the students.

24.7. Describe all measures that will be taken during the recruitment and consent process to ensure that individuals have adequate time to consider participation and to safeguard against potential coercion and undue influence: (check all that apply) *Guidance*

- They will not be forced, threatened or coerced in any way to participate in this research, and no undue influence or other form of constraint will be used to recruit individuals to participate in this research or to retain currently enrolled subjects. (Note: "Coercion" is the use or threat of the use of force to gain compliance. "Undue influence" is when an individual who is in a position of authority (e.g., physician, teacher, employer) exerts inappropriate or excessive manipulation to gain power and compliance over a vulnerable individual (potential research subject). "Constraint" means force, obligation or pressure.)
- They will not be punished or denied something which they would normally receive (e.g., threatening to withdraw health services to which an individual would otherwise be entitled) if they choose not to participate in this research or choose to withdraw early from participation.
- They will be given an adequate amount of time to consider participation in the study relative to the initiation of study procedures.
- The information presented to individuals during recruitment and consent will reflect that provided in the informed consent document/informed consent script.
- The recruitment and consent process will not promise them a certainty of cure or benefit beyond what is outlined in the informed consent document/informed consent script.
- The recruitment and consent process will take place in an area in which it is possible to maintain privacy and confidentiality.
- They will be given the opportunity to take the informed consent document home in order to discuss participation with their family, friends and/or others before making a definitive decision.
- They will receive payment for their participation, but the amount of payment will be commensurate with the their participation (not an inducement for participation), and receipt of the payment will not be contingent upon the individual's completion of the study. (Note: The specific method, schedule and amount of payment must be outlined in the payment section of the application.)
- Other (explain below)

24.7.1. If Other, please explain: *Guidance*

Students will be informed that their decision to participate will have no influence on their Handoffs scores, and they may decline participation or withdraw from the study at any time. Should they decide to participate, their data will be de-identified and securely stored. No individual identifying information will be included in any reports or publications that result from the study.

25. Financial Obligation and Compensation

25.1. Financial Obligation: Describe who pays for financial obligations that the subject may incur as a result of participating in the study. *Guidance*

All costs are paid by the sponsor or funding agency.

Research costs are paid by the sponsor or funding agency. Other costs are the responsibility of the participants and/or their healthcare plans.

All costs are the responsibility of the participants and/or their healthcare plans.

Study drug will be provided but not the costs of preparation or administration, which will be the responsibility of the participants and/or their healthcare plans.

All costs are covered by the department/division.

There are no financial obligations related to participation.

Other

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. Describe the proposed method of timing and disbursement. If children are involved, please specifically address how the compensation will be distributed to children. *Guidance*

None

iStar ID: HS- -

Application Version Date: 8/5/2012
Version: 1. 0

26. Participant Privacy and Data Confidentiality

26.1. *Guidance*

Privacy Protections: Privacy is a participant’s ability to control how other people see, touch, or obtain information about his/her self. Violations of privacy can involve circumstances such as being photographed or videotaped without consent, being asked personal questions in a public setting, being seen without clothing, being observed while conducting personal behavior, or disclosing information about abortions, HIV status, or illegal drug use.

Select the provisions to protect the privacy of the individual during screening, consenting, and conduct of the research: (check ALL that apply)

Research procedures will be conducted in person in a private setting.

Data will be captured and reviewed in a private setting.

Only authorized research study personnel will be present during research related activities.

The collection of information about participants is limited to the amount necessary to achieve aims of the research.

Participants will not be approached in a setting or location that may constitute an invasion of privacy or could potentially stigmatize them.

Other (specify below)

26.1.1. Please specify: *Guidance*

Data will be collected as part of Intersessions handoffs skills assessment. Student names will not be included in the reports - they will be identified by an ID number only

26.2. *Guidance*

Confidentiality Precautions: Confidentiality is an extension of the concept of privacy; it refers to the participant’s understanding of, and agreement to, the ways identifiable information will be collected, stored, and shared. Identifiable information can be printed information, electronic information, or visual information such as photographs.

How will the research data/specimens be recorded? (check ALL that apply)

Data and/or specimens will be directly labeled with personal identifying information. (Identifiable)

Data and/or specimens will be labeled with a code that the research team can link to personal identifying information. (Coded)

Data and/or specimens will not be labeled with any personal identifying information, nor with a code that the research team can link to personal identifying information. (Anonymous)

Other (explain below)

26.3. How will the research data and/or specimens be protected against inappropriate use or disclosure? (check ALL that apply)

Guidance

Locked office

Locked storage unit

Restricted access to authorized study personnel

Secure computer/laptop

Individual ID plus password protection

Encryption of digital data

Network Restrictions

Security software (firewall, antivirus, anti-intrusion) is installed and regularly updated in all servers, workstations, laptops, and other devices used in the study

Restrictions on copying study related materials

Destruction of source data immediately after data collection (to preserve anonymity of participants)

Audio and/or video recordings will be transcribed and then will be destroyed

Audio and/or video recordings will be modified to eliminate the possibility that study participants could be identified

Photos or images will be modified to eliminate the possibility that study participants could be identified

Study personnel will sign statements agreeing to protect security and confidentiality of study information

Access rights are terminated when authorized study personnel leave the study

Not Applicable

Other (specify below)

26.4. Will coded or identified data and/or specimens be released to a third party (external to USC/CHLA)?

Guidance

Yes **No**

26.5. What will happen to the research data and/or specimens at the conclusion of the study? (check ALL that apply)

Guidance

Direct identifiers and/or the key to the codes will be destroyed upon completion of the research (all data/specimens will be stripped of identifying information and/or the key to codes destroyed, paper documents shredded, electronic files purged, electronic media securely erased).

Retained for study record keeping purposes per institutional policy.

Retained by the investigator for future research use.

Retained for future research use (create data or tissue repository/bank).

Restricted use data will be destroyed or returned to the source.

No direct or indirect identifiers are being collected. The anonymous data and/or specimens will be retained at the discretion of the investigator.

This research is a clinical trial conducted under FDA regulations. Direct identifiers and/or the key to the codes will be destroyed as directed by the sponsor (IND/IDE holder) in accordance with FDA regulations.

Other (specify below)

iStar ID: HS- -

Application Version Date: 8/5/2012

Version: 1. 0

28. Risk/Benefit Analysis - Potential Benefits and Alternatives

28.4. Risks in relation to benefits:

[Guidance](#)

The potential benefits to the research participants justify exposure of the participants to the risks.

The potential benefits to humanity justify exposure of the participants to the risks.

Other (specify below)

iStar ID: HS- -

Application Version Date: 8/5/2012

Version: 1. 0

35. Is the HIPAA Privacy Rule Applicable?

35.1.

[Guidance](#)

Do you intend to access, review, collect, use or disclose protected health information (PHI) in your research? Answer yes if you intend to do any of the following:

- Look at medical records (paper or electronic) to identify potential research participants
- Look at clinic logs to identify potential research participants
- Record demographic information obtained from medical records (paper or electronic)
- Record health information obtained from medical records (paper or electronic)
- Obtain information from laboratory reports, pathology reports, radiology reports or images, or other reports from medical or mental health testing and treatment
- Obtain information from medical billing records
- Record or use medical record numbers or other information that could be used to identify an individual (review the list of HIPAA identifiers below)

Yes **No**

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

[Guidance](#)

Yes **No**

- 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*

- 35.3. Are you going to record only the personal identifiers marked with an asterisk (*)? If so, you may be able to obtain or use such health information from a healthcare provider for research purposes without an authorization. Under the HIPAA Privacy Rule, this data constitutes a “limited data set”. If you are creating or obtaining a limited data set, you must complete a Data Use Agreement. Attach a copy of the signed Data Use Agreement below.**

[Guidance](#)

| name | Version | Modified |
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There are no items to display

[USC Template Data Use Agreement](#)

iStar ID: HS- - -

Application Version Date: 8/5/2012

Version: 1. 0

39. Conflict Of Interest Information

- 39.1.** Does the **Investigator, Research Personnel** or **Close Relation** have an **ownership interest** (any equity in a non-publicly traded company, regardless of value, or stock, stock options or warrants, in a publicly traded company of \$5,000 or more excluding mutual funds) in:

- The sponsor of the research; or
- An entity that has a license or is negotiating a license to the intellectual property (e.g., patents) developed from this research; or
- An entity that has an economic interest in the research.

[Guidance](#)

Yes **No**

39.2.

Does the **Investigator, Research Personnel** or **Close Relation** have a **management role** (such as director, officer, scientific, or technical appointment), or any other role with significant decision-making authority, in:

- The sponsor of the research; or
- An entity that has a license or is negotiating a license to the intellectual property (e.g., patents) developed from this research; or
- An entity that has an economic interest in the research.

[Guidance](#)

Yes **No**

- 39.3.** Did the **Investigator, Research Personnel** or **Close Relation** receive in the last twelve months or does the Investigator, Research Personnel or Close Relation expect to receive in the next twelve months any payments for **services** (such as speakers fees, payments for consulting, participation on an advisory board, or assistance with protocol design) from

- The sponsor of the research; or
- An entity that has a license or is negotiating a license to the intellectual property (e.g., patents) developed from this research; or
- An entity that has an economic interest in the research.

[Guidance](#)

This does not include salary for services as an investigator/staff on the research study. Also excluded are payments from the federal government for services performed (i.e. peer review, study section participation, seminars, lectures, or service on advisory committees).

Yes **No**

- 39.4.** Does the **Investigator, Research Personnel** or **Close Relation** personally receive **intellectual property rights** (e.g. patents, copyrights, or royalties) directly from:

- The sponsor of the research; or
- An entity that has a license or is negotiating a license to the intellectual property (e.g., patents) developed from this research; or

- An entity that has an economic interest in the research.

This does not include royalties paid directly from USC

Yes No

- 39.5. To the investigator's knowledge, does the Institution have financial and or intellectual property interests in the sponsor or the products used in this project?** *An institutional conflict may occur when a financial interest of the University has the potential to bias the outcome of research conducted by its employees or students or to create an unacceptable risk to human subjects.*

Yes No

iStar ID: HS- - -

Application Version Date: 8/5/2012

Version: 1. 0

40. Additional Supporting Documents

- 40.1. Attach any other documents that have not been specifically requested in previous questions, but are needed for IRB review.** [Guidance](#)

| 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 include it below.** [Guidance](#)
Please note, this section should not be used instead of the standard application items.

iStar ID: HS- - -

Application Version Date: 8/5/2012

Version: 1. 0

99. Instructions for Submission

You have reached the end of the application. When you are sure of the content, the following steps may be taken to submit your application for review.

1. Click the "**Finish**" button on the top or bottom application navigator bar to return to the workspace.
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-Investigators with instructions for reviewing and submitting the application.
4. **All listed Co-Investigators (indicated in item 2.1.) must use the "Agree to Participate" activity and answer yes.**
5. Once all the Co-Investigators have agreed to participate, the **Principal Investigator** (indicated in item 2.1.) can submit the application 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 application is submitted. The state indicator in the top left of the workspace will no longer display Pre Submission.
8. The PI and Study Contact Person will receive an email confirming the application has been submitted.