USC Children's Hospital Los Angeles LAC+USC Healthcare Network iStar

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NOT HUMAN SUBJECTS RESEARCH(NHSR) APPLICATION (USC ONLY)

This application is used to determine if a project meets the regulatory definition of human subjects and/or research. When the IRB determines a project does NOT meet the regulatory definitions, a determination letter will be generated which states IRB approval is not required. If the IRB determines the project DOES meet the regulatory definitions, a "New Study" application must be submitted for IRB approval. *Guidance*

DO NOT use this application for:

- Projects involving FDA regulated products
- Projects that meet the regulatory definition of human subjects research
- Projects that involve only Coded Data/Specimens

These projects will not be reviewed through this application, and need to be submitted as a "New Study" application in iStar.

To proceed, click the Continue button. Otherwise, click the Back button.

I. Project Information:

Guidance

* **Specify a title for this project:** Compliance with anti-tobacco legislation in Cape Town, South Africa

Guidance

* **Please indicate which IRB you are requesting review from:**
University Park IRB (UPC)

* **Is the Principal Investigator a student, resident, fellow, other trainee, or visiting scholar?** *Guidance*
(•) **Yes** ( ) No

Please designate a Faculty Advisor: *Guidance*
[redacted] HS Certification: Current (4/22/2015)

II. Does Project Meet Regulatory Definitions

"Human Subjects"

1. * **Does the study involve interaction or intervention with live human subjects?** *Guidance*
   No
   (Though interaction or intervention may have occurred previously, specimen(s)/data/information were collected from live subjects. Cadavers, autopsy specimens or specimens/information from subjects now deceased is not human subjects).

2. * **Is the information/data/specimen(s) obtained about the subjects?** *Guidance*
   No
   (i.e. does the research data sought pertain to the individual subject, or is the data sought merely

provided by the subject. For example, a quality improvement project for an education program may ask teachers to provide information on how to improve the program. This information is not "about" the teacher but information provided by the teacher about the education program.).

3. * **Is the collected information/data/specimen(s) private information?** *Guidance*
   No
   (Private information is that which allows identity of individual to be associated with the information/specimen/data)

"Research"

1. * **Is your study designed to produce generalizable knowledge?** *Guidance*
   Yes
   (Generalizeable knowledge is when the intended use of the research findings can be applied to populations or situations beyond the studied unit.)

2. * **Is the study systematic?** *Guidance*
   Yes
   (Follows step by step procedures organized according to interrelated ideas or principles evidenced by a research plan and objectives.)

III. Study Description

Additional information (to determine whether or not your project qualifies as human subjects research:

1. * **Provide a brief (1 to 2 paragraph) description of the study in LAY LANGUAGE. This should not be a scientific abstract.** *Guidance*
   I will travel to Cape Town South, Africa to examine compliance with anti tobacco legislation in bars around the city. I will look to see whether smoking is currently occurring or whether there is evidence of previous smoking such as cigarette butts. I will also look to see whether the bar is encouraging of smoking through things like selling cigarettes or providing ashtrays.

2. * **Describe the subject population being studied.** *Guidance*
   Various bars throughout the city.

3. * **Provide a brief description of the design and methodology of the study.** *Guidance*
   I will have a simple yes/no checklist of items to check off in each bar as described above. I will not be interacting with patrons or bar staff at all.

4. **Submit the survey or questions that the subjects will be asked (if applicable).** *Guidance*

name	Version	Modified

There are no items to display