



Date: Friday, February 28, 2014 2:43:01 PM

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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:

* Specify a title for this project: Documenting Spirituality Infusion in Wellness Centers_IRB Information Request -

[Guidance](#)

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

[Guidance](#)

* Is the Principal Investigator a student, resident, fellow, other trainee, or visiting scholar?

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Yes No

II. Does Project Meet Regulatory Definitions

"Human Subjects"

1. * Does the study involve interaction or intervention with live human subjects?

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Yes

(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*
 No
 (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*
 The California Mental Health Initiative report on spirituality (2010) indicates that 80% of consumers and families surveyed support the integration of spirituality into mental health services. Two thirds of the respondents agreed that the public mental health system in California should do more to support clients and families in utilizing their spirituality as a wellness and recovery resource. However, we do not know how these agencies are addressing this need. The primary focus of this project is to document the wellness center programs (i.e., mental health recovery programs) that offer various spirituality-oriented opportunities for consumers with mental illness. We want to illustrate the range of activities a mental health agency might consider to integrate spirituality into consumer recovery plans.

 We hope to illustrate the variety of potential avenues for meeting the spirituality needs (by publishing our findings (de-identified) in a journal accessible to agency staff and administrators). We also will provide the list of current spirituality related activities to the LADMH Clergy Advisory Committee to inform their ongoing mission. This project may also provide information to support a future grant application regarding spirituality interventions in wellness centers.
2. *** Describe the subject population being studied.** *Guidance*
 The population is the list of DMH direct service and contracted wellness and client run agencies (publically available) that serve people with mental illness with a goal toward increasing their quality of life and independent functioning. The clients served at the agencies are not being studied. The staff at these agencies are not subjects and will not be asked personal questions.
3. *** Provide a brief description of the design and methodology of the study.** *Guidance*
 This is exploratory and descriptive information gathering. Project assistants will call or visit each site on the list of agencies provided by the Department of Mental Health. During site visitations, a project assistant will examine bulletin boards, fliers, calendars, and speak with front desk, clinical, and/or administrative personnel if necessary to ascertain the presence of spirituality-related activities within the current year. Total interaction time with staff is expected to be brief as only basic information is being sought. The analyses will include descriptions such as categorizing activities and providing counts of these categories and may discuss findings related to the questions attached in the next section. The agency names are not expected to be used in academic publication of the findings.

Agencies (and, if they agree, potential contact personnel facilitating the activity) will be identified in the resource directory provided to LADMH staff as this is necessary for the intended purpose. The information collected is publically available. This project is not sponsored or funded by LADMH and is not being conducted at their request.

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

Guidance

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Sample questions for Wellness Project.doc	0.01	7/17/2012 1:00 AM