

A Non-Profit, Public Policy Research Organization

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315 West Ninth Street, Suite 1209

Los Angeles, CA 90015



February 20, 2009

Ms. Yolanda Arias, Chair
Institutional Review Board
Economic Roundtable
315 West Ninth Street, Suite 1209
Los Angeles, CA 90015

Dear Ms. Arias:

I am writing to request approval of the procedures for protection of human subjects in a study of the cost for public services to mentally ill homeless individuals before and after they are housed. The attached application explains this project and requests a full IRB review because the project entails working with identifiable medical data for a vulnerable population.

No funds will be disbursed for research activities until the IRB has approved this project. We propose to submit reports on protection of human subjects, data security and project design to the IRB annually or more often if requested. Should there be any study-related events that endanger human subjects or compromise data security, these events will be reported immediately to the IRB as well as any organizations whose data is affected.

The attachments include:

1. Request for IRB Approval
2. Project flow chart
3. Informed consent document prepared and approved by County Counsel
4. Funding contract with the Los Angeles Homeless Services Authority

I am available to answer any questions you may have and to provide any further information that may be needed. Thank you for your consideration of this request.

Sincerely,

A handwritten signature in blue ink, appearing to read "Daniel Flaming".

Daniel Flaming, Ph.D.
Principal Researcher

**Economic Roundtable
Institutional Review
Board (IRB)**

Request for IRB Approval

Must be completed for all projects
involving human subjects

315 W. 9th St. Suite 1209
Los Angeles, CA 90015
Phone: 213-892-8104
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Follow the format shown below to provide requested information

TITLE	<i>Homeless Cost Avoidance Study</i>
PRINCIPAL INVESTIGATOR	<i>Daniel Flaming, President, Economic Roundtable</i>
FUNDING	<i>Los Angeles Homeless Services Authority.</i>
LEVEL OF REVIEW	<p>Indicate the level of IRB review you are requesting for this project:</p> <p><input type="checkbox"/> Level I: Exempt Research and Review (no foreseeable risk) Level II: Expedited Research and Review (minimal risk) <input checked="" type="checkbox"/> Level III: Research and Full Board Review (more than minimal risk or protected subjects)</p> <p>The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.</p>
SCOPE OF WORK	<p>Layout the project tasks, detailing work processes for this project:</p> <p><i>The project team covered by this research protocol includes Economic Roundtable staff and consultants, the Los Angeles County Chief Executive Office (a subcontractor for this project), participating County departments, and Skid Row Collaborative member agencies.</i></p> <p><i>Purpose of Study:</i></p> <p><i>To determine the cost of public services, particularly services provided by Los Angeles County, to different cohorts of homeless individuals (differentiated by characteristics such as type and severity of disability, education, age, gender, and work history) before and after they are housed. This information will be analyzed to identify those cohorts for which net public costs are reduced by providing housing (often in the form of supportive housing).</i></p> <p><i>Study Population:</i></p> <p><i>Identifiable Data for Pre- and Post-housing Costs:</i></p> <ol style="list-style-type: none"> <i>a. 110 participants in the Skid Row Collaborative Project, made up primarily of mentally ill homeless individuals – identifiable records of individuals out of this population who provide informed consents will be used in the study.</i> <i>b. 600 formerly homeless individuals who reside in subsidized and supportive housing in Skid Row, ranging from mentally ill and dually diagnosed to economically disadvantaged – identifiable records of individuals out of this population who provide informed consent will be used in the study.</i>

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- c. *50 participants in Project 50, made up of mentally ill and vulnerable homeless residents who have received supportive housing – identifiable records of individuals out of this population who provide informed consent will be used in the study.*

Additional De-identified Data for Pre-housing Costs

- d. *De-identified records from the General Relief Adult Linkage Project of individuals who have similar attributes to individuals in identified homeless cohorts will be used in this study to expand the number of records providing data about costs before housing is provided.*

Steps that will be carried out in this project are as follows:

1. *Obtain informed consent from homeless and previously homeless individuals whose data will be used in identifiable form in this study. The informed consent document has been prepared by Los Angeles County Counsel to address the requirements for waiving confidentiality under laws regulating the county departments of Health, Public Health, Mental Health, Public Social Services, Probation, and Sheriff, and in conformance with National Institute of Health guidelines. The Roundtable will:*
 - a. *Use the informed consent form prepared by County Counsel (copy attached) to inform prospective project participants of the objectives of the research, the procedures to be followed, the risks and potential benefits, and enable them to freely consent or decline to participate.*
 - b. *Provide the informed consent document to the Skid Row Consortium and assist the Consortium in requesting waivers from project participants.*
 2. *Gather basic data from consenting research subjects and from electronic client records maintained by the Skid Row Consortium.*
 - a. *The Economic Roundtable will offer food (pizza) to participants as part of the presentation meeting where the project is discussed and one-on-one discussions are held about participating in the project. Case management staff from the Skid Row Housing Trust will be present to support potential project participants in these discussions. In collaboration with the Skid Row Consortium and case managers, the research team will make presentations summarizing the study and the informed consent document to prospective participants. The research team and case managers will meet one-on-one with individuals who have difficulty understanding the informed consent document, have questions or desire additional information. Individuals who decide to sign the informed consent document and participate in the project will be asked to provide basic information about themselves that may be missing in other records, including: veteran's status, education, work history, duration of homelessness, incarceration history, history and type of substance abuse problems, history and type of disabilities, and use of private hospitals.*
 - b. *Those participating in these discussions will receive a \$10 gift card for a restaurant, grocery store, bookstore, Starbucks, or telephone*
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calling card as compensation for the time spent in the interview, whether or not they agree to sign the informed consent document.

3. *CEO-SIB Data Linkage I: The Economic Roundtable's dataset for ~300 homeless individuals who signed informed consent forms will be given to the CEO-SIB Research and Evaluation Unit in order to carry out a series of data linkages:*
 - a. *The CEO-SIB Research and Evaluation Unit will carry out a multi-departmental data linkage project to increase the information on the ~300 research subjects by integrating client data from each of the following County Departments: Public Social Services, Health, Public Health, Mental Health, Probation and Sherriff.*
 - b. *This data linkage will be done by loading identifying information for the ~300 research subjects who have signed informed consent forms into a portable desktop computer (on a dolly), which will be transported by Los Angeles County CEO-SIB staff to the six county departments. At each department, CEO-SIB staff will connect their portable desktop computer to the department's client database system, and run software that carries out probabilistic matching between the ~300 research subjects in the Economic Roundtable's dataset and that department's much larger client database. For all record matches, based upon name, sex, date of birth, social security number and other identifying information, CEO-SIB staff will obtain case history information regarding service usage types, amounts and time periods. CEO-SIB staff will then disconnect their mobile computer and move on to the next department for carrying out a data linkage, without leaving any information on the research subjects on the department's client database system.*
 - c. *After linkages are carried out with all six county departments, the CEO-SIB staff will return the expanded file of ~300 research subjects (now with expanded service usage information appended) to the Economic Roundtable.*
4. *The Economic Roundtable and its statistical consultant, Gerald Sumner, will analyze the expanded data and identify variables to be used for defining distinct and meaningful subgroups within the project population of mentally ill homeless individuals. Depending on the availability of data, possible variables include:*
 - a. *Age and Gender*
 - b. *Ethnicity*
 - c. *Education*
 - d. *Work history*
 - e. *Social Security Number*
 - f. *Arrests by law enforcement, time spent in jail*
 - g. *Disability status*
 - h. *Emergency Transport, EMS service and emergency room use*
 - i. *Inpatient medical and psychiatric services*
 - j. *Outpatient mental health treatment*
 - k. *Substance abuse treatment (including emergency detoxification)*
 - l. *Duration of homelessness*

5. *CEO-SIB Data Linkage II: After defining distinct and meaningful subgroups within the project population of ~300 mentally ill homeless individuals, the Economic Roundtable will return the dataset to the CEO-SIB Research and Evaluation Unit.*
 - a. *CEO-SIB will use probabilistic record matching software to create de-identified comparison group cohorts similar to this project's participant cohorts. These larger comparison groups are General Relief participants in CEO-SIB's existing Adult Linkages Project database. (The County of Los Angeles serves roughly 65,000 participants on a given day in its General Relief (GR) program. In a given year, 120,000 unique participants enter the GR program, and more than 200,000 participants enter the program over three years. A substantial proportion of General Relief participants receive multiple services from separate county departments. More than one-third of the GR population is homeless.)*
 - b. *CEO-SIB's de-identified data from the Adult Linkage Project dataset already includes relevant service usage and cost data from multiple county departments (Health, Public Health, Mental Health, and Sheriff's Custody Division). This comparison group data will expand the amount of pre-housing cost data for cohorts that are similar to cohorts of homeless individuals that have signed informed consent forms.*
6. *Cost Factors: Determine cost per typical unit of service. The Roundtable and CEO-SIB Research and Evaluation Unit will work with county departments to delineate service costs by unit and by person.*
 - a. *The CEO-SIB Research and Evaluation Unit will develop life course, or age progression, cohorts of individuals of differing ages who share similar underlying diagnoses and attributes. This will be used to chart service usage trends associated with different life stages of subpopulations of chronically homeless individuals.*
 - b. *The Roundtable and CEO-SIB will determine the service delivery and cost history of subpopulations in the overall General Relief population that are closely similar to subgroups within the case study population.*
7. *ERT Data Analysis: The Roundtable will produce cost avoidance estimates for homeless individuals who received housing and in most cases supportive services:*
 - a. *Cost without housing*
 - b. *Actual cost*
 - c. *Cost avoidance measured in dollars*
 - d. *Cost avoidance measured in percent*
8. *The Economic Roundtable and CEO-SIB Research and Evaluation Unit will prepare and submit the project report, followed by briefings of stakeholders and policy makers.*

The attached flow chart shows the steps to be undertaken in this project.

RISK LEVEL

Identify the level of risk that this project will create for human subjects as defined in Section VI of the Economic Roundtable policy on protection of human subjects:

Less than minimal risk

Minimal Risk

Greater than minimal risk but with direct benefit to subjects

Greater than minimal risk but no direct benefit to subjects

Briefly summarize the facts that support the risk level you have identified. If the study involves greater than minimal risk, identify all direct benefits to the human subjects as well as any additional safeguards.

This is a Level III project, involving some protected subjects who may need assistance in understanding the informed consent document due to cognitive impairment (mental illness). The informed consent document is lengthy because it waives confidentiality of information provided by multiple county departments that have multiple legal constraints concerning confidentiality. Aside from the pizza and gift card, no direct benefits are likely to accrue to human subjects, although it is possible that project findings will increase the housing security of these subjects. It is also possible that the findings of this study will benefit other chronically homeless residents through expanded access to supportive and affordable housing and improved service delivery.

Although it is recommended that the IRB review this research project as "Level III" because some participants have varying forms of mental illness and therefore may need assistance in comprehending the detailed informed consent form, there is minimal risk to the human subjects. Information collected from interview participants will be safeguarded in the Economic Roundtable and CEO-SIB Research and Evaluation Unit offices, and will not be shared with any outside organizations, except in de-identified form. De-identified data records cannot be linked with specific individuals due to having names, birth dates and other information removed.

For the purpose of creating data linkages to a larger database of DPSS General Relief clients, the Economic Roundtable will deliver identified participant data to the LA County Chief Executive Office, Service Integration Branch (CEO-SIB), a subcontractor of the Economic Roundtable for this project. CEO-SIB will link the Economic Roundtable's records with client data from each of the following County Departments: Public Social Services, Health, Public Health, Mental Health, Probation, and Sherriff. CEO-SIB will conduct this data linkage work with a portable computer that does not share any information with the participating departments. CEO-SIB will also link the participant records to their own larger database of DPSS General Relief clients (the "Adult Linkage Project"), and will operate under the Economic Roundtable's policy for protections of human subjects, as per paragraph #6 of ERT's subcontract with CEO-SIB. This second linkage task will produce a larger comparison group of chronically homeless, mentally ill Skid Row residents that is closely matched to the project group and can be studied by the research team.

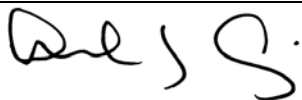
The remainder of this study poses no greater than minimal risk to human

	<p><i>subjects, because the analysis will be conducted under the Economic Roundtable's policy for protections of human subjects, by staff of the Economic Roundtable and CEO-SIB. After the initial interview with each human subject, there will be no direct interaction with the human subjects being studied. Project data analysis will not detail service usage and pre-/post-housing costs of individuals, but instead will group them into larger cohorts within the project population of mentally ill homeless individuals and General Relief clients. The final report and briefings to policy makers likewise will present only de-identified data, which are aggregated into summary tables of larger groups and cohorts.</i></p>
<p>HEALTH INFORMATION</p>	<p>Identifiable Health Information:</p> <p>(1) Do you need to access or use patient/subject identifiable health information (e.g. medical records, mental health information, lab reports, x-rays, tissue samples) for this research study? YES</p> <p>If yes, go to question (2). If no, you do not need to satisfy HIPAA education requirement.</p> <p>(2) Have all investigators and individuals authorized to obtain identifiable health information in this study completed an education program regarding federal (HIPAA) and state privacy requirements? YES, certificates attached.</p> <p>If yes, Please provide certificates of completion and go to question (3). If no, Your study will not be reviewed until all of the requested information has been provided and your application may be returned to you for completion.</p> <p>(3) Describe the specific procedures and safeguards that will be used to de-identify health information of human subjects in this project</p> <ol style="list-style-type: none"> 1. <i>Access to data will be limited only to those with a need to know.</i> <i>Only authorized researchers will be allowed access to confidential data and only for approved research activities. Only individuals carrying out approved research that requires them to use confidential data will be considered for authorization to access confidential data. As part of the authorization process, individuals who are candidates for working with confidential data will be instructed regarding the constraints for handling confidential data: (a) The confidential nature of the information, and (b) the sanctions against unauthorized use or disclosures found in the law as well as Economic Roundtable policies. To become authorized to use confidential data researchers must be approved by a corporate officer of the Economic Roundtable as well as by the agency providing the data (if required by that agency), and must sign all confidentiality agreements required for the project for which the data was obtained.</i> 2. <i>Computer access will be protected through the use of passwords and other protections.</i> <i>Computers that store confidential data will be password protected by alpha-numeric passwords that are unique to each computer and known only by the assigned, authorized computer user and the data manager.</i> 3. <i>Research records will be protected through the use of locked cabinets in locked rooms, storage of identifiers separate from analysis data, and other methods.</i>

	<p><i>Computer media used to store confidential data (diskette, CD-ROM, tape back-up) will be kept secure in a locked cabinet in the Economic Roundtable office, accessible only by the President and the data manager. Any identifier files will be stored in a different locked cabinet. Confidential data will not used or stored on wireless devices. This prohibition includes notebook computers and Personal Digital Assistants (PDAs). The Economic Roundtable office in which secure data is stored is located in a building with 24-hour security.</i></p> <p>4. <i>Data will not be reused or provided to any persons outside of the research team.</i></p> <p><i>Data will be accessible only on a need-to-know basis by approved members of the research team. Confidential data will not be provided to any person outside the team.</i></p> <p>5. <i>Information will not be published that could possibly be used to identify an individual subject.</i></p> <p><i>In publishing information, no individual whose identity was obtained through confidential sources will be identified. Geographic identities will be specified only in areas that include five or more individuals in order to protect confidentiality. Cells with fifteen or fewer subjects will be analyzed to determine if there is any risk of identifying subjects, and if any risk is identified the cells are rolled up with other cells to a more aggregate level. All work products containing any material derived from confidential data will be reviewed to ensure that they comply fully with these policies as well as the terms of the applicable confidentiality agreement(s) prior to distribution or public release.</i></p> <p>6. <i>Confidential data will not be stored in laptop computers.</i></p> <p><i>Confidential data will not be used or stored in laptop computers. Confidential data will be loaded only onto approved, stand-alone computers</i></p>
<p>INFORMED CONSENT</p>	<p>Indicate the type of informed consent that will be utilized in the study. If a waiver of written informed consent is requested a script of the proposed verbal informed consent should be provided. If a waiver of informed consent is requested please make certain the protocol detail justifies this request.</p> <p><i>A written informed consent will be utilized in this study; no verbal waivers of written informed consent will be used. Informed consent will be obtained at the outset of the interview process. The research team will present information to small groups of potential participants in the buildings where they reside. Their caseworkers will be present. The information will include explanations of the study and the informed consent form.</i></p> <p><i>The informed consent document, which is approved by the legal counsels of all participating county departments (listed below), is submitted as an attachment to this request for approval. It waives data confidentiality for:</i></p> <ul style="list-style-type: none"> <i>• Skid Row Collaborative housing and social service providers</i> <i>• Los Angeles County Department of Public Social Services.</i>

	<ul style="list-style-type: none"> • <i>Los Angeles County Department of Health</i> • <i>Los Angeles County Department of Public Health</i> • <i>Los Angeles County Department of Mental Health</i> • <i>Los Angeles County Department of Sheriff</i> • <i>Los Angeles County Department of Probation</i> • <i>Los Angeles Homeless Services Authority</i> • <i>Veteran's Administration</i>
<p>LOCATION</p>	<p>Indicate the location where the human subjects involvement will occur.</p> <p><i>Contact with homeless individuals who are prospective project participants will take place in the common areas of their buildings. The list of buildings starts with those operated by the Skid Row Housing Trust, and will include:</i></p> <ul style="list-style-type: none"> • <i>Rainbow Apartments, 643 S. San Pedro Street, Los Angeles, CA 90014</i> • <i>The St. George Hotel, 115 E. 3rd Street, Los Angeles, CA 90013</i> • <i>The Simone, 520 San Julian St, Los Angeles, CA 90013</i> <p><i>In order to maximize the size of the study sample, the Economic Roundtable may also seek access to homeless individuals housed by other service providers.</i></p> <p><i>All confidential data for project participants will be kept at the two offices of the project team:</i></p> <p style="padding-left: 40px;"><i>Economic Roundtable 315 West Ninth Street, Suite 1209 Los Angeles, California 90015.</i></p> <p style="padding-left: 40px;"><i>Research and Evaluation Services Chief Executive Office, Service Integration Branch 222 S. Hill Street, Los Angeles, CA 90012</i></p> <p><i>No confidential data will leave these offices. All data will be managed in conformance with ERT's data security policy.</i></p>
<p>SUBJECTS</p>	<p>Carefully indicate the characteristics of the human subjects that will be involved in the project. When special populations are included or when some or all of the subjects are likely to be vulnerable to coercion or undue influence, indicated what additional safeguards have been included in the study to protect the rights and welfare of these subjects.</p> <p><i>The population being studied is homeless individuals in downtown Los Angeles. Many of these individuals are mentally ill and/or substance abusers. The research team is seeking to produce estimates of the cost of leaving chronically homeless individuals on the street (absorbed by the LA County Departments of Health, Public Health and Mental Health, Public Social Services, and Sheriff's Custody Division), and the costs avoided by providing housing and supportive services.</i></p> <p><i>Data obtained about these individuals will include background information collected following signing of the informed consent document, information</i></p>

	<p><i>collected by housing providers, and client records from the six county departments. This information from county departments, particularly health and mental health, departments is the most sensitive and has the greatest potential to cause embarrassment to project participants.</i></p> <p><i>Disclosure of information assembled for this study would likely cause embarrassment and it is remotely possible that it could compromise entitlement to services or public assistance. It is also remotely possible that client records will include information about substance abuse or anti-social behavior that could lead to criminal prosecution. Safeguards that will be used to protect this potentially vulnerable population include:</i></p> <p><i>The research team will follow all procedures set forth in the Economic Roundtable's Confidential Data Management Policy and Policy on the Protection of Human Subjects, and this Request for IRB approval to ensure that no information that can be linked to specific individuals is seen by anyone other than authorized members of the research team.</i></p>
<p>REPORTING AND MONITORING</p>	<p>Describe the protocols that will be followed for reporting back to the Institutional Review Board and monitoring data security.</p> <p><i>The research team will follow all of the procedures set forth in the Economic Roundtable's Confidential Data Management Policy as well as in agreements with organizations providing confidential data.</i></p> <p><i>Any study-related events that endanger human subjects or adverse data security events will be promptly reported to the IRB as well as any other organizations whose data is affected.</i></p> <p><i>Reports on protection of human subjects, data security and project design will be submitted to the IRB semi-annually or more often if requested.</i></p>
<p>ATTACHMENTS</p>	<p>The following additional documentation supports this request for IRB approval:</p> <ol style="list-style-type: none"> 1) Project flow chart. 2) A transmittal letter stating that no funds will be disbursed to individuals to do research involving human subjects until the proposed project has been reviewed and approved by the IRB. 3) A copy of the funding contract with LAHSA, including the scope of work. 4) The informed consent document prepared and approved by Los Angeles County Counsel. <p>NIH certificates of completion for the principal investigator and research staff are posted on the IRB web site: http://www.economicrt.org/irb/</p>



Signature of Principal Investigator

Daniel Flaming

Print Name of Principal Investigator

February 20, 2009

Date of Signature

President

Title

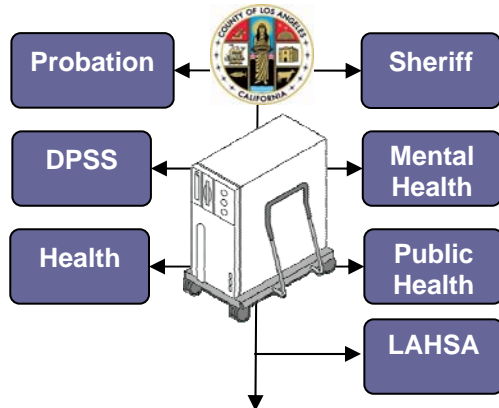


Homeless Cost Avoidance Study

Project Flow Chart



Los Angeles County Departments and Related Agencies:



4. CEO-SIB Data Linkage I
Integrated record of County services for each person pre- and post-housing

3. Participant Data:
Collect data from participants and integrate with Skid Row Collaborative data

2. Informed Consent:
Approximately 300 homeless participants

1. Institutional Review Board:
Review and approve research protocol for protection of human subjects

5. ERT Data Analysis:
Define cohorts among participants

Adult Linkage Project database
of linked records for General Relief

6. CEO-SIB Data Linkage II
Create de-identified comparison group cohorts similar to project participant cohorts to obtain more pre-housing cost data

7. Cost Factors:
Determine cost per typical unit of service

8. ERT Data Analysis:
Determine costs avoided for each cohort

9. Prepare report:
Request review by County departments

10. CEO Report:
Brief Board of Supervisors and stakeholders