Economic Roundtable
Institutional Review
Board (IRB)

Request for IRB Approval

Must be completed for all projects involving human subjects

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Follow the format shown below to provide requested information

TITLE	*Pilot Project to Screen and House High Need Homeless Individuals*
PRINCIPAL INVESTIGATOR	*Daniel Flaming, President, Economic Roundtable*
FUNDING	*Conrad N. Hilton Foundation through the Corporation for Supportive Housing*
LEVEL OF REVIEW	Indicate the level of IRB review you are requesting for this project: ☐ Level I: Exempt Research and Review (no foreseeable risk) Level II: Expedited Research and Review (minimal risk) **X** **Level III: Research and Full Board Review** (more than minimal risk or protected subjects) 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.
SCOPE OF WORK	Layout the project tasks, detailing work processes for this project: *The project team covered by this research protocol includes Economic Roundtable staff and consultants, the Corporation for Supportive Housing, Los Angeles County Sheriff's Department, Los Angeles County Department of Health Services, Los Angeles County Department of Mental Health, and hospitals and clinics that refer patients for screening.* *Purpose of Study:* *The Economic Roundtable and Corporation for Supportive Housing (CSH) are collaborating with housing providers, health providers, jails, and community-based federally qualified health clinics to implement a pilot screening, referral, advocacy, and housing project to move 30 high-cost, high-need homeless individuals into permanent supportive housing. These are individuals with a permanently disabling condition who, in the absence of ongoing case management and permanent affordable housing, are likely to have frequent health or social crises that are resolved in hospitals or jails. Approximately 100 homeless individuals will be screened to identify the 30 individuals with the highest level of need. This project is being carried out in three areas: Downtown Los Angeles, Hollywood, and the West Side.* *Study Population:* *Homeless single adults who are hospital inpatients, hospital emergency room visitors, patients at clinics who have recently been hospital inpatients or emergency room users, or jail inmates with mental disorders or chronic medical conditions.* *Steps that will be carried out in this project are as follows:*

1. *Obtain informed consent from homeless patients in medical facilities and jail inmates. The informed consent document has been prepared by Los Angeles County Counsel to address the requirements for waiving confidentiality under laws regulating the county Department of Health Services and the Sheriff's Department and in conformance with National Institute of Health guidelines. There will be two versions of the attached informed consent document. The first version for use in medical facilities will use the first 5 pages of the attachment; the second version for use in jails will use the first two and the last page of the attachment. 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 pilot project, the procedures to be followed, the risks and potential benefits, and enable them to freely consent or decline to participate.*
    b. *The informed consent document will be translated into Spanish and when a subject whose primary language is Spanish is encountered, a Spanish speaker will explain the informed consent document and conduct the screening interview.*
    c. *When presenting the informed consent document to individuals with mental disabilities the researcher working with the subject will assess his/hers ability to understand the project and the informed consent document. This will be done by discussing the proposed research project with the prospective subject during the consent process, followed by a series of questions to assess the person's understanding of key issues. These questions will include the purpose of the research, foreseeable risks, and anticipated benefits of study participation.*
    d. *Provide the informed consent document to the medical facility or jail to enable them to provide patient or inmate information for the screening process.*
2. *Gather basic data from consenting research subjects through an interview in which the attached Housing Needs Questionnaire is completed and from electronic and paper client records maintained by the hospital, clinic or jail.*
    a. *Meetings will be held with each referring institution to familiarize discharge planning staff with the screening tool and screening procedures, and to develop working plans for carrying out the screening.*
    b. *Economic Roundtable staff will be accompanied by hospital, clinic or jail staff in individual meetings with patients and inmates to summarize the pilot project and the informed consent document to prospective participants. 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: background information about age, sex and place of birth, work history, disabilities, health conditions, use of hospitals and emergency rooms, and incarceration history.*

	3. *Screening Tool: The screening tool was developed using the database created through the Roundtable's recently completed study of public costs when individuals are homeless compared to when they are housed. The results of this study are presented in the Roundtable report, "Where We Sleep," and are available on the Roundtable web site: http://www.economicrt.org. This study showed that the ten percent of homeless single adults with the most acute needs have public costs of over $8,000 per month. The screening tool was developed to identify these individuals. The current version of the tool is described in the Roundtable paper, "Tools for Identifying High-Cost, High-Need Homeless Persons," which can be downloaded from the Roundtable web site along with the screening tool. The screening tool is currently being modified to include medical data, including diagnostic codes, in order to increase its accuracy. The tool is designed to balance the trade-offs between incorrectly including and incorrectly excluding people in the highest need category. The determinations it makes are accurate more than 75 percent of the time. As an added safeguard for ensuring that high need individuals are not incorrectly excluded from receiving special assistance, the screening process will include the option for a clinical over-ride of the screening results by health care professionals.* 4. *Screening Process: Roundtable staff will collaborate with institutional staff in the screening process, including obtaining informed consents, obtaining data for each person from client records, interviews and questionnaires, inputting data into the screening tool, and providing information about outplacement options to each person. Further modifications will be made in the screening tool as screenings are being conducted in order to increase its effectiveness. Possible modifications include eliminating types of data that are not available from the screening organizations or clients. If medical or jail staff determine that an individuals is likely to have frequent future crises that require hospitalization or incarceration, they will have the prerogative to over-ride the assessment results and include the individual in the highest need group. At the end of the pilot project, the intent is to hand-off the screening tool and process to staff at clinics, hospitals and jails.* 5. *Post-Screening Follow-up for High Need Individuals: CSH will arrange immediate temporary housing slots and follow-on permanent supportive housing slots in each geographic area where screening will be carried out. In addition, housing placement services will be arranged to ensure that high-cost, high-need individuals have realistic prospects for gaining access to permanent supportive housing. This is a key service because many of these individuals are mentally ill and have great difficulty completing the application process and producing the documentation of disabilities, homeless status and income required for admission to supportive housing. Given that many of the referred individuals will need high levels of supportive services, it is desirable to arrange access to supportive housing units that have high levels of on-site services.* 6. *Post-Screening Follow-up for Individuals not in the Highest Need Group: Individuals who are not in the highest need group will receive a printed directory of housing and social services in the area where the screening*

	is conducted and one-on-one counseling to advise them about how to apply for those services. The intent is to ensure that everyone who participates in the screening process obtains some benefit from it. 7. *Capacity Building: CSH will foster collaboration among integrated services and housing teams in each of the three target communities and offer capacity building sub-grants. Technical assistance, and training as needed will be provided to strengthen the effectiveness of these teams in maintaining housing stability among tenants. CSH will convene "learning circles" to facilitate cross-team learning among peers from all three communities.* *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 **X 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 mental illness. Furthermore, the project will obtain medical information about participants.* *Direct benefits in the form of access to permanent supportive housing are likely to accrue to human subjects in the highest need group. Individuals not in the highest need group will receive lesser benefits in the form of information about housing and services that are available to them and counseling about how to obtain housing and services.* *Although it is recommended that the IRB review this pilot project as "Level III" because some participants have varying forms of mental illness and therefore may need assistance in comprehending the informed consent form, and because medical data will be obtained, there is minimal risk to the human subjects. Information collected from interviewing participants and from medical and jail records will be safeguarded in the Economic Roundtable and will not be shared with any outside organizations.* *This pilot project will be conducted under the Economic Roundtable's policy for protections of human subjects. The assessment report on the pilot project and briefings to policy makers will present only de-identified data, which are aggregated into summary tables of larger groups and cohorts.*
HEALTH INFORMATION	Identifiable Health Information: (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***

If yes, go to question (2).

If no, you do not need to satisfy HIPAA education requirement.

(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.*

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.

(3) Describe the specific procedures and safeguards that will be used to de-identify health information of human subjects in this project

1. *Access to data will be limited only to those with a need to know.*

   Only authorized researchers at the Economic Roundtable will be allowed access to confidential data and only for approved project activities.

2. *Computer access will be protected through the use of passwords and other protections.*

   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.

3. *Research records will be protected through the use of locked cabinets in locked rooms, storage of identifiers separate from analysis data, and other methods.*

   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.

4. *Data will not be reused or provided to any persons outside of the research team.*

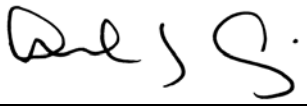
   Data will be accessible only on a need-to-know basis by approved members of the research team. Confidential data will not be provided to any person outside the team.

5. *Information will not be published that could possibly be used to identify an individual subject.*

   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. *6. Confidential data will not be stored in laptop computers.* *Confidential data will not be used or stored in laptop computers. Confidential data will be loaded only onto approved, stand-alone computers*
INFORMED CONSENT	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. *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 individual participants in clinics, hospitals and jails. Medical or jail staff will be present. The information will include explanations of the project and the informed consent form.* *The informed consent document, which was prepared by County Counsel for the homeless cost avoidance study, is submitted as an attachment to this request for approval. It waives data confidentiality for:* • *Medical records* • *Jail records* • *Information provided by individuals in the attached questionnaire and through the accompanying interview*
LOCATION	Indicate the location where the human subjects involvement will occur. *Contact with homeless individuals who are prospective project participants will take place in clinics, hospitals and jails.* *All confidential data for project participants will be kept at the office of the Economic Roundtable:* *Economic Roundtable* *315 West Ninth Street, Suite 1209* *Los Angeles, California 90015.* *No confidential data will leave this office. All data will be managed in conformance with ERT's data security policy.*
SUBJECTS	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, indicate what additional safeguards have been included in the study to protect the rights and welfare of these subjects. *The population being studied is homeless individuals in downtown Los Angeles, Hollywood and the West Los Angeles-Santa Monica area. Many of these individuals are mentally ill and/or substance abusers. The project team is seeking to place the highest need individuals in permanent*

	supportive and to provide concrete assistance to other individuals in obtaining needed services. *Data obtained about these individuals will include background information collected following signing of the informed consent document, medical information collected by health care providers, and jail records.* *Disclosure of information assembled for this project would likely cause embarrassment and it is remotely possible that it could compromise entitlement to services. 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 following 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 project team.*
REPORTING AND MONITORING	Describe the protocols that will be followed for reporting back to the Institutional Review Board and monitoring data security. *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.* *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.* *Reports on protection of human subjects, data security and project design will be submitted to the IRB semi-annually or more often if requested.*
ATTACHMENTS	The following additional documentation supports this request for IRB approval: 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 CHS, including the scope of work. 4) The informed consent document prepared and approved by Los Angeles County Counsel. 5) The client questionnaire. NIH certificates of completion for the principal investigator and research staff are posted on the IRB web site: http://www.economicrt.org/irb/



Signature of Principal Investigator	October 12, 2010 Date of Signature
Daniel Flaming Print Name of Principal Investigator	President Title