In order to ascertain whether IRB Review is needed for a project, a Human Subject Research Determination (HSR) may be requested via email ([IRBEducation@stanford.edu](mailto:IRBEducation@stanford.edu)), phone (IRB Education line: 650-724-7141) or by completing this form and attaching it to the HSR application in eProtocol.

*For additional guidance, please refer to:* [*Does My Project Need IRB Review?*](https://stanfordmedicine.box.com/shared/static/vqeuewr5axycjpu8h0wat77vqdpua9ru.pdf)

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| **I. Project Information - Please answer all questions.** | |
| Project Title: Driving Times to Opioid Treatment Programs and Pharmacies | |
| Purpose of the project:  The purpose of this project is to compare the mean driving time to the closest Opioid Treatment Program and pharmacy for a sample of residential addresses across the United States. | |
| Does this project use California State Death Records/Indices? Yes  No  If Yes, **STOP**, and [submit an IRB application](https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/faqs#protocol-submission) in eProtocol. | |
| Does this project utilize Radiologic or other images? Yes  No | |
| Samples or data from deceased individuals (only)? Yes  No | |
| Is the activity primarily designed to **improve clinical care** at  STANFORD/LPCH/SHC or VAPAHCS, or to **improve some other** **program**? Yes  No | |
| Indicate **where** the activities/project will take place (STANFORD/LPCH/SHC, VAPHCS or other site): Stanford | |
| Describe all project procedures. *If this project involves sites outside of STANFORD, please indicate that here, and specify exactly what Stanford’s role is in the project.*  Procedure:  The National Address Database of the United States Department of Transportation will be used to generate a sample of residential addresses and geographic coordinates.  The SAMSHA Opioid Treatment Program (OTP) Directory will be used to generate a list of addresses of all opioid treatment programs in the United States.  The United States Census tool (or Google Maps) will be used to geocode all addresses of Opioid Treatment Programs.  A National Database of Pharmacies (Rx Open) will be used to identify all addresses and geographic coordinates of pharmacies in the United States.  We will develop a program to find the closest Opioid Treatment Program and Pharmacy to each address in the sample.  Google Maps/Google Maps API will be used to find the driving time to the nearest OTP and pharmacy.  Paired t-tests will be used to compare address to OTP driving time with address to pharmacy driving time.  A statistical software will be used to generate descriptive statistics and perform the statistical analyses.  County classification will occur based on the 2013 NCHS Urban-Rural Classification Scheme for Counties. | |
| **Information/Data and Specimens:** | |
| MC900303657[1]a) List **all variables or data elements** that you will access or obtain for this project. Alternatively, please upload your data collection tool(s). [HIPAA & PHI](https://stanfordmedicine.box.com/shared/static/nodcdo1dq3y0gncfyv74kc3d78zi6ww6.pdf)  Addresses and geographic coordinates from the National Address Database of the United States Department of Transportation  SAMSHA Opioid Treatment Program (OTP) list will be used to generate a list of addresses of all opioid treatment programs in the United States.  The United States Census tool (or Google Maps) will be used to geocode all addresses of Opioid Treatment Programs.  Rx Open will be used to identify all addresses and geographic coordinates of pharmacies in the United States.  Google Maps/Google Maps API will be used to find the driving time between the sampled addresses and the nearest OTP and pharmacy. | |
| b) Identify the source(s) of the information or specimens (i.e., from whom/where):  *If receiving data or specimens from outside of STANFORD, you may need a Data Use Agreement (DUA) or Material Transfer Agreement (MTA). See the* [*Privacy office FAQs on DUAs*](https://privacy.stanford.edu/other-resources/data-use-agreement-dua-faqs) *or the* [*Industrial Contracts Office - MTA page*](https://ico.sites.stanford.edu/mtas)*.* | |
| c) Were/are the data or specimens collected/obtained from participants specifically for this project(Y/N)? If for a different project, which one? If for clinical purposes, please explain: No. All data used in publicly available. | |
| d) Are the data or specimens de-identified, or will they be? Yes  No  *If “yes”, who did, or will, de-identify the data or specimens?* Data is obtained from public databases | |
| e) Are the data or specimens coded, or will they be? Yes  No  *If “yes”, Will you have access to the key to the code?* Yes  No | |
| **Drugs or Devices** | |
| a) Does the project meet the FDA definition of a clinical investigation? 21 CFR 50.3(c)\* | Yes No |
| b) Does the project studying the safety or efficacy of a drug (either investigational or commercially approved)?  c) Does the project include testing of a [medical device](https://www.fda.gov/medical-devices/classify-your-medical-device/product-medical-device) including [*In Vitro* Diagnostic (IVD) Device](https://www.fda.gov/media/71075/download) or [software](https://www.fda.gov/medical-devices/digital-health/software-medical-device-samd)? ? | Yes No    Yes No |
| d) Will any data resulting from this activity be submitted to the FDA? | Yes No |
| **Results** | |
| a) How will the results of this project be used? Further understanding of access to opioid treatment programs  b) Will the results be added to another ongoing research study? Yes  No | |
| c) Results are **intended** to be widely applicable to populations beyond your specific project population at STANFORD/LPCH/SHC or VAPAHCS:  **True  False** | |
| d) Extrapolation or generalization of the project results to other settings (e.g. outside of STANFORD/LPCH/SHC or VAPAHCS ) is possible, but **not** the main intent of the project.  **True  False** | |

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| **II. Project Documents** |
| **Please upload to the Attachments section any of the following that pertain to your project:**   * Surveys/questionnaires/instruments * Interview or focus group questions * Data collection tools * Data Use Agreements (DUA) or Material Transfer Agreements (MTA) |

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| MC900303657[1]**III. Quality Assessment and/or Quality Improvement:** An activity conducted to assess, analyze, critique, and improve current processes in an institutional setting, involving data-guided, systematic activities designed to bring about prompt improvements. [**Note**](https://stanfordmedicine.box.com/shared/static/nvuzhf3pjqsrzx4890jax7uwbglbxcp4.pdf) **– projects can be published as QA/QI.** | |
| Do you consider this project to meet the definition of **QA/QI** as noted above? | **Yes No** |

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| MC900303657[1]**IV. Research**: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [*More info*](https://stanfordmedicine.box.com/shared/static/ay0l6dewep46o49qm696g4llf3vpx0u9.pdf) | |
| Do you consider this project to meet the definition of ***research***? | **Yes No** |

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| **V. Stem cells or Fetal tissue Yes No** | |
| Does your project involve the use of fetal tissue? If yes, name the source in the procedures box and state whether you plan to create iPSCs. **If creating iPSCs, contact the** [**SCRO Panel**](https://researchcompliance.stanford.edu/panels/scro)**.** |  |
| Does your project involve human embryonic stem cells (hESC), adult human stem cells, pluripotent cells or somatic nuclear transplantation? **If yes, contact the** [**SCRO Panel**](https://researchcompliance.stanford.edu/panels/scro)**.** |  |
| Is your project being conducted all or in part at the VA, or with VA resources or personnel? |  |

\**Clinical investigation* means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.