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 estimate the mean driving time, for patients in the United States, to the closest Opioid Treatment Program and pharmacy | |
| 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.*  The United Census Bureau 2010 data about census tracts will be downloaded, including mean center of population for each tract, population in the census tract, county and state of the census tract.  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.  A list of all Drug Enforcement Agency (DEA)-registered entities will be purchased from the National Technical Information Service of the U.S. Department of Commerce (https://classic.ntis.gov/products/dea/). This list contains DEA numbers, addresses, business activity types, and controlled substance schedules for all DEA-registered entities. This will be used to identify the addresses of pharmacies in the United States that are currently permitted to dispense opioids. If possible with the dataset, pharmacies will be restricted to pharmacies permitted to dispense Schedule II narcotics.  ArcGIS software will be used to geocode all addresses of Opioid Treatment Programs and pharmacies. Addresses that are unclear may require hand review, including visiting the website and/or calling the facility for clarification of the address.  An algorithm will find the ten closest, by point-to-point distance, Opioid Treatment Programs and pharmacies for each mean center of population for each census tract  The ArcGIS software will be used to find the driving times to the nearest ten OTPs and pharmacies (with an upper limit of a 12 hour one-way driving distance). The OTP and pharmacy which have the lowest driving times will be taken as the "closest" OTP or pharmacy for assessment of the primary outcome.  The primary outcome is the population-weighted mean of driving times across the United States to the closest OTP and pharmacy. This will be calculated by taking the mean of driving times from the mean center of population in each census tract to the closest OTP and pharmacy, weighted by the population of the census tract. A paired, weighted t-test will be used to compare the driving times between the closest OTP and closest pharmacy. (This will be implemented as a one-sample, two-tailed, weighted t-test on the difference between the driving time to the closest OTP and driving time to the closest pharmacy). If there is no driving route available to either the closest OTP or pharmacy, the census tract and driving times for both the closest OTP and pharmacy will be excluded from the primary outcome analysis and described separately.  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. T-tests will be used to compare weighted mean driving time in each classification. Weighted mean driving times will calculated for each state. Driving distances to the nearest OTP and pharmacy will also be reported. | |
| **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)  The United Census Bureau 2010 data about census tracts will be downloaded, including mean center of population for each tract, population in the census tract, county and state of the census tract.  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.  A list of all Drug Enforcement Agency (DEA)-registered entities will be purchased from the National Technical Information Service of the U.S. Department of Commerce (https://classic.ntis.gov/products/dea/). This list contains DEA numbers, addresses, business activity types, and controlled substance schedules for all DEA-registered entities. This will be used to identify the addresses of pharmacies in the United States that are currently permitted to dispense opioids. If possible with the dataset, pharmacies will be restricted to pharmacies permitted to dispense Schedule II narcotics.  ArcGIS software will be used to geocode all addresses of Opioid Treatment Programs and pharmacies. Addresses that are unclear may require hand review, including visiting the website and/or calling the facility to obtain the address.  An algorithm will find the ten closest, by point-to-point distance, Opioid Treatment Programs and pharmacies for each mean center of population for each census tract  The ArcGIS software will be used to find the driving times to the nearest ten OTPs and pharmacies (with an upper limit of a 12 hour one-way driving distance). The OTP and pharmacy which have the lowest driving times will be taken as the "closest" OTP or pharmacy for assessment of the primary outcome.  The primary outcome is the population-weighted mean of driving times across the United States to the closest OTP and pharmacy. This will be calculated by taking the mean of driving times from the mean center of population in each census tract to the closest OTP and pharmacy, weighted by the population of the census tract. A paired, weighted t-test will be used to compare the driving times between the closest OTP and closest pharmacy. (This will be implemented as a one-sample, two-tailed, weighted t-test on the difference between the driving time to the closest OTP and driving time to the closest pharmacy). If there is no driving route available to either the closest OTP or pharmacy, the census tract and driving times for both the closest OTP and pharmacy will be excluded from the primary outcome analysis and described separately.  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. T-tests will be used to compare weighted mean driving time in each classification. Weighted mean driving times will calculated for each state. Driving distances to the nearest OTP and pharmacy will also be reported. | |
| b) Identify the source(s) of the information or specimens (i.e., from whom/where): Public databases of US Census bureau data, SAMSHA OTP locations. The dataase of DEA registrations is available for purchase from https://classic.ntis.gov/products/dea/.  *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 and pharmacies  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.