Title : Driving Times to Opioid Treatment Programs and Pharmacies in the United States

Approval Period: **Draft**

Protocol Director

Name		**Degree (Program/year if student)**		**Position, e.g. Assistant Professor, Resident, etc.**
Robert Kleinman		MD		Resident
Department	**Mail Code**	**Phone**	**Fax**	**E-mail**
School of Medicine - Dean's Office		650-***-****		rkleinman@stanford.edu
CITI Training current				Y

Admin Contact

Name		**Degree (Program/year if student)**		**Position, e.g. Assistant Professor, Resident, etc.**
Robert Kleinman		MD		Resident
Department	**Mail Code**	**Phone**	**Fax**	**E-mail**
School of Medicine - Dean's Office		650-***-****		rkleinman@stanford.edu
CITI Training current				Y

Investigator

Name		**Degree (Program/year if student)**		**Position, e.g. Assistant Professor, Resident, etc.**
Department	**Mail Code**	**Phone**	**Fax**	**E-mail**
CITI Training current				

Other Contact

Name		**Degree (Program/year if student)**		**Position, e.g. Assistant Professor, Resident, etc.**
Department	**Mail Code**	**Phone**	**Fax**	**E-mail**
CITI Training current				

Academic Sponsor

Name		**Degree (Program/year if student)**		**Position, e.g. Assistant Professor, Resident, etc.**
Department	**Mail Code**	**Phone**	**Fax**	**E-mail**

Other Personnel

Participant Population(s) Checklist	**Yes/No**
• Children (under 18)	N
• Pregnant Women and Fetuses	N

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• Neonates (0 - 28 days)	N
• Abortuses	N
• Impaired Decision Making Capacity	N
• Cancer Subjects	N
• Laboratory Personnel	N
• Healthy Volunteers	N
• Students	N
• Employees	N
• Prisoners	N
• Other (i.e., any population that is not specified above)	Y

Study Location(s) Checklist

	Yes/No
• Stanford University	Y
• Clinical & Translational Research Unit (CTRU)	N
• Stanford Hospital and Clinics	Y
• Lucile Packard Children's Hospital (LPCH)	N
• VAPAHCS (Specify PI at VA)	
• Other (Specify other study locations)	

General Checklist

Multi-site

	Yes/No
• Is this a multi-site study? A multi-site study is generally a study that involves one or more medical or research institutions in which one site takes a lead role.(e.g., multi-site clinical trial)	N

Collaborating Institution(s)

	Yes/No
• Are there any collaborating institution(s)? A collaborating institution is generally an institution that collaborates equally on a research endeavor with one or more institutions.	N

Cancer Institute

	Yes/No
• Cancer-Related Studies (studies with cancer endpoints), Cancer Subjects (e.g., clinical trials, behavior/prevention) or Cancer Specimens (e.g., blood, tissue, cells, body fluids with a scientific hypothesis stated in the protocol).	N

Tissues and Specimens

	Yes/No
• Human blood, cells, tissues, or body fluids (tissues)?	N

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• Tissues to be stored for future research projects?	N
• Tissues to be sent out of this institution as part of a research agreement? For guidelines, please see https://sites.stanford.edu/ico/mtas	N
• Human Embryos or Gametes?	N

Veterans Affairs (VA)	**Yes/No**
• The research recruits participants at the Veterans Affairs Palo Alto Health Care System(VAPAHCS).	N
• The research involves the use of VAPAHCS non-public information to identify or contact human research participants or prospective subjects or to use such data for research purposes.	N
• The research is sponsored (i.e., funded) by VAPAHCS.	N
• The research is conducted by or under the direction of any employee or agent of VAPAHCS (full-time, part-time, intermittent, consultant, without compensation (WOC), on-station fee-basis, on-station contract, or on-station sharing agreement basis) in connection with her/his VAPAHCS responsibilities.	N
• The research is conducted using any property or facility of VAPAHCS.	N

Payment	**Yes/No**
• Subjects will be paid/reimbursed for participation? See payment considerations.	N

Funding	**Yes/No**
• Training Grant?	N
• Program Project Grant?	N
• Federally Sponsored Project?	N

Funding

NONE

Funding - Grants/Contracts

Funding - Fellowships

Gift Funding

Dept. Funding

Other Funding

Exempt Form

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In order to qualify as Exempt, a protocol must be no more than minimal risk AND must only involve human subjects in one or more of the following paragraphs.

Select one or more of the following paragraphs:

1. N **Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.**

2. N **Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:**

i) N The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

ii) N Any disclosure of the human subjects responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, educational advancement, or reputation; or

iii) N The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by # .111(a)(7)

3 N **(i)Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: See (3)(ii) below for more on the definition of a benign behavioral intervention.**

A) N The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

B) N Any disclosure of the human subjects responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, educational advancement, or reputation; or

C) N The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by # .111(a)(7).

ii) **For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant**

adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

iii) **If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.**
Is deception involved?

4. Y **Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:**

i) Y The identifiable private information or identifiable biospecimens are publicly available;

ii) N Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

iii) Reserved for future use.

iv) N The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5. N **Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.**

i) Each Federal department or agency conducting or supporting the research and (i) demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the

research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

ii) [Reserved]

6. N **Taste and food quality evaluation and consumer acceptance studies:**

i) N If wholesome foods without additives are consumed, or

ii) N If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. **Reserved for future use.**

8. **Reserved for future use.**

Resources :

a) Qualified staff.

Please state and justify the number and qualifications of your study staff.

This is a sole investigator project. I am a fourth-year psychiatry resident at Stanford with the necessary programming and statistical training to complete the project.

b) Training.

Describe the training you will provide to ensure that all persons assisting with the research are informed about the protocol and their research-related duties and functions.

This is a sole-investigator project and I authored, and am familiar with, the protocol.

c) Facilities.

Please describe and justify.

The analysis requires use of a ArcGIS, a geospatial software available through the Stanford GIS lab.

d) Sufficient time.

Explain whether you will have sufficient time to conduct and complete the research. Include how much time is required.

This necessary code has already been written, as has the manuscript, based on use of a previous pharmacy database. There are approximately 30 - 40 hours left of work to complete the project. I have two days per week to work on research.

e) Access to target population.

Explain and justify whether you will have access to a population that will allow recruitment of the required number of participants.

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All data files are publicly available over the internet.

f) Access to resources if needed as a consequence of the research.

State whether you have medical or psychological resources available that participants might require as a consequence of the research when applicable. Please describe these resources.

Not applicable - data is being used from data files that are publicly available over the internet.

g) Lead Investigator or Coordinating Institution in Multi-site Study.

Please explain (i) your role in coordinating the studies, (ii) procedures for routine communication with other sites, (iii) documentation of routine communications with other sites, (iv) planned management of communication of adverse outcomes, unexpected problems involving risk to participants or others, protocol modifications or interim findings.

1. Purpose

a) In layperson's language state the purpose of the study in 3-5 sentences.

The purpose of this study is to compare driving times to Opioid Treatment Programs and pharmacies for United States residents.

b) State what the Investigator(s) hope to learn from the study. Include an assessment of the importance of this new knowledge.

Methadone maintenance treatment for opioid use disorder (OUD can be dispensed through pharmacies in Canada, Australia and the United Kingdom. In the United States, methadone maintenance is primarily distributed through Opioid Treatment Programs (OTPs). As pharmacy-based dispensing is an alternative model of care delivery for methadone maintenance treatment, this study will compare driving access to methadone maintenance under the current OTP-dispensing framework and under a widespread pharmacy-dispensing model. This will provide important contributions for discussions around ways to increase access to OUD treatment. This is an important public health issue as many individuals with OUD do not receive treatment and are at high risk for morbidity and mortality.

c) Explain why human subjects must be used for this project. (i.e. purpose of study is to test efficacy of investigational device in individuals with specific condition; purpose of study is to examine specific behavioral traits in humans in classroom or other environment)

No human subjects will be used for this research.

2. Study Procedures

a) Describe all the research procedures, from screening through closeout, which the human subject must undergo in the research project, including study visits, drug treatments, randomization and the procedures that are part of standard of care.

The following is an amended version of the study procedures, previously determined not to be human subjects research in IRB-54060, IRB-53489.

As part of previous protocols that have been determined not to be Human Subjects Research by the IRB , the United Census Bureau 2010 data about census tracts was 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 was used to generate a list of addresses of all opioid treatment programs in the United States.

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ArcGIS software has previously been used to geocode all addresses of Opioid Treatment Programs. OTP addresses that were unclear required individual review, including visiting the website, calling the facility for clarification of the address/directions, using alternative mapping techniques (e.g. online maps or Google Maps).

What has changed since the previous submission is the database for obtaining pharmacy addresses. The new database that will be used is the National Provider Identifier (NPI) database. This is a publicly available downloadable file of all NPI records in the United States (http://download.cms.gov/nppes/NPI_Files.html). Records are also freely searchable by anyone over the internet: https://npiregistry.cms.hhs.gov/.

The following statements describe the individuals who must obtain NPIs and the provision of public records:
"All health care providers who are HIPAA-covered entities, whether individuals or organizations, must obtain an NPI" (source: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/NPI-What-You-Nee
"The information disclosed on the NPI Registry and in the downloadable files are FOIA-disclosable and are required to be disclosed under the FOIA and the eFOIA amendments to the FOIA. There is no way to 'opt out' or 'suppress' the NPPES record data for health care providers with active NPIs." (source: https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/NationalProvIdentStand/DataDissemination)

From the NPI database, addresses of pharmacies (specifically community/retail pharmacies) will be obtained. These addresses will be geocoded with ArcGIS software.

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.

ArcGIS software with StreetMaps Premium will be used to find the driving times to the nearest ten OTPs and pharmacies. The OTP and pharmacy which have the lowest driving time will be taken as the "closest" OTP or pharmacy for assessment of the primary outcome.

The primary outcome is the population-weighted mean driving time 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 time 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. Other urban-rural classification schemes may also be used.

b) Explain how the above research procedures are the least risky that can be performed consistent with sound research design.

This research protocol uses only publicly available information related provided by organizations. Individual information related to business practice is also present in the NPI database. There are limited anticipated risks to individuals by using this publicly available data. Similarly, the research will provide information that could inform policy decisions to improve care for patients with OUDs.

c) State if deception will be used. If so, provide the rationale and describe debriefing procedures. Since you will not be fully informing the participant in your consent process and form, complete an

alteration of consent (in section 9). Submit a debriefing script (in section 11).

Deception will not be used

d) State if audio or video recording will occur. Describe what will become of the recording after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the recordings.

No audio or video recordings will occur

3. Background

a) Describe past findings leading to the formulation of the study.

Prior research has found that driving times to OTPs are longer in rural areas than urban areas. Prior research has also found that driving times to OTPs are longer than to other healthcare facilities.

4. Participant Population

a) State the following: (i) the number of participants expected to be enrolled at Stanford-affiliated site(s); (ii)the total number of participants expected to enroll at all sites; (iii) the type of participants (i.e. students, patients with certain cancer, patients with certain cardiac condition) and the reasons for using such participants.

(i) Number of enrolled participants: None
(ii) Number of enrolled participants: None
(iii) No participants are enrolled in this study. The NPI database contains information about individual HIPAA-covered healthcare providers, including trainees and employees of healthcare organizations. This information will not be used in this project (only organization information will be used), but I will have access to this information. All this information is publicly available and searchable over the internet.

b) State the age range, gender, and ethnic background of the participant population being recruited.

NA

c) State the number and rationale for involvement of potentially vulnerable subjects in the study (including children, pregnant women, economically and educationally disadvantaged, decisionally impaired, homeless people, employees and students). Specify the measures being taken to minimize the risks and the chance of harm to the potentially vulnerable subjects and the additional safeguards that have been included in the protocol to protect their rights and welfare.

NA

d) Describe how potential participants will be identified for recruitment (e.g., chart review, referral from individual's treating physician, those individuals answering an ad). Describe how participants will be recruited and how they will initially learn about the research (e.g., clinics, advertising). Attach recruitment materials in Section #11 (Attachments). You may not contact potential participants prior to IRB approval. See guidance Advertisements: Appropriate Language for Recruitment Material.

NA

e) Inclusion and Exclusion Criteria.

Identify inclusion criteria.

All community and retail pharmacies with an active NPI that can be geocoded during batch geocoded will be included.
All OTPs will be included.

Identify exclusion criteria.

Duplicate locations of OTPs or pharmacies. Census tracts that do not have driving routes to both an OTP

and a pharmacy will be excluded in the primary analysis.

f) Describe your screening procedures, including how qualifying laboratory values will be obtained. If you are collecting personal health information prior to enrollment (e.g., telephone screening), please request a limited waiver of authorization in section #10.

NA

g) Payment/reimbursement. Explain the amount and schedule of payment or reimbursement, if any, that will be paid for participation in the study. Substantiate that proposed payments are reasonable and commensurate with the expected contributions of participants and that they do not constitute undue pressure on participants to volunteer for the research study. Include provisions for prorating payment. See payment considerations

NA

h) Costs. Please explain any costs that will be charged to the participant.

NA

i) Estimate the probable duration of the entire study. Also estimate the total time per participant for: (i) screening of participant; (ii) active participation in study; (iii) analysis of participant data.

NA

5. Risks

a) Describe risks. Include risks to privacy, confidentiality, etc..

The NPI database includes business locations, mailing addresses, along with other identifying information of all individuals and healthcare organizations that are registered for an active NPI. This database is publicly available and is updated monthly. This database is being used to identify addresses of community/retail pharmacies in the United States (and potentially the number of pharmacies and/or healthcare organizations in the US).

Use of this information could reduce privacy for pharmacies and affiliates. Use of the database could reduce privacy for other providers (including individuals) though this is not the purpose of the study. These risks are mitigated by the database already being publicly available for download at https://download.cms.gov/nppes/NPI_Files.html.

b) If you are conducting international research, describe the qualifications/preparations that enable you to both estimate and minimize risks to participants. Provide an explanation as to why the research must be completed at this location and complete the [LINKFORINTERNATIONALREASEARCHFORM] International Research Form. If not applicable, enter N/A.

N/A

c) Could any disclosure of the participant's response outside the research reasonably place them at risk of loss of insurability, criminal or civil liability, or be damaging to the participant's financial standing, employability, or reputation?

No human participants are included

6. Benefits

a) Describe the potential benefit(s) to be gained by the participants or by the acquisition of important knowledge which may benefit future participants, etc.

There are no participants in this study.

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7. Privacy and Confidentiality

Privacy Protections

a) Describe how the conditions under which interactions will occur are adequate to protect the privacy interests of participants (e.g., privacy of physical setting for interviews or data collection, protections for follow-up interactions such as telephone, email and mail communications).

There will be no health information collected. Addresses of business locations/mailing addresses provided by HIPAA-covered entities will be used. Other identifying information provided by the HIPAA-covered entities is included in the database.

Confidentiality Protections

b) Specify the PHI (protected health information) or other individually identifiable data or specimens you will obtain, use or disclose to others. PHI is health information linked to one or more of the HIPAA identifiers listed above. List BOTH health information AND identifiers.

There will be no health information collected. Addresses of business locations/mailing addresses provided by HIPAA-covered entities that are publicly available will be used.

c) Describe: (i) how data will be maintained (e.g., paper or electronic spreadsheet, desktop computer, laptop or other portable device); (ii) how you will maintain the confidentiality and data security, (e.g., password protected computer, encrypted files, locked cabinet and office); and (iii) who will have access to the data (e.g., research team, sponsors, consultants)

Data will be maintained in electronic laptops on personal laptop computers, Stanford GIS desktop and/or server, online datasheets, email systems, and online data repositories (e.g. Github).

d) If you will be sharing data with others, describe how data will be transferred (e.g., courier, mail) or transmitted (e.g., file transfer software, file sharing, email). If transmitted via electronic networks, describe how you will secure the data while in transit. See http://www.stanford.edu/group/security/securecomputing/ http://www.stanford.edu/group/security/securecomputing/ .

Data will be shared via email and online file storage/transfer.

e) If you plan to code the data, describe the method in which it will be coded and indicate who will have access to the key to the code.

There is no plan to code the data.

f) How will you educate research staff to ensure they take appropriate measures to protect the privacy of participants and the confidentiality of data or specimens collected (e.g. conscious of oral and written communications, conducting insurance billing, and maintaining paper and electronic data)?

There are no participants in this study.

8. Potential Conflict of Interest

Investigators are required to disclose any financial interests that reasonably appear to be related to this protocol.

Financial Interest Tasks

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Investigators	Role	Email	Has Financial Interest?	Date Financial Interest Answered	Date OPACS Disclosure Submitted	Date OPACS Review Completed
Robert Kleinman	PD	rkleinman@stanford.edu	N	02/11/2020		

9. Consent Background

10. Assent Background (less than 18 years of age)

11. Attachments

Attachment Name	Attached Date	Attached By	Submitted Date

Obligations

The Protocol Director agrees to:

- Adhere to principles of sound scientific research designed to yield valid results
- Conduct the study according to the protocol approved by the IRB
- Be appropriately qualified to conduct the research and be trained in Human Research protection, ethical principles, regulations, policies and procedures
- Ensure all Stanford research personnel are adequately trained and supervised
- Ensure that the rights and welfare of participants are protected including privacy and confidentiality of data
- Ensure that, when de-identified materials are obtained for research purposes, no attempt will be made to re-identify them.
- Disclose to the appropriate entities any potential conflict of interest
- Apply relevant professional standards.

Additional Responsibilities

- Any change or modification in the research protocol must be submitted to and approved by the IRB prior to the implementation of such change, except when necessary to eliminate apparent immediate hazards to the participant.
- For studies with expiration dates, submit a Continuing Review prior to the end of the approval period. An IRB Continuing Review (Renewal) Notice to Renew Protocol is sent to the Protocol Director prior to the expiration date of the protocol.
- https://stanfordmedicine.box.com/shared/static/qbsi8u8h47qsotxhdpuzz50xlrqa0sgo.pdf Report promptly any new information, complaints, possibly serious and/or continuing noncompliance, or unanticipated problems involving risks to participants or others.

Record Retention

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All data including signed consent form documents must be retained for a minimum of three years past the completion of the research. Additional requirements may be imposed by your funding agency, your department, or other entities. (Policy on Retention of and Access to Research Data, Research Policy Handbook, http://doresearch.stanford.edu/policies/research-policy-handbook/conduct-research/retention-and-access-research-data)

Questionnaries and Interview Guide

Y **By checking this box, I verify that I, as the Protocol Director (PD) responsible for this research protocol, have read and agree to abide by the above obligations, or that I have been delegated authority by the PD to certify that the PD has read and agrees to abide by the above obligations.**

APPROVAL LETTER/NOTICE NOTE: List all items (verbatim) that you want to be included in your approval letter (e.g., Amendment date, Investigator's Brochure version, consent form(s) version(s), advertisement name, etc.) in the box below.

Notice of Exempt Review includes:

Comments

Comment Title	Comments / Responses	Response Necessary