Title: ABC4567YZ, A Phase II Trial of Treatment of Sleepiness in the Office with Coffee versus Tea.

**Protocol Director**
Dr. Chandra Reddy Devireddy  
**Degree:** MD/PhD  
**Title:** Project Manager

<table>
<thead>
<tr>
<th>Dept</th>
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<th>Phone</th>
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<td>Medicine</td>
<td>1234</td>
<td>650-555-1212</td>
<td>650-555-1313</td>
<td><a href="mailto:chandrad@stanford.edu">chandrad@stanford.edu</a></td>
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**Admin Contact**
ammy hill  
**Degree:** MD/PhD  
**Title:** Business Analyst

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<tr>
<td>Information Technology Systems &amp; Services</td>
<td>2224</td>
<td>+1 (650) 725-6231</td>
<td></td>
<td><a href="mailto:ammyh@stanford.edu">ammyh@stanford.edu</a></td>
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**Co-Protocol Director**

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**Other Contact**

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**Faculty Sponsor**

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**Other Personnel:**

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<thead>
<tr>
<th>Name</th>
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**Subject Population**

- Minors (under 18): N
- Pregnant Women: N
- Fetuses: N
- Abortuses: N
Mentally Disabled N  
Decisionally Challenged N  
Laboratory Personnel N  
Healthy Volunteers Y  
Students N  
Employees N  
Prisoners N  
Other (i.e., any population that is not specified above) N  

**General CheckList**  

Training Grant N  
Program Project Grant? N  
Cooperating Institution(s)? N  
Federally Sponsored Project? N  
Industry Sponsored Clinical Trial? N  
Radioisotopes/radiation-producing machines, even if standard of care? N  
Human blood, cells, tissues, or body fluids (tissues)? N  
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 [http://otl.stanford.edu](http://otl.stanford.edu)  
Human Embryos? N  
Human Embryonic Cells? Provide NIH Code Number(s) or state that no federal funding will be used to support this research.  
Use of Patient related equipment? If Yes, equipment must meet the standards established by Hospital Instrumentation and Electrical Safety Committee (725-5000) N  
Medical equipment used for human patients/subjects also used on animals? N  
Subjects will be paid for participation? N  
Protocol involves studying potentially addicting drugs? N  
Investigational drugs, reagents, or chemicals? N  
Commercially available drugs, reagents, or other chemicals administered to subjects (even if they are not being studied)? Y  
Investigational Device? N  

**Study Location(s) Checklist**  

Stanford University Y
The research recruits subjects at the VAPAHCS, or
The research involves the use of the VAPAHCS's nonpublic information to
identify or contact human research subjects or prospective subjects or to use
such data for research purposes, or
The research is sponsored (i.e., funded) by the VAPAHCS, or
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, or
The research is conducted using any property or facility of VAPAHCS.

Funding Checklist

Funding_grants/contracts
Funding_fellowships
Funding_NONE

1. Purpose
   a) Provide a 3-5 sentence lay summary of the purpose of the study.
   b) What does the Investigator(s) hope to learn from the study?

2. Study Procedures
   a) Describe all the 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.
   b) Explain why human subjects must be used for this project?
   c) Alternative Procedures. Describe alternative procedures, if any, that might be advantageous
to the subject. Describe the important potential risks and benefits associated with the
alternative procedure(s) or course(s) of treatment. Any standard treatment that is being
withheld must be disclosed. Include this information in the consent form.
   d) Will it be possible to continue the more (most) appropriate therapy for the subject(s) after
      the conclusion of the study?
3. Background

a) Describe past experimental and/or clinical findings leading to the formulation of the study.

b) Describe any animal experimentation and findings leading to the formulation of the study.

4. Radioisotopes or Radiation Machines

a) State whether the radiation procedures are performed as a normal part of clinical management for the medical condition that is under study or whether they are being performed because the research subject is participating in this project (extra CT scans, more fluoroscopy time, additional Nuclear Medicine Studies, etc.). If some are Standard of Care and some are Not Standard of Care, check both boxes.

<table>
<thead>
<tr>
<th>NOT STANDARD OF CARE</th>
<th>STANDARD OF CARE</th>
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| If it is not standard of care, complete the rest of this section. | If it is only standard of care, skip the rest of this section.

Note: Only applications from the faculty of the Stanford School of Medicine or senior medical staff at the Veterans Affairs Palo Alto Health Care System will be accepted. In general the Protocol Director must be a licensed clinician; however, in the unusual circumstance that the protocol director is not a physician, collaboration and appropriate assistance by such a physician is mandatory and both names must appear.

b) For radioisotope projects, provide the following radiation-related information:
   - Identify the radionuclide and chemical form.
   - For each dosage, provide the route of administration and the amount administered (mCi).
   - Provide dosimetry information and reference the source documents (package insert, MIRD calculation, peer reviewed literature).

c) For radiation machine projects, provide the following diagnostic procedures:
   - For well-established radiographic procedures, identify the procedures and the number of times each will be performed on a single research subject.
   - For each radiographic procedure, provide the setup and technique sufficient to permit dose modeling. The chief technologist can usually provide this information.
   - For radiographic procedures that are not well-established, provide FDA status of the machine, and information sufficient to permit dose modeling.

d) For radiation machine projects, provide the following therapeutic procedures:
   - For a well-established therapeutic procedure, identify the area treated, dose per fraction and number of fractions. State whether the therapeutic procedure is being performed as a normal part of clinical management for the research subject’s medical condition or whether it is being performed because the research subject is participating in this project.
   - For a therapeutic procedure that is not well-established, provide FDA status of the machine, basis for dosimetry, area treated, dose per fraction and number of fractions.

5. Medical Equipment for Human Subjects and Laboratory Animals

6. Investigational Devices
7. Drugs, Reagents, or Chemicals

a) Please list in the table below all investigational drugs, reagents or chemicals to be administered to subjects.

b) Please list in the table below all commercial drugs, reagents or chemicals to be administered to subjects.

8. Subject Population

a) State how many subjects will be involved and describe the type of subjects (e.g., students, patients with cardiac problems, particular kind of cancer, etc.) and state the reason for using such subjects.

b) State the age range, gender, and ethnic background.

c) State the number and rationale for involvement of potentially vulnerable subjects to be entered into the study, including minors, pregnant women, economically and educationally disadvantaged, decisionally impaired, and homeless people. Specify the measures being taken to minimize the risks and the chance of harm to the potentially vulnerable subjects.

d) If women, minorities, or minors are not included, a clear compelling rationale must be provided. Examples for not including minors: disease does not occur in children; drug or device would interfere with normal growth and development; etc.

e) State the number, if any, of subjects who are healthy volunteers. Provide rationale for the inclusion of healthy volunteers in this study. Specify the measures being taken to minimize the risks and the chance of harm to the volunteers.

f) State the number, if any, of subjects who are laboratory personnel, employees, and/or students. They should render the same written informed consent. If compensation is allowed, they should also receive it. (Please see Stanford University policy at http://www.stanford.edu/dept/DoR/rph/7-5.html).

g) Describe how potential subjects will be identified for recruitment (e.g., chart review, referral from individual’s treating physician, those individuals answering an ad). Describe how subjects will be recruited and how they will initially learn about the research, e.g., clinics, advertising (attach recruitment materials in Section #16 (Attachments). You may not contact potential subjects prior to IRB approval.

h) Inclusion and Exclusion Criteria.

Identify inclusion criteria.

Identify exclusion criteria.

i) Describe your screening procedures, including how qualifying laboratory values will be obtained. If you are collecting personal health information prior to enrollment, please request a limited waiver of authorization in section #16.

j) Describe how you will be cognizant of other protocols in which subjects might be participating. Please Explain If subjects will be participating in more than one study.
k) Payment. Explain the amount and schedule of payment, if any, that will be paid for participation in the study. Include provisions for prorating payment.

l) Costs. Please explain any costs that will be charged to the subject.

m) Estimate the probable duration of the entire study as well as an estimate of the total time each subject is to be involved and data about the subject is to be collected (e.g., This is a 2 year study).

9. Risks

HHS Regulations define a subject at risk as follows: "...any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service."

a) For the following categories include a scientific estimate of the frequency, severity, and reversibility of potential risks. Wherever possible, include statistical incidence of complications and the mortality rate of proposed procedures. Where there has been insufficient time to accumulate significant data on risk, a statement to this effect should be included. (In describing these risks in the consent form to the subject it is helpful to use comparisons which are meaningful to persons unfamiliar with medical terminology.) Address any risks related to:

- Use of investigational devices. Please include the clinical AEs associated with each of the devices with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure.

- Use of investigational drugs. Please include the clinical AEs associated with each of the drugs with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure.

- Use of commercially available drugs, reagents or chemicals. Please include the clinical AEs associated with each of the drugs with an indication of frequency, severity and reversibility. This information can often be found in the package.

- When performing procedures, please include all investigational, non-investigational and non-invasive procedures (e.g., surgery, blood draws, treadmill tests).

- Radioisotopes/radiation-producing machines (e.g., X-rays, CT scans, fluoroscopy).

For the following categories, include an estimate of the potential risk.

- Physical well-being.

- Psychological well-being.

- Economic well-being.

- Social well-being.

b) In case of overseas research, describe qualifications/preparations that enable you to estimate and minimize risks to subjects.

c) Special Precautions. Describe the planned procedures for protecting against or minimizing potential risks. Include the means for monitoring to detect hazards to the subject and/or to a potential fetus, and the point at which the experiment will terminate. If appropriate, include the standards for termination of the participation of the individual subject. Discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to
the subjects.

d) Data Safety Monitoring
   Is there a Data Monitoring Committee (DMC)?
   If yes, describe its role and indicate who set up the Data Monitoring Committee (e.g.,
   sponsor or Protocol Director).
   Describe the data and safety monitoring plan developed to ensure the safety of participants
   and the validity and integrity of research data. Monitoring should be commensurate with
   risks and with the size and complexity of the trials.

e) Evaluation of level of Risk. Indicate the level of risks. (Please check one: low, medium or
   high.)

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

11. Procedures to Maintain Confidentiality
   a) Describe procedures protecting the privacy of the subjects and for maintaining
      confidentiality of data, as required by federal regulations, if applicable.
   b) If information derived from the study will be provided to the subject's personal physician, a
      government agency, or any other person or group, describe to whom the information will be
      given and the nature of the information.
   c) Specify where and under what conditions study data will be kept, how samples will be
      labeled, who has access to data, and what will be available to whom.

12. Potential Conflict of Interest
   a) Do any of the involved investigators or their immediate family (as described
      below) have consulting arrangements, management responsibilities or equity
      holdings in the Sponsoring company, vendor(s), provider(s) of goods, or
      subcontractor(s)?
   b) Do any investigators or their immediate family have any financial relationship
      with the Sponsoring company, including the receipt of honoraria, income, or
      stock/stock options as payment?
   c) Is any Investigator(s) a member of an advisory board with the Sponsoring
      company?
   d) Do any investigators receive gift funds from the Sponsoring company?
   e) Do any investigators or their immediate family have an ownership or royalty
      interest in any intellectual property utilized in this protocol?
   f) Does Stanford University have an ownership or royalty interest in any
      intellectual property utilized in this protocol?

"Immediate family" means a spouse, dependent children as defined by the IRS, or a domestic partner.
If one or more of the above relationships exist, please include a statement in the consent form to
 disclose this relationship, i.e., a paid consultant, a paid member of the Scientific Advisory Board, has
stock or stock options, or receives payment for lectures given on behalf of the sponsor (see sample consent form). The consent form should disclose what institution(s) or companies are involved in the study through funding, cooperative research, or by providing study drugs or equipment (see sample consent form).

If you answer yes to any of the questions above, you must file a CoI disclosure with your School Dean. If you are a faculty member in the School of Medicine, contact Barbara Flynn @ 723-7226, or email bflynn@stanford.edu. http://www.stanford.edu/dept/DoR/ad_hoc.html.

13. Consent Background

You can add different Consent Forms, Alteration Forms, and Waivers. Provide consent process background information, in the table below, for each Consent Form(s), Alteration Form(s), and Waiver(s).

13.1 Consent Form primary consent form

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study.

The researcher will obtain consent during the first meeting with the volunteer.

How is consent being obtained?

In writing, after reviewing the consent form in detail.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?

Volunteers will undergo a phone screening and then will meet with the researcher in person prior to enrollment in the study.

14. Assent Background (Up to 18 years of age)

All minors must provide an affirmative consent to participating by signing a simplified assent form, unless the Investigator(s) provides evidence to the IRB that the minors are not capable of assenting because of age, maturity, psychological state, or other factors.

15. HIPAA

Are you using PHI? N
Protected Health Information (PHI) is health information with one or more of the following identifiers. More information can be obtained at http://www.med.stanford.edu/HIPAA

1. Names
2. Social Security numbers
3. Telephone numbers
4. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combing all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000
5. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated
into a single category of age 90 or older
6. Fax numbers
7. Electronic mail addresses
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique
code assigned by the Investigator(s) to code the research data)

Provide HIPAA background information, in the table below, for each waiver of authorization or alteration
of authorization requested, e.g., waiver of authorization for access to medical records. Include HIPAA
authorization language in the consent form(s) as appropriate, e.g., when enrolling subjects.

Use table below ONLY when requesting waiver/alteration of HIPAA authorization.

16. Attachments

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<th>Submitted Date</th>
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Obligations

Any change in the research protocol must be submitted to the IRB for review prior to the
implementation of such change. Any complications in subjects or evidence of increase in the
original estimate of risk should be reported at once to the IRB before continuing with the project.
Inasmuch as the Institutional Review Board (IRB) include faculty, staff, legal counsel, public
members, and students, protocols should be written in language that can be understood by all
Panel members. The investigators must inform the participants of any significant new knowledge
obtained during the course of the research.

All continuing projects and activities must be reviewed and re-approved at least annually by the
IRB. IRB approval of any project is for a maximum period of one year. It is the responsibility of the
Investigator(s) to resubmit the project to the IRB for annual review prior to the end of that year. (A
"RENEWAL" form [notice to renew protocol] is sent to the Protocol Director 7 weeks prior to the
expiration date of the protocol.)

Department Chair must approve faculty and staff research that is not part of a sponsored
project. VA applicants must have Division Chief or Ward Supervisor approval. E-mail the
Department Chair approval to IRBCoordinator@lists.stanford.edu.

All data including all 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

List all items (verbatim) you want to be reflected in your approval letter, i.e., Amendment, Investigator's Brochure, consent form(s), advertisement, telephone script, diary card, etc. Include number and date when appropriate.

**Approval Includes:**

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Y The Protocol Director has read and agrees to abide by the above obligations.