

**NOTICE OF INTENT TO RELY ON ANOTHER UC IRB
At UC Berkeley, LBNL, UC Davis or UC San Francisco**

Instructions to the Principal Investigator/Lead Investigator at the <i>Reviewing</i> IRB	Instructions to the Principal Investigator/Lead Investigator at the <i>Relying</i> IRB
1. Read the decision tree for an overview of the process and points to consider when determining which IRB should provide review.	1. Read the decision tree for an overview of the process and points to consider when determining which IRB should provide review.
2. Complete this Notice and ensure that information about the research at the other UC sites is included.	2. Ensure you provide the necessary information, for this Notice to be completed, to the PI/LI at the <i>Reviewing</i> IRB.
3. Obtain the signature of the Relying PI/LI on the Notice.	3. As the Relying PI/LI, sign the Notice which will be transmitted to you by the <i>Reviewing</i> PI/LI and return it to the <i>Reviewing</i> PI/LI. Please note, an electronic signature is acceptable.
4. Submit the completed Notice with your IRB Application Forms to your <i>Reviewing</i> IRB.	4. Wait for notification of IRB Approval from the <i>Reviewing</i> PI/LI.
5. Once approved, provide a complete packet of the IRB approved study and forms to the Relying PI/LI.	5. Once you receive a complete copy of the IRB approved study from the <i>Reviewing</i> PI/LI, submit a copy of the signed Notice to your IRB (Relying IRB) who will issue you an Acknowledgment Letter.
6. You can begin the study.	6. You can begin the study.

A. Reviewing Campus Principal Investigator/Lead Investigator:		
1. UC Location Which Will Provide IRB Review/Project Number or IRB Approval Number:		
<input checked="" type="checkbox"/> UC Berkeley / 2004-1-94	<input type="checkbox"/> Lawrence Berkeley National Lab /	<input type="checkbox"/> UC San Francisco /
<input type="checkbox"/> UC Davis /		
2. Funding Information		
a. Type of Funding	b. Award Information:	
<input checked="" type="checkbox"/> Contract/Grant	<input type="checkbox"/> Federal Government	
<input type="checkbox"/> Subcontract	<input type="checkbox"/> Other Gov. (e.g., State, local)	
<input type="checkbox"/> Drug/device donation	<input checked="" type="checkbox"/> Industry	
<input type="checkbox"/> Departmental	<input type="checkbox"/> Other Private	
<input type="checkbox"/> Gift	<input type="checkbox"/> Campus/UC-Wide program	
<input type="checkbox"/> Student project	<input type="checkbox"/> Departmental Funds	
<input type="checkbox"/> Other: ___	<input type="checkbox"/> Other:	
Have funds been awarded?	Specify name of sponsor: <u>EISAI/PFIZER</u>	
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> Pending <input type="checkbox"/> No		
3. Who is the Primary Awardee Institution?	4. Who is the PI on this award?	
UC Berkeley	Dr. Adam Gazzaley	
5. PI/LI on the IRB Application:		
Name and degree	University Title	Department
Adam Gazzaley M.D., Ph.D.	Associate Professor	Neurology, Physiology
Mailing Address	Phone Number	E-mail Address
1700 4 th Street	(415) 476-2164	adam.gazzaley@ucsf.edu
Byers Hall room 102C		
San Francisco, CA 94158		
Contact Person:		
Name and degree	University Title	Department
Anne Berry B.A.	Staff Research Associate	Neurology
Mailing Address	Phone Number	E-mail Address
same as above	(415) 476-2164	anne.berry@ucsf.edu
Additional Contact Person (if any):		
Name	University Title	Department
Campus Mailing Address (Box No.)	Phone Number	E-mail Address
6. Study Title:	7. Application Type	8. Review Type
"Cholinergic Modulation of Top-Down Visual Processing in	<input type="checkbox"/> New	<input checked="" type="checkbox"/> Full Committee

Individuals with Mild Cognitive Impairment (MCI)	<input type="checkbox"/> Modification <input checked="" type="checkbox"/> Renewal (Continuing Review)	<input type="checkbox"/> Expedited Review <input type="checkbox"/> Exempt
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9. Provide a brief synopsis or abstract of the entire study: **Space limit: half page**

Please provide a general description of the overall study. The synopsis should be no more than half a page.

The primary goal of this project is to increase our understanding of the nature of cholinergic influence on attention and memory and how regulation of the cholinergic system benefits patients with mild cognitive impairment (MCI). The objective is to study individuals diagnosed with MCI using our newly developed cognitive paradigm and fMRI to study the impact of treatment with a cholinesterase inhibitor (donepezil) at three time points (onset of treatment, 1 month and 3 months after treatment onset). I hypothesize that increasing cholinergic levels will lead to enhancement of our functional biomarkers of attention and memory and this will correlate with improved behavioral performance. This will serve to inform us as to the mechanism of action of these frequently used medications, as well as the role of the cholinergic system in memory and attention.

B. Relying Campus Principal Investigator/Lead Investigator: Note: Copy this section (B) to include information for each relying campus.

1. UC Location Which Will Rely on the Reviewing IRB Review/Project Number or IRB Approval Number:

<input type="checkbox"/> UC Berkeley /	<input type="checkbox"/> Lawrence Berkeley National Lab /
<input type="checkbox"/> UC Davis /	<input checked="" type="checkbox"/> UC San Francisco /

2. Funding Information

a. Type of Funding	b. Award Information:
<input checked="" type="checkbox"/> Contract/Grant <input type="checkbox"/> Subcontract <input type="checkbox"/> Drug/device donation <input type="checkbox"/> Departmental <input type="checkbox"/> Gift <input type="checkbox"/> Student project <input type="checkbox"/> Other: ___	<input type="checkbox"/> Federal Government <input type="checkbox"/> Other Gov. (e.g., State, local) <input checked="" type="checkbox"/> Industry <input type="checkbox"/> Other Private <input type="checkbox"/> Campus/UC-Wide program <input type="checkbox"/> Departmental Funds <input type="checkbox"/> Other:
Have funds been awarded? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> Pending <input type="checkbox"/> No	Specify name of sponsor: EISAI/PFIZER_

3. PI/LI at the relying campus:

Name and degree Adam Gazzaley M.D., Ph.D. (same as above)	University Title Associate Professor	Department Neurology, Physiology
Mailing Address 1700 4 th Street Byers Hall room 102C San Francisco, CA 94158	Phone Number (415) 476-2164	E-mail Address adam.gazzaley@ucsf.edu

Contact Person:

Name and degree Anne Berry, B.A. (same as above)	University Title Staff Research Associate	Department Neurology
Mailing Address same as above	Phone Number (415) 476-2164	E-mail Address anne.berry@ucsf.edu

Additional Contact Person (if any):

Name	University Title	Department
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Campus Mailing Address (Box No.)	Phone Number	E-mail Address
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4. Provide a summary of the Relying PIs/LIs scope of work and activities. For example, please include any of the study procedures, interventions, diagnostics, or analysis that will take place.

Dr. Adam Gazzaley will oversee data collection and analysis at UC San Francisco. Activities at UC San Francisco will include 1)

Neuropsychological assessments to determine study eligibility 2) fMRI scans 3) drug intervention 4) data analysis.

6. Will the Relying PI/LI recruit and consent subjects Yes No

If yes, please provide a brief discussion of the following:

a. Types and numbers of subjects, and
15 additional subjects will be recruited with a diagnosis of MCI.

b. How, when, where, and by whom are potential subjects approached?
Potential subjects are contacted over the phone using a standard script. Potential subjects who have expressed an interest in participating in research are referred by the UC San Francisco Memory and Aging Center. Potential subjects are contacted during working hours by Anne Berry (Staff Research Associate).

c. Provide a brief description of how informed consent
Participants are mailed a copy of the Consent Form and the research participant's Bill of Rights before the first appointment for the study. At the first research appointment, the Consent Form and Bill of Rights are reviewed by the researcher before the participant signs. At this time, the subject will be given an opportunity to ask questions about the consent form and protocol. Patients with MCI have minimal or no deficit in reading comprehension. They are by definition not demented and will not have difficulty understanding the consent form. The consent form is written in non-technical language so that persons with at least an eighth grade education can easily understand. Those obtaining informed consent have undergone HIPPA training.

C. Other Approvals/Regulated Materials: Does this study require approval or authorization from any of the following oversight or regulatory committees, or involve the use of regulated materials listed below? Yes No

If "Yes", complete the applicable section(s) below and identify which UC School will or has provided the review.

Acknowledgment Letters will not be provided from the Relying IRB if the below approvals are not in place.

Cancer Center Protocol Review Committee	Date of review:	<input type="checkbox"/> UC Davis <input type="checkbox"/> UC San Francisco	
Institutional Biosafety Committee	BUA# for each site:	<input type="checkbox"/> UC Berkeley <input type="checkbox"/> Lawrence Berkeley National Lab	<input type="checkbox"/> UC Davis <input type="checkbox"/> UC San Francisco
Human Stem Cells	Oversight Review Committee Approval:	<input type="checkbox"/> UC Berkeley <input type="checkbox"/> Lawrence Berkeley National Lab	<input type="checkbox"/> UC Davis <input type="checkbox"/> UC San Francisco
Radiation Safety Committee	RUA#:	<input type="checkbox"/> UC Berkeley <input type="checkbox"/> Lawrence Berkeley National Lab	<input type="checkbox"/> UC Davis <input type="checkbox"/> UC San Francisco
Radioactive Drug Research Committee (RDRC)	Approval date:	<input type="checkbox"/> UC Berkeley <input type="checkbox"/> Lawrence Berkeley National Lab	<input type="checkbox"/> UC Davis <input type="checkbox"/> UC San Francisco
List any Investigational Drugs and Biologics	Name and IND#:	<input type="checkbox"/> UC Berkeley <input type="checkbox"/> Lawrence Berkeley National Lab	<input type="checkbox"/> UC Davis <input type="checkbox"/> UC San Francisco
List any Investigational Devices and Non-Significant Risk Devices	Name and IDE# or NSR Determination:	<input type="checkbox"/> UC Berkeley <input type="checkbox"/> Lawrence Berkeley National Lab	<input type="checkbox"/> UC Davis <input type="checkbox"/> UC San Francisco

D. Relying Campus Principal or Lead Investigator's Assurance to the Reviewing IRB:

- I certify that the information provided in this application is complete and correct.
- I certify that I will follow the IRB-approved Protocol.
- I will comply with all applicable federal and state laws regarding the protection of human subjects in research.
- I will make sure that the personnel performing this study are qualified and adhere to the provisions of this IRB-approved protocol.
- I will not modify this protocol or any attached materials without first submitting an amendment to the previously approved protocol and receiving subsequent IRB approval from the Reviewing IRB.
- I accept responsibility for the conduct of this study at this site, the ethical performance of the project, and the protection of the rights and welfare of the human subjects who are directly involved at this site.

Relying Principal or Lead Investigator's Signature
(If more than one UC site)

Date

Relying Principal or Lead Investigator's Signature

Date

Relying Principal or Lead Investigator's Signature

Date

4/18/08

UC Berkeley

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OPHS@berkeley.edu
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UC Davis

Institutional Review Board Administration
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<http://www.research.ucdavis.edu/irbadmin>

UC San Francisco

Committee on Human Research
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Lawrence Berkeley National Lab

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