Request for Authorization to Use a Commercial IRB for Review of a Human Subjects Research Project

Complete this Request for Authorization of Services between the commercial Institutional Review Board (IRB) ¹ and UC Berkeley and
submit it to the Office for Protection of Human Subjects (OPHS) at irb_reliance@berkeley.edu. See Commercial Institutional Review
Board (IRB) Review for more information.

Name of Commercial IRB:
Name of Research Project:
Name of Principal Investigator (PI):
Name of Co-PI or Student Investigator (<i>if any</i>):
Sponsor/Funding Agency:
Award Number (if any):
In a few sentences, describe the purpose of this research project, the subject population, and list the procedures to be used.

1. Check all that app	oly:
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- a. Industry-authored study.
- b. Industry-funded/sponsored study.
- C. Industry-funded clinical trial or multisite clinical trial.
- d. A Contract Research Organization (CRO) will be doing the IRB submission(s) on my behalf for this study.
- e. As the PI, I will be directly submitting the protocol for IRB review.
- ☐ f. Federally funded multi-site clinical trial or federally funded study with payment authorization and budget for external IRB review.
- On behalf of all members of the research team, the PI must complete and submit the <u>CPHS Checklist for Financial Conflict of</u> <u>Interest Human Subject Studies</u> form to OPHS at irb_reliance@berkeley.edu. If there are any "yes" answers on the Checklist, a more detailed <u>COI form</u> must be filled out and submitted for each individual who has a "yes" response on the Checklist.
- 3. Do you have approval/s from any of the following? If yes, please provide the approval number. Note that, as the PI, you are responsible for obtaining all necessary compliance approvals before the research can begin.

a.	CLEB (Biosafety):	🗌 Yes 🗌 No	BUA #:	Expiration Date:			
b.	Laser Safety:	🗌 Yes 🗌 No	LSA #:	Expiration Date:			
c.	. Other institutional committee approvals, as applicable.						

¹ WCG IRB (formerly WIRB), Advarra, and Sterling

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4. Please complete the table below for UC Berkeley team members' human subjects research training dates of completion as applicable. Attach an additional sheet if needed. See <u>Policy requirements</u> and the <u>CPHS Education and Training page</u> for more information. Also see the CPHS <u>Good Clinical Practice (GCP) FAQ</u> for guidance about which GCP training to take.

Team Member	CITI Biomedical	CITI Social/ Behavioral	Good Clinical Practice (GCP), Group 1, 2, or 3, or SBR Best Practices	NIH-Funded – PHRP Training	HIPAA

The PI is responsible for ensuring and documenting that all research team members working on this study have completed, at a minimum, the UC Berkeley required CITI Basic Training as appropriate to Social-Behavioral or Biomedical procedures in the study. The reviewing IRB can require additional training as part of its review and approval.

5a. Has the Industry Alliances Office (IAO) been notified that a commercial IRB will be reviewing this project?

5b. Has the IAO completed negotiations and fully executed the contract?

I certify that the information provided is accurate and complete. I acknowledge that I am responsible for adhering to all applicable UCB policies and compliance processes, including obtaining any necessary approvals (e.g. biosafety, laser safety, COI, etc.).

Principal Investigator Signature: _____ Date: _____

Principal Investigator Name:

□ Yes □ No