Continuing Review Form/Closure

For use by ORI only:

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IRB Designate Approval:

………………………………….

………………………………….

HS-

**I – General information**This IRB continuing review or closure request must be typed out and submitted via e-mail along with all the required documents and signatures. Some continuing reviews may need to be reviewed by the full board.
 **1. IRB application number: HS-**

 **Title of Research Study**

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| --- |
|       |

 **2. Researcher (e.g., UCR faculty, student, postdoc, visiting professor):**

|  |  |
| --- | --- |
| Title (e.g., Dr., Mr., etc.):        | Name:       |
| Department:       |
| Phone:        | Institutional e-mail:       |

**3. UCR Faculty Advisor or UCR Faculty sponsor (Q3 is to be filled out only if person in Q2 is a UCR student, trainee, postdoc, or visiting scholar; for faculty research, this question should be blank)**

|  |  |
| --- | --- |
| Title (e.g., Dr. / Ms. / Prof):        | Name:       |
| Department:       | Phone:       |

 **4. Are you submitting changes to the project roster only? Y****es** [ ]  **No**[ ]  **(if so, submit the revised project roster with an amendment request form)**

|  |  |  |
| --- | --- | --- |
| **True** | **False** |  **Current Status[[1]](#footnote-1)** |
| [ ]   | [ ]   | The IRB application/protocol is permanently closed to enrollment at this institution |
| [ ]   | [ ]   | No additional identifiable private information about the subjects is being obtained by this institution’s researcher(s) |
| [ ]   | [ ]   | Analysis of private identifiable information at this institution is completed. *(This can be checked even if a statistical center at another institution will analyze private identifiable information from subjects enrolled at this institution.)* |
| [ ]   | [ ]   | **If all above are checked "True", do you wish to close the study permanently?** |
| **True** | **False** | ***Do not*** fill in this section if you checked "**True**" to close the study permanently. |
| [ ]   | [ ]   | The remaining protocol/study activities are limited to **identifiable** data analysis |
| [ ]   | [ ]   | The protocol/study remains active only for long-term follow-up of subjects/participants. |
| **Financial Interest Declaration** |
| * “Related Financial Interest” means any of the following interests in the sponsor, product(s) or service(s) being tested, or competitor of the sponsor held by the individual or the individual’s immediate family that was received within the last 12 months or that you expect to receive in the next 12 months:
	+ Ownership interest of any value including, but not limited to stocks and options, exclusive of interests in publicly-traded, diversified mutual funds.
	+ Compensation of any amount including, but not limited to honoraria, consultant fees, royalties, or other income.
	+ Proprietary interest of any value including, but not limited to patents, trademarks, copyrights, and licensing agreements.
	+ Board or executive relationship, regardless of compensation.
	+ Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center.
* “Immediate Family” means spouse, domestic partner, children, and dependents.
 |
| [ ]  Yes [ ]  No | Do you or any personnel involved in the design, conduct, or reporting of the protocol have a Related Financial Interest, as defined above? |
| [ ]  N/A [ ]  Yes [ ] No | If yes, were financial interest previously disclosed? |
| [ ]  N/A [ ]  Yes [ ]  No | If yes, has there been any change(s) in any of the investigator(s) financial interest within the last 12 months? |
| [ ] N/A [ ]  Yes [ ]  No | If yes to above, have you submitted new financial interest disclosure forms (e.g., 700-U, Form 500 and Supplemental Form) **If yes, please attach determination from the *Promoting Research Objectivity (PRO) Committee*** |
| **Yes** | **No** | **The following questions refer to all sites involved in the protocol since last IRB review or study renewal)** |
| [ ]  | [ ]  | Have subjects experienced any harms (unexpected or increased frequency and/or severity of expected)? |
| [ ]  | [ ]  | Have subjects experienced any benefits?  |
| [ ]  | [ ]  | Have there been any unanticipated problems involving risks to subjects or others?  |
| [ ]  | [ ]  | Have any subjects withdrawn, been discontinued or terminated early from the study? |
| [ ]  | [ ]  | Have any subjects or others complained about the protocol?  |
| [ ]  | [ ]  | Have there been any publications in the literature relevant to risks or potential benefits?  |
| [ ]  | [ ]  | Have there been any interim findings?  |
| [ ]  | [ ]  | Have there been any multi-center trial reports?  |
| [ ]  | [ ]  | Have there been any data safety monitoring board reports?  |
| [ ]  | [ ]  | In the opinion of the principal investigator, have the risks or potential benefits changed?  |
| [ ]  | [ ]  | Are there any problems that required prompt reporting that have NOT been submitted?  |
| [ ]  | [ ]  | Have there been any regulatory actions that could affect safety and risk assessments? |
| [ ]  | [ ]  | Have there been any other relevant information regarding this protocol, especially information about risks? |
| [ ]  | [ ]  | Have there been any written reports from the study monitors? |
| **Explanation of any “Yes” responses to items in above sections:****Type "N/A" if not applicable** **Type "See Attached" if attaching a separate document addressing all "yes" responses** |
|       |
| **Federal regulations require the IRB to conduct continuing review (study renewal). The IRB requires information from the investigator to complete the continuing review process, and needs sufficient time to conduct this review. If this report is not being submitted at least 30 days prior to the study expiration date, please explain why the form was late, and provide a corrective action plan to prevent the submission of late reports in the future.** |
| Is this report being submitted past the administrative due date? |
| [ ]  No | This report is being submitted at least 30 days prior to the expiration date. |
| [ ]  Yes | This form was submitted late because:       |
| If you are submitting this report after the date your study **expired**, were research-related activities conducted during the time IRB approval of this research was expired? [ ]  Yes [ ]  NoIf “yes,” what activities were conducted?       |
| It is very important that you submit your study renewal documentation on or before the required administrative due date. To obtain approval of study renewal you must develop a plan to ensure that you submit required reports. You must be able to follow this plan because failure to submit required reports by the due date could lead to a determination of “Continuing Non-Compliance,” which is a reportable determination. Please note that failure to receive the courtesy renewal reminder from the IRB is not justification for failing to submit you documents on time. ***Please document your plan here***:       |
| **Federal regulations require the IRB to have a procedure in place to ensure that changes to approved research are not initiated without first obtaining IRB approval unless, the change is necessary to eliminate an apparent immediate hazard to subjects** |
| [ ]  Yes [ ]  No | Have any changes, revisions, modifications, or alterations to the protocol, research procedures, or research documents been implemented since the last initial or continuing review (study renewal) ***without IRB review and approval***?       |
| **Brief Summary of the Progress of the IRB application****Type "See Attached" if attaching a separate document addressing each section below** |
| 1. Briefly summarize the research activity since last review and approval.      |
| 2. Provide a summary of all Reportable New Information reported to the IRB during the current approval period/since last approval. This summary should include the following: date the PI became aware of the event, date of IRB submission, brief description of information, resolution/corrective action plan, and the IRB determination ([sample document available](http://research.ucdavis.edu/wp-content/uploads/RNI-Summary-Table-2.docx)).      |
| **Provide one copy of the following documents:** |
| **Principal Investigator Acknowledgement** |
| I will conduct this protocol in accordance with requirements as outlined in my approved IRB application  |
| Faculty Advisor Signature | Date |
|  |  |

**III. ORI Continuing review request submission instructions:**

**All IRB continuing review requests must be submitted via email (****irb@ucr.edu****) with the required signatures in place. The request should be submitted as a in as few attachment as possible in PDF or Word format.**

**Signatures (electronic or scanned signatures are acceptable; taking a single picture of all the signatures in place is acceptable; inserting a jpeg of the signature is acceptable, also)**

**My signature as researcher, confirms that this study has been designed to protect human participants. I am responsible for the scientific and ethical conduct of the research and providing all reports and information to the IRB, as well as other related groups.**

**Researcher’s signature ----------------------------------------------- Date: -------------------**

**My signature as UCR faculty advisor and/or supervisor, confirms that this amendment has been designed to protect human participants. I have read and approved all aspects of this proposal. As a UCR faculty supervisor, I am ultimately responsible for the scientific and ethical conduct of the research and providing all reports and information to the IRB, as well as other groups.**

**UCR Faculty advisor’s / faculty sponsor’s signature ---------------------------------- Date: ------------------**

1. This refers to the status of the IRB application under the supervision of the investigator, not the status of the study at all centers/sites. [↑](#footnote-ref-1)