Determination of Activity Form

(*For use by UCR faculty researchers)*

**General information**If there is ***any question*** whether your project is***human subject research*** (according to the federal definitions) you must submit this form to the ORI. ***This process usually takes around 2 weeks from submission.***

This form must be typed out and submitted via e-mail (irb@ucr.edu) along with all the relevant appendices. All the applicable questions should be answered. Do not delete or alter any questions on this application form. Try to follow the suggested length requirements. These determinations take approximately 2 weeks.The ORI will send you a ***Notice of Determination of Activity*** letter or will contact you for additional information.

Activities that are ***clinical investigations*** covered under FDA regulations [FDA [21 CFR 50.3(c)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.3); [21 CFR 50.3(e)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.3); [21 CFR 56.102(g)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.102)] require IRB review, and an IRB application must be submitted to the ORI.

**1. Title of the project / activity**

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 **2. Principal Investigator**

1. **List the Principal Investigator (PI) for the project/activity. PIs must meet PI eligibility as defined by** [**UCR Policy #527-3**](https://redit.ucr.edu/OrApps/RED/Policies.aspx?k=6)**. Only PIs can submit the Determination of Activity Form.**

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| --- | --- |
| Title (e.g., Dr., Mr., etc.):        | Name:       |
| Department:       |
| Phone:        | Institutional e-mail:       |
| Alternate contact (e.g., research coordinator, department administrator) name:       | Alternate contact Institutional e-mail:       |

1. **If the project will be led by a researcher other than the PI (e.g., student, trainee, postdoc, or visiting scholar), please list the researcher information below. Skip section if not applicable.**

|  |  |
| --- | --- |
| Title (e.g., Dr., Prof):        | Name:       |
| Department:       |
| [ ]  Doctoral [ ]  Masters [ ]  Undergrad [ ]  Post-Doctoral [ ]  Visiting professor/External researcher [ ]  Other (specify:      )  |

**3. Funding**

|  |  |
| --- | --- |
| Is the project supported by funding? *\* If funding is Federal, provide copy* *of grant proposal with this form.* | [ ]  No [ ]  Yes *If “yes”, provide the source and type of grant:*      *If “yes”, provide status of funding:* [ ]  Secured [ ]  Pending  |

**4. Conflict of Interest**

|  |  |
| --- | --- |
| Do you or any other study personnel (or the spouse, registered domestic partner and/or dependent children thereof) have a direct or related financial interest that might affect, or even appear to affect, the rights and welfare of participants involved in this research? | [ ]  No [ ]  Yes *If “yes”, contact* [*PRO*](https://research.ucr.edu/ori/pro) *for a separate review* |

**5. Purpose of the project:**

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| *(Provide a 4-5 sentence lay description, and what you hope to learn from this project)*      |

**6. Project procedures:**

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| --- |
| *(Describe all project procedures; ½ page max)*      |

**7. Is this project QA/QI?**

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| --- | --- |
| **Quality Assessment and/or Quality Improvement:** An activity conducted to assess, analyze, critique, and improve current processes in an institutional setting, involving data-guided, systematic activities designed to bring about prompt improvements at a local level. |  **Yes No** |
| Do you consider this project to meet the definition of ***QA/QI*** as noted above? | [ ] [ ]  |
| Will the activity involve randomization into different intervention groups? | [ ] [ ]  |
| Is the activity primarily designed to:* Improve clinical care at or to improve some other program?
* Be applied to populations beyond your specific study population?
 | [ ] [ ] [ ] [ ]  |
| Will the activity generate data or information designed to be shared outside of a local context? * Describe how this information will be disseminated or published:
 | [ ] [ ]  |

**NB**: If this activity is deemed to be QA/QI, you must specify that any conclusions or learnings were not gained through research but within a framework of quality improvement/assessment carried out in the local context. If the project is to be published in a research journal, please ensure that the intended journal has been contacted to determine whether they require IRB review as one of the conditions of publication.

**8. Is this project Research [OHRP & FDA]?**

|  |  |
| --- | --- |
| **Research**: A systematic investigation designed to develop or contribute to generalizable knowledge**FDA**: Clinical investigations involving human subjects: ***Must*** submit an IRB application | **Yes No** |
| Do you consider this project to meet the definition of ***research*** as noted above?  | [ ] [ ]  |
| Is the activity a systematic investigation, including (but not limited to) a hypothesis, research development, testing, and evaluation?  | [ ] [ ]  |
| Is the activity primarily designed to develop ***new*** knowledge?  | [ ] [ ]  |
| Is the activity for your thesis, dissertation, or part of your degree requirements? | [ ] [ ]  |
| Are you applying for one of the Federal [Exempt Categories](https://research.ucr.edu/ori/resources#institutional_review_boards_irbsb_and_irbclin) (1-6)? If so, specify which      ***Please note****: If your project is determined to be Exempt, you will be required to submit the General IRB Application Form and Project Roster.*  | [ ] [ ]  |

**9. Does the activity involve human subjects?**

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| --- | --- |
| **Does your project involve:** | **Yes No** |
| Living individuals? | [ ] [ ]  |
| Intervention, including manipulation of a person, or a person’s environment? | [ ] [ ]  |
| Interaction (through surveys, interviews, tests, or observations)?  *If “yes”, attach the survey, interview, or test questions*  | [ ] [ ]  |
| Obtaining identifiable private information ***about*** living individuals? | [ ] [ ]  |

**10. Does the project use existing data or specimens?** (Skip section if not applicable)

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| --- | --- |
| Describe the source of the data or specimens (i.e., from whom/where):       | **Yes No** |
| Are the data or specimens publicly available? | [ ] [ ]  |
| Can the researcher identify the individual associated with the data or specimens? | [ ] [ ]  |
| Are the data or specimens de-identified?*If “yes”, who did, or will, de-identify the data or specimens?*       | [ ] [ ]  |
| Are the data or specimens coded?*If “yes”, will you or your team have access to the key to the code?* [ ]  **No** [ ]  **Yes** | [ ] [ ]  |
| Does this data set involve use medical records, designated record set, or any of the 18 identifiers for [HIPAA](https://research.ucr.edu/ori/hipaa)? If so, specify:       | [ ] [ ]  |
| Were the data or specimens originally collected for this project? | [ ] [ ]  |
| Were the data or specimens originally collected as part of clinical care? | [ ] [ ]  |
| Were the data or specimens originally collected for research purposes under a UCR IRB approved application?  *If “yes”, provide the IRB number:*      . *If not obtained at UCR, attach the consent form under which the data or specimens were obtained.* | [ ] [ ]  |
| Does the party providing the data have an ownership interest in the data? | [ ] [ ]  |
| Is the party providing the data expected to contribute to the publication? | [ ] [ ]  |
| Has any IRB approved or disapproved use of the data? *If “yes”, please identify the IRB(s) and state whether the use of the data was approved*  *or disapproved:*       | [ ] [ ]  |

**11. Is this project a Clinical Investigation [FDA]?** (Skip section if not applicable)

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| **FDA**: Clinical investigations involving human subjects: ***Must*** submit an IRB application | **Yes No** |
| Does your project include testing the safety and efficacy of a drug or device in a human subject, including analysis or comparison of outcome data about a drug or device?  | [ ] [ ]  |
| Does your project include a non-FDA-approved assay or In *Vitro* Diagnostic Device? | [ ] [ ]  |
| Will any data resulting from this activity be submitted to the FDA? | [ ] [ ]  |

**12. Other Considerations**

|  |  |
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|  | **Yes No** |
| Does your project involve the use of fetal tissue? *If “yes”, name the source in the procedures box.* | [ ] [ ]  |
| Does your project involve human embryonic stem cells, adult human stem cells, pluripotent cells or somatic cell nuclear transfer? | [ ] [ ]  |
| Is your project being conducted all or in part at another UCR-affiliated institution?  *If “yes”, specify where:* | [ ] [ ]  |
| Are you planning on submitting genotype/phenotype data to any of the following NIH-supported repositories (i.e., dbGaP, GEO, SRA or CaHUB)?  | [ ] [ ]  |
| Is this study generating human or non-human genomic data (e.g., SNP arrays, genome sequencing, RNA sequencing, transcriptomic, metagenomics, epigenomic and gene expression data, GWAS studies) from more than 100 individuals?  | [ ] [ ]  |