

## Questions at a Glance for KR Protocols

**Questions at a Glance - Non human Subjects Research:** UC Irvine IRB review is required for *most* activities that constitute engagement in human subjects research, as federally defined. This *Questions at a Glance* aid is intended to help you 1) determine if your project involves activities that require IRB Review and 2) prepare you in advance for questions that may be asked in KR Protocols.

<b>Project Details</b>					
Specify the Activity Title	Type in answer and continue to next question.				
Lead Researcher/Investigator	Begin typing the name to expand the dropdown menu, select name and continue.				
Department	Begin typing on the line under the paragraph to expand the dropdown menu, select department and continue to <a href="#">General Questionnaire</a> .				
<b>General Questionnaire</b>					
Describe the purpose of the proposed activity?	Summarize under 250 words and continue.				
<b>Study Team Personnel</b>					
Who may serve as Lead Researcher of an UCI Protocol Application?	List Faculty Sponsor and/or Administrative Contact (as applicable) by clicking the "Add Line" button and proceed to <a href="#">NIH Genomic Data Sharing (GDS) Policy</a>				
<b>NIH Genomic Data Sharing (GDS) Policy</b>					
Is the research subject to the <a href="#">NIH Genomic Data Sharing (GDS) Policy</a> (see <a href="#">policy FAQs</a> )?	<table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;">Y</td> <td>If "Yes", requires IRB Review - "Abandon" to exit</td> </tr> <tr> <td style="text-align: center;">N</td> <td>If "No", proceed to <a href="#">Determining Whether Research Is Clinical Investigation per FDA Regulations</a></td> </tr> </table>	Y	If "Yes", requires IRB Review - "Abandon" to exit	N	If "No", proceed to <a href="#">Determining Whether Research Is Clinical Investigation per FDA Regulations</a>
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Does the research involve a human subject as defined by FDA (21 CFR 50.3(g))?	<table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;">Y</td> <td>If "Yes", continue to next question.</td> </tr> <tr> <td style="text-align: center;">N</td> <td>If "No", proceed to <a href="#">Determination of "Research"</a></td> </tr> </table>	Y	If "Yes", continue to next question.	N	If "No", proceed to <a href="#">Determination of "Research"</a>
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Is the research a <i>clinical investigation</i> ?	<table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;">Y</td> <td>If "Yes", requires IRB Review - "Abandon" to exit</td> </tr> <tr> <td style="text-align: center;">N</td> <td>If "No", proceed to <a href="#">Determination of "Research"</a>.</td> </tr> </table>	Y	If "Yes", requires IRB Review - "Abandon" to exit	N	If "No", proceed to <a href="#">Determination of "Research"</a> .
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Does the proposed activity involve a <i>systematic</i> approach?	<table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;">Y</td> <td>If "Yes", continue to next question.</td> </tr> <tr> <td style="text-align: center;">N</td> <td>If "No", proceed to <a href="#">Engagement of Institutions</a>.</td> </tr> </table>	Y	If "Yes", continue to next question.	N	If "No", proceed to <a href="#">Engagement of Institutions</a> .
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Is the intent of the proposed activity to develop or contribute to generalizable knowledge? (i.e. Is it Quality Improvement (QI) research?)	<table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;">Y</td> <td>If "Yes", proceed to <a href="#">Determination of "Human Subject"</a> .</td> </tr> <tr> <td style="text-align: center;">N</td> <td>If "No", proceed to <a href="#">Engagement of Institutions</a>.</td> </tr> </table>	Y	If "Yes", proceed to <a href="#">Determination of "Human Subject"</a> .	N	If "No", proceed to <a href="#">Engagement of Institutions</a> .
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<b>Determination of "Human Subject"</b>					
Does the research involve obtaining information or biospecimens about <i>living individuals</i> through <i>intervention</i> or <i>interaction</i> with the individuals?	<table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;">Y</td> <td>If "Yes", requires IRB Review - "Abandon" to exit.</td> </tr> <tr> <td style="text-align: center;">N</td> <td>If "No", continue to next question.</td> </tr> </table>	Y	If "Yes", requires IRB Review - "Abandon" to exit.	N	If "No", continue to next question.
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Does the research involve obtaining <i>identifiable private information</i> or <i>identifiable biospecimen</i> about living individuals?	<table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;">Y</td> <td>If "Yes", requires IRB Review - "Abandon" to exit.</td> </tr> <tr> <td style="text-align: center;">N</td> <td>If "No", continue to next question.</td> </tr> </table>	Y	If "Yes", requires IRB Review - "Abandon" to exit.	N	If "No", continue to next question.
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Does the research involve the use or disclosure of protected health information (PHI) about <i>deceased</i> individuals?	<table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;">Y</td> <td>If "Yes", requires IRB Review - "Abandon" to exit.</td> </tr> <tr> <td style="text-align: center;">N</td> <td>If "No", continue to next question.</td> </tr> </table>	Y	If "Yes", requires IRB Review - "Abandon" to exit.	N	If "No", continue to next question.
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Does the research involve the use of a limited data set (LDS)? An LDS may include only the following PHI identifiers: 1) five digit zip code; 2) dates of birth and death; 3) dates of admission and discharge; 4) a geographic subdivision other than street address.	<table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;">Y</td> <td>If "YES", proceed to <a href="#">Engagement of Institutions</a>.</td> </tr> <tr> <td style="text-align: center;">N</td> <td>If "No", continue to next question.</td> </tr> </table>	Y	If "YES", proceed to <a href="#">Engagement of Institutions</a> .	N	If "No", continue to next question.
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N	If "No", continue to next question.				
Does the research involve the use of coded private information/specimens?	<table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;">Y</td> <td>If "Yes", continue to next paragraph.</td> </tr> <tr> <td style="text-align: center;">N</td> <td>If "No", proceed to <a href="#">Engagement of Institutions</a>.</td> </tr> </table>	Y	If "Yes", continue to next paragraph.	N	If "No", proceed to <a href="#">Engagement of Institutions</a> .
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The investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information/specimens pertain. (Confirm one of four options listed)

**1st, 2nd or 3rd** If options 1, 2 or 3 are selected, proceed to [Engagement of Institutions](#).

**4th** **If selected, requires IRB Review** - "Abandon" to exit.

### Engagement of Institutions

**NOTE: In this section and you will be asked a series of questions and, based on various combinations of answers to those questions, be instructed to either continue to Activity Information or "Abandon" .**

#### Questions

Has UCI received an award through a grant, contract or cooperative agreement directly from [HHS entities](#) or [signatories of the Common Rule](#) for non-exempt human subjects research and all activities involving human subjects are carried out by employees or agents of another institution (i.e. Subaward involved)?

Will employees or agents intervene for research purposes with any human subjects of the research by performing invasive or noninvasive procedures (e.g., conduct research interviews or administer questionnaires, collect saliva or blood, administer drugs or other treatments; surgically implant medical devices)?

Will employees or agents **only** perform commercial or other services for investigators provided that the services performed do not merit professional recognition or publication privileges, the services performed are typically performed for non-research purposes, and employees or agents do not administer any study intervention being tested or evaluated under this protocol?

Will employees or agents intervene for research purposes with any human subject of the research by manipulating the environment (e.g., control environmental light, sound, or temperature; orchestrate social interactions)?

Will employees or agents **only** perform commercial or other services for investigators provided that the following statements are true?

Will employees or agents obtain for research purposes identifiable private information or identifiable biological specimens from any source for the research (e.g., observing or recording private behavior; using for research purposes identifiable private information or identifiable specimens provided by another institution; or identifiable private information or using identifiable specimens already in the possession of the investigators)?

### Activity Information

Were the information/specimens originally collected for research purposes? Select one option:

Not originally collected for research.

Collected for research under an UCI IRB approved protocol.

Collected for research under a non-UCI IRB approved protocol.

Collected for research by a commercial vendor.

#### Options

**1st** If selected, provide explanation and proceed to next section to indicate [Source\(s\)](#) .

**2nd** If selected, specify the Approved UCI IRB Protocol #, check one of the options under **Confirmation** and proceed to [Source\(s\)](#) .

**3rd** If selected, check one of the options under **Confirmation** and proceed to [Source\(s\)](#) .

**4th** If selected, check one of the options under **Confirmation** and proceed to [Source\(s\)](#) .

**Sources** - Please note that more than one source may be applicable and each one has specific instructions.

Indicate the source and how the study team will access the de-identified information and/or de-identified biospecimens. (Check all that apply).

Internet sources

UCI Health Data: UCI Health Enterprise Data & Analytics / Honest Broker (HDGC Data Steward & IRB approved protocol HS# 2012-8757)

UCI Health Data: Center for Artificial Intelligence in Diagnostic Medicine (CAIDM) (HDGC Data Steward & IRB approved protocol HS# 2018-4417)

UCI Health Data: Experimental Tissue Resources (ETR) (HDGC Data Steward & IRB approved protocol HS# 2012-8716)

UCI IRB approved protocol

Commercial entity/vendor

The study team will obtain biospecimens directly from the UCI Health clinic or the operation room.

Other, non-UCI health

#### Checkbox

**1st** If applicable, check box and proceed to [Internet Sources](#).

**2nd** If applicable, check box and proceed to UCI Health Data: **UCI Health Enterprise Data & Analytics**.

**3rd** Proceed to [Submission Information](#).

**4th** Proceed to [Submission Information](#).

**5th** Proceed to [UCI IRB Approved Protocol](#).

**6th** Proceed to [Commercial Entity/Vendor](#).

**7th** 1) Enter Clinic/Operation room information 2) check box to confirm you will maintain Pathology Clearance documentation in your records, and then 3) proceed to [Submission Information](#).

**8th** Proceed to [Other, non-UCI health](#).

### Internet Sources

Check box to confirm Confirmation statement is true and proceed to [Submission Information](#).

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<b>UCI Health Enterprise Data &amp; Analytics</b>		
Cohort selection criteria/clinical terms from the Cohort Discovery Tool (e.g., Demographics: Gender, Diagnoses: Asthma, Procedures: Operations on digestive system):		Provide all requested information and continue.
Expected cohort size/patient count:		Provide all requested information and continue.
Cohort attributes or data elements (e.g., lab test values, medication, etc.):		Provide all requested information and proceed to <a href="#">Submission Information</a> .
<b>UCI IRB Approved Protocol</b>		
Enter the Approved UCI IRB Protocol #:		Type in requested information and proceed to <a href="#">Submission Information</a> .
<b>Commercial Entity/Vendor</b>		
Enter entity/vendor:		Type in requested information and proceed to <a href="#">Submission Information</a> .
<b>Other, non-UCI health</b>		
Provide explanation		Type in requested information and proceed to <a href="#">Submission Information</a> .
<b>Submission Information</b>		
Do you need written confirmation from the Human Research Protections (HRP) office that UCI is “Not Engaged in Human Subjects Research”?	<b>Y</b>	If "Yes" is selected, click <b>"Submit"</b> button at top right to submit your NHSR determination form to HRP office and the <b>"Back"</b> button to return to the Manage Protocols List page. Here you will see your submitted NHSR form in the Protocol List and current status.
	<b>N</b>	If "No" is selected, you do <b>NOT</b> need to submit this form to the HRP office, unless you require written confirmation. Please click the <b>'Abandon'</b> button at the top right to withdraw the form. You may click on the <b>'Print'</b> button to print a copy of the completed form for your records.

### Next Steps

HRP staff will now review your submission and make a determination. If the HRP office determines your proposed activity **DOES NOT** constitute human subjects research, you will receive a confirmation email from KR Protocols. This is your official written confirmation, please do not delete this email.

If the HRP office determines your proposed activity DOES constitute human subjects research, you will receive a notification email from KR Protocols with instructions on how to submit either an [IRB Application](#) for UCI IRB review or how to complete the [Exempt Self-Determination Tool](#).