

# NIH Single IRB Policy Guidance for UC Davis Investigators

## Applicability Checklist

If all conditions below are met, the NIH Single IRB Policy is applicable:

<input type="checkbox"/>	<p>The research receives NIH support through a grant, cooperative agreement, contract, or Intramural Research (1 or 2 is true):</p> <ol style="list-style-type: none"><li>1. The grant application <u>is submitted</u> to NIH on or after January 25, 2018, and<ul style="list-style-type: none"><li>○ The grant is an “R”, “P”, or “U” grant; and</li><li>○ The application is for a competing grant (new, renewal, revision, or resubmission).</li></ul></li><li>2. The NIH contract solicitation <u>is issued</u> on or after January 25, 2018.</li></ol> <p>Includes:</p> <ul style="list-style-type: none"><li>• Cooperative agreements</li><li>• NIH Intramural studies submitted for initial IRB review</li><li>• Small Business Innovation Research (SBIR)</li><li>• Small Business Technology Transfer (STTR)</li><li>• Cooperative Research and Development Agreements (CRADAs)</li><li>• Interagency Agreements (IAA)</li></ul>
<input type="checkbox"/>	<p>The human subject research is not exempt.</p> <ul style="list-style-type: none"><li>• The research requires IRB review and approval at the Expedited or Full Board level</li></ul>
<input type="checkbox"/>	<p>Two or more U.S. sites/institutions conduct the research</p>
<input type="checkbox"/>	<p>The same protocol will be conducted at each U.S. site/institution.</p> <ul style="list-style-type: none"><li>• Protocols that address the same research questions, involve the same methodologies, and evaluate the same outcomes and the only variations are in enrollment of subjects due to local context considerations; or</li><li>• A separate site is used for study coordination or coordination of data and statistical analysis.</li></ul>

The NIH Single IRB Policy does not apply to:

- Career development, research training or fellowship awards (“K”, “T”, and “F” grants)
- Ongoing projects that are *not* being submitted for consideration of a competing grant (such as non-competing continuing grant)
- Other Transaction Agreements (OTAs)
- Foreign research collaborating institutions/sites

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### Exceptions to the Policy

The following are exceptions to the NIH Single IRB Policy. If you plan to use one or more exceptions, you must identify and justify the exceptions in the plan for IRB Review section of your proposal.

<input type="checkbox"/>	<p><b>Policy-based</b></p> <ul style="list-style-type: none"> <li>When review by a single IRB would be prohibited by federal, tribal, or state laws, regulations or policies.</li> </ul>
<input type="checkbox"/>	<p><b>Time-limited</b></p> <ul style="list-style-type: none"> <li>When ancillary studies are part of ongoing studies or parent studies</li> <li>Not required to use a single IRB until the parent study is expected to comply with the single IRB policy.</li> </ul>
<input type="checkbox"/>	<p><b>Compelling Justification - <i>Requires NIH Exceptions Review Committee Approval</i></b></p> <ul style="list-style-type: none"> <li>Other requests for exceptions that are not based on a legal, regulatory, or policy requirement if there is a compelling justification for the exception.</li> </ul> <p>Requests for exceptions that are not based on a legal, regulatory, or policy requirement will be considered if there is a compelling justification for the exception. The NIH will determine whether to grant an exception following an assessment of the need.</p> <p>NIH anticipates granting very few of these exception requests. Most exceptions are expected to be site-specific, that is, the exception to single IRB review will be made for a particular site, but all other sites conducting the same protocol will rely on the single IRB.</p> <p>NIH will post case studies and guidance for compelling justification after the NIH has evaluated a number of actual requests. There is no scheduled date for release of this guidance.</p>

**When in doubt regarding whether your proposed study must comply with the single IRB policy, consult with your Program Officer.**

### Single IRB Plan Checklist

Your proposal must include the single IRB plan. At minimum, the plan:

<input type="checkbox"/>	Identifies an IRB of Record that is registered with OHRP and is willing to serve as the IRB of Record.
<input type="checkbox"/>	States that all participating domestic sites will agree to rely on the designated IRB of Record
<input type="checkbox"/>	<p>Indicates who will maintain the IRB Authorization records and other documentation</p> <ul style="list-style-type: none"> <li>UC Davis IRB maintains all IRB Authorization records</li> <li>Other documentation maybe maintained by others at UC Davis</li> </ul>
<input type="checkbox"/>	Briefly describes how communication between sites and the sIRB will be handled.
<input type="checkbox"/>	<p>Explains and justify any exceptions:</p> <ul style="list-style-type: none"> <li>Policy-based: cites legal or policy basis for exception</li> <li>Time-limited: provides parent study information</li> <li>Compelling Justification: provides justification</li> </ul>
<input type="checkbox"/>	If the study is delayed onset, include information regarding compliance with the NIH Policy in the delayed onset study justification. A complete Single IRB plan must be provided to the NIH prior to initiating the study.

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## Sample Single IRB Plan

The single IRB Plan is an attachment to the application. Do not attach IRB Authorization Agreements or the communication plans. The following sample text may be used as a starting point for the single IRB. The plan will need to be consistent with the needs of the proposed research. Consult with the IRB Reliance Team before submitting the proposal to ensure the IRB agrees with your plan.

The University of California, Davis will serve as the single IRB for this study for all participating sites, including the lead site, data coordinating center, and those selected or added after award. Sites will sign a reliance agreement that will include a communication plan. All participating sites will agree to rely on the designated single IRB, with the exceptions requested below.

IRB Authorization Agreements and other documentation necessary in order to document compliance with the NIH single IRB policy are maintained by University of California, Davis IRB.

The single IRB uses several mechanisms to communicate with the sites, including IRBNet, email, phone calls, and direct person-to-person communications as needed. Official IRB determinations are issued through IRBNet.

### EXCEPTION TO POLICY REQUEST

We are requesting an exception from the single IRB requirement for the following participating sites. Each site will obtain separate IRB review.

<b>Name of Institution</b>	<b>Justification for Exception</b>
Veteran's Affairs, [NAME OF SITE]	Policy-based: Local VA policy [CITE POLICY NUMBER] prohibits external IRB review.
[NAME OF TRIBAL ORGANIZATION]	Policy-based: Tribal policy [CITE POLICY NUMBER] require local IRB review.
[NAME OF ORGANIZATION]	Policy-based: [NAME OF ORGANIZATION] will obtain IRB review and approval from the State's IRB [NAME OF IRB]. State Law [CITE LEGISLATION] requires review by the State's IRB for research conducted by [NAME OF ORGANIZATION] and involving identifiable health information obtained from the State records.
[NAME OF ORGANIZATION]	Time-limited: This is an ancillary study to [GRANT ID and NAME OF PARENT STUDY]. The parent study is an on-going study that is not subject to the Policy. The site(s) will comply with the single IRB policy when the parent study is submitted for competitive renewal.
[NAME OF ORGANIZATION]	Compelling Justification: [PROVIDE JUSTIFICATION]

### DELAYED ONSET

This study is delayed onset because the plans for human subjects research cannot be defined at this time. Initial results from Part A of the study is required before determining whether a portion of the research will involve human subjects, as described in the Delayed Onset Study Justification attachment.

If the study requires research involving human subjects, all participating sites will follow the NIH single IRB policy. We will provide the single IRB plan prior to the start of the study.

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## Budget

IRB costs may be Direct or Indirect. Be sure to allocate the fees in the correct section of the Budget. If fees are direct cost fees, they are factored into the total Direct Cost Cap.

**Policy-based and Time-limited exceptions should not be included in the budget.** These are standing exceptions and should not generate single IRB costs.

**Budget as if there are no Compelling Justification exceptions.** Do not assume that the request will be granted. If the exception is approved, NIH will adjust the budget prior to award to remove single IRB costs for the excepted sites.

Consider Additional Staffing:

- IRB Liaison to manage IRB communications - Expect studies with more than a handful of sites to require significant additional staffing resources to manage the complex communications and document management associated with the use of a single IRB and with IRB-related coordination across sites. Consider adding additional staffing to Key Personnel and/or Budget Justification sections of a NIH grant.
- Personnel to ensure compliance with document management requirements for all sites

## UC Davis Fee Schedule

When UC Davis is the IRB of record, fees are expected to be charged per relying non-UCD site and are **Direct Costs**. Visit the [IRB Fees webpage](#) for more information.

Consult with the Reliance Team regarding whether a reliance agreement already exists with the proposed participating sites and which cost is applicable for a participating site.

There are no proposed fees for submission of amendments, closure of a site, or reportable information.

Review of submissions for UC Davis sites are incorporated in the Indirect Costs allocation. There will be no direct charge for these submissions.

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### Responsibilities

The NIH single IRB policy outlines responsibilities of involved parties. Ensure you understand your responsibilities and know to whom tasks are delegated.

	<b>Applicant / Offeror</b>	<b>Awardee (Institution)</b>	<b>IRB of Record</b>	<b>All Sites</b>	<b>Investigator (all sites)</b>
Submitting a plan describing the use of a single IRB	X				
Ensuring compliance with NIH Policy	X				
Ensuring that authorization agreements are in place (Tasks may be delegated.)		X			
Maintaining copies of authorization agreements and other necessary documentation in order to document compliance with the policy (Tasks may be delegated.)		X			
Ensuring that a mechanism for communication between the single IRB and participating sites is established (Tasks may be delegated.)		X			
Conducting the ethical review as specified under the regulations at 45 CFR Part 46			X		
Collaborating with the awardee to establish a mechanism for communication between the single IRB and the participating sites			X		
Rely on the designated single IRB for regulatory and ethical review				X	
Meeting other regulatory obligations				X	
Communicate relevant information necessary for the single IRB to consider local context issues and state/local regulatory requirements during its deliberations				X	
Following the approved protocol					X
Communication with the single IRB					X
Submission of reportable events to the single IRB					X
Submission of proposed amendments to the single IRB					X

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## NIH Resources

- Policy: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html>
- FAQ: <https://osp.od.nih.gov/clinical-research/implementation-of-the-sirb-policy/>
- Email: [SingleIRBPolicy@mail.nih.gov](mailto:SingleIRBPolicy@mail.nih.gov)

## Submission to UC Davis IRB

Consult with the Reliance Team ([HS-IRBreliance@ucdavis.edu](mailto:HS-IRBreliance@ucdavis.edu)) to:

- Ensure IRB Authorization Agreements are in place and fully executed
- Receive instructions for submission to the IRB
  - Request to Rely: UC Davis IRB requires submission of a request to rely along with applicable documentation prior to agreeing to rely on another IRB.
  - When UC Davis is the IRB of record, the set-up of the submissions will likely require submission of a CORE (study-wide) package and separate, but linked packaged for each site. The IRB Reliance Team will ensure the packages are set-up correctly.