

University of California, Irvine  
Human Research Protections  
Standard Operating Procedures

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**Title: IRB Delegation of Authority for Human Subject Research**

**Date of Last Revision: 05-31-2016, 03-08-2018, 04-15-2019, 10-07-2019, 12-05-2022**

**Audience: IRB Chairs, HRP Staff**

**Reviewers:**

An experienced Reviewer is an IRB Committee Chair, his/her designee(s) for subcommittee or an HRP Staff Reviewer (**TIER 1** and **TIER 2**) who has received training relative to the exempt and expedited review categories and HRP policies. HRP Staff Reviewers are delegated the authority to review and approve minimal risk research as noted on Page 2. Exceptions are noted. This document is to be maintained on the [WIKI](#).

HRP Staff will use best judgement when considering if an item that falls within their scope of review, ultimately would be best considered for approval by a non HRP Staff IRB Member.

**NON HRP STAFF IRB MEMBER:**

- Chair, Vice Chair or another designated IRB member or alternate member.

**HRP STAFF REVIEWER:**

- **TIER 1:** Administrator or above, CIP certified **and** appointed as IRB members or alternate members.
- **TIER 2:** Analysts or above, CIP certified. Those without current CIP have been designated by an IRB Chair, Director or Assistant Director of Human Research Protections to have the appropriate experience to review minimal risk protocols.

TYPE OF SUBMISSION	EXEMPT <sup>1</sup> NEW, AMEND <sup>2</sup> , RENEW	EXPEDITED NEW, AMEND <sup>2</sup> , RENEW
WHO CAN REVIEW THESE?	<b>IRB MEMBER (NON-STAFF)</b> <b>HRP STAFF REVIEWER TIER 1</b> <b>HRP STAFF REVIEWER TIER 2</b>	<b>IRB MEMBER (NON-STAFF)</b> <b>HRP STAFF REVIEWER TIER 1</b> <b>HRP STAFF REVIEWER TIER 2</b>
WHAT ARE THE EXCEPTIONS?	<p><b>Only an IRB MEMBER or TIER 1 may review:</b></p> <ol style="list-style-type: none"> <li>1. Limited IRB review</li> <li>2. New or changes to waiver of HIPAA</li> <li>3. Involves California Information Practices Act</li> </ol> <p><b>Only an IRB MEMBER may review:</b></p> <ol style="list-style-type: none"> <li>4. New or changes to disclosure of financial interest</li> <li>5. Potential noncompliance or unanticipated problem reported during last approval period</li> </ol>	<p><b>EXPEDITED RESEARCH:</b></p> <p><b>Only an IRB MEMBER or TIER 1 may review:</b></p> <ol style="list-style-type: none"> <li>1. Inclusion of vulnerable populations</li> <li>2. New or changes to waiver of HIPAA</li> <li>3. Involves California Information Practices Act</li> <li>4. Expedited Categories: 8a, 8c</li> </ol> <p><b>Only an IRB MEMBER may review:</b></p> <ol style="list-style-type: none"> <li>5. FDA regulated research</li> <li>6. New or changes to disclosure of financial interest</li> <li>7. New or changes to inclusion of prisoners</li> <li>8. Expedited Categories: 1, 8b, 9, 13</li> <li>9. Potential noncompliance or unanticipated problem reported during last approval period</li> </ol> <p><b>EXPEDITED AMENDMENTS FOR GREATER THAN MINIMAL RISK RESEARCH:</b></p> <p><b>Only an IRB MEMBER may review:</b></p> <ol style="list-style-type: none"> <li>1. Change in LR or FS or a Co-R</li> <li>2. Changes to existing eligibility criteria or the addition of a new subject population</li> <li>3. Adding <i>any</i> new procedures</li> <li>4. Adding questions about sensitive behavior and health status</li> <li>5. Changes to consent process</li> <li>6. Changes to compensation plan</li> </ol>

<sup>1</sup> INCLUDES BOTH PRE-2018 COMMON RULE AND 2018 COMMON RULE EXEMPT CATEGORIES.

<sup>2</sup> FOR EXAMPLES OF ACCEPTABLE AMENDMENTS TO BE REVIEWED BY DESIGNATED REVIEWERS (NOT INCLUSIVE), SEE HRPP POLICY # 17.

**IRB CHAIR APPROVAL:**

I have reviewed the updated plan for HRP Staff Reviewer Delegation of Authority as summarized above and noted in HRPP policy and find the plan acceptable. The revised plan will take effect on January 01, 2023 or later on a per committee basis as determined by the date of the IRB Chair's signature.

DocuSigned by:



12/12/2022

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**Tahseen Mozaffar, MD**  
**Chair, Institutional Review Board "A"**

**Date**

DocuSigned by:



12/12/2022

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**Kenneth G. Linden, MD, PhD**  
**Chair, Institutional Review Board "B"**

**Date**

DocuSigned by:



12/12/2022

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**Elizabeth Cauffman, PhD**  
**Chair, Institutional Review Board "C"**

**Date**

DocuSigned by:



12/12/2022

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**Cristobal Barrios, MD**  
**Vice-Chair, TEAM "D"**

**Date**