

**August 22, 2022**

**To:** Human Research Protection Program Offices  
**Subject:** Guidance on Certain Terms in IRB Reliance Agreements

### **Purpose**

The purpose of this Guidance Memo is to provide information to Human Research Protection Program (HRPP) staff about important concepts in Reliance Agreements that should be carefully considered, and when applicable, the appropriate campus office or official that should be consulted.

### **Definitions**

**Reliance Agreement:** A formal, written document that provides a mechanism for an institution engaged in human subjects research to delegate institutional review board (IRB) review to an IRB of another institution or an independent IRB. The agreement outlines the responsibilities of each party (such as reporting requirements, research oversight, and communication among the sites) and delegates review authority to one site, typically known as the IRB of Record. Institutions may use different descriptive terms for a Reliance Agreement, such as a cooperative agreement, IRB authorization agreement (IAA), or memorandum of understanding (MOU).

**Participating Institution:** An institution that is a signatory to a Reliance Agreement.

**Reviewing IRB, Single IRB, or IRB of Record:** The IRB to which authority for IRB review and oversight has been ceded by a Participating Institution for an instance of research under the Reliance Agreement.

**Relying IRB:** A Participating Institution that cedes IRB review to a Reviewing IRB for an instance of Research under the Reliance Agreement.

### **Background: Federal Single IRB Requirements and Reliance Agreements**

On June 21, 2016, the National Institutes of Health (NIH) issued a [Policy on the use of single IRBs](#). A single IRB review is an arrangement where one IRB provides review services for one or more sites participating in a study. The NIH Single IRB Policy requires institutions participating in NIH-funded non-exempt human subjects research where each domestic site is conducting the same protocol to cede IRB review to one IRB for that project. This Policy only applies to domestic sites conducting research supported by NIH through grants, cooperative agreements,

contracts, or the NIH Intramural Research Program with receipt dates on or after January 25, 2018. The NIH website has [more information on NIH's Single IRB Policy](#).

Effective January 20, 2020, the revised Common Rule requires that US institutions engaged in federally supported cooperative research rely on a single IRB to oversee the portion of the research conducted at US sites. Cooperative research is defined at [45 CFR 46.114\(a\)](#) as research projects that involve more than one institution.

Institutions engaged in single IRB review must document their reliance arrangement. Regulations do not prescribe how such documentation must be accomplished, but typically they are achieved by the establishment of a Reliance Agreement. Reliance Agreements may cover one protocol, multiple protocols, or all research within a certain set of parameters.

As with any other contract, Reliance Agreements must be signed on behalf of the University by a person with written delegated authority to do so. At UC, Institutional Officials (IOs), or their designees, are vested with the authority to make the decision to review for or rely on another IRB and have the authority to sign Reliance Agreements. Some Reliance Agreements, such as the [SMART IRB Agreement](#), may require participating institutions to identify an individual (known as the Point of Contact) who will communicate on behalf of the institution regarding the Reliance Agreement.

### **Guidance on Certain Terms in Reliance Agreements**

While Reliance Agreements typically delegate IRB review responsibilities and oversight to one IRB, some Reliance Agreements might introduce certain terms that commit UC to legal requirements, such as imposing liability upon UC, or conversely, terms that limit the liability of other Participating Institutions. As a result, HRPP staff are advised to carefully review certain provisions in a Reliance Agreement. These terms, discussed in detail below, include 1) indemnification, 2) insurance, and 3) governing law. If these terms appear in a Reliance Agreement and do not conform to the guidance below, consult the appropriate campus office or official identified below.

#### **1. Indemnification**

An indemnification provision in an agreement transfers risk of damages or loss from one party to another party. Indemnification obligations can flow to both parties. For example, a Reviewing IRB could agree to indemnify a Relying IRB for damages caused by the Reviewing IRB's failure to appropriately review a study. Conversely, a Relying IRB could also agree to indemnify the Reviewing IRB for damages the Reviewing IRB incurs arising from the Relying IRB's negligent failure to substantially comply with any applicable regulatory requirements.

The language of an indemnification clause should only hold UC liable for the culpable acts or omissions of its own employees, officers, agents, students, invitees or guests. Requiring UC to assume liability for other parties such as subcontractors and consultants that are not under UC's control is considered "third party liability."

[Standing Order 100.4\(dd\)\(9\)](#) prohibits UC from assuming liability for the conduct of persons other than UC officers, agents, employees, students, invitees, and guests. If the indemnification obligations are not directly limited to the actions (or inactions) of UC, the terms may violate the Standing Order. Assumption of such "third party liability" cannot be accepted in a Reliance Agreement, except as specifically approved by the Board of UC Regents. Accordingly, the

language in an indemnification clause should only hold UC liable for the acts or omissions of its own officers, employees, students or agents.

UC can comply with the Standing Order by ensuring that its obligations to indemnify are limited “in proportion and to the extent such losses are directly caused by the acts or omissions of UC, its employees and agents.” This phrase is commonly referred to as the “proportionality clause,” and it ensures there is a direct connection between UC’s actions and its indemnity liability. Indemnification provisions that require UC to indemnify for losses “caused by,” “resulting from” or “arising from” UC’s performance under the agreement are acceptable so long as the proportionality clause is included. Note that it is unacceptable to agree to UC indemnifying for losses “pertaining to,” “incidental to,” “connected to,” or “relating to” the agreement or UC’s performance under the agreement because those phrases do not establish a tight enough connection between the losses and UC’s liability.

Whether UC is the Relying IRB or Reviewing IRB, UC should seek terms in its Reliance Agreements for which the other party agrees to indemnify UC for any damages to UC caused by the other party’s acts or omissions. Mutual indemnification, where each party indemnifies the other, is also appropriate.

In evaluating whether to accept terms that include no obligation for the other party to indemnify UC, or the appropriateness of an indemnification provision, UC should evaluate the risks and consider the types of liability it could face, for example:

- Is UC the Reviewing or Relying IRB?
- Who is the other party and what confidence do we have with their role?
- What is the likelihood that UC could incur damages?
- What type of study is being conducted?
- Are invasive procedures involved?

Below are some examples of unacceptable and acceptable indemnification provisions. The appropriateness of any provision should take into consideration the risk assessment described above.

	<b>Example of Unacceptable Indemnification Provision</b>	<b>Example of Acceptable Indemnification Provision</b>
<b>Example of where UC indemnifies the other party</b>	UC shall indemnify, defend and hold harmless ABC from liability <i>relating to</i> the negligent acts or omissions of UC.	UC shall indemnify, defend and hold harmless ABC from liability <i>arising out of UC’s performance of work under this agreement, but only in proportion to and to the extent such liability is caused by</i> the negligent or intentional acts or omissions of UC.
<b>Example of mutual indemnification</b>	Each party shall defend, indemnify, and hold the other, its officers, employees, and agents harmless from and against any and all losses,	Each party shall defend, indemnify, and hold the other, its officers, employees, and agents harmless from and against any and all losses, expenses (including,

	<p>expenses (including, without limitation, reasonable attorney's fees and costs), damages, and liabilities of any kind ("Damages") <b>in connection with</b> the Indemnifier's performance of this Agreement.</p>	<p>without limitation, reasonable attorney's fees and costs), damages, and liabilities of any kind ("Damages") <b>resulting from or arising out of</b> the Indemnifier's performance of this Agreement, <b>but only in proportion to and to the extent such liability, loss, expense, attorney's fees, or claims for injury or damages are caused by or result from</b> the negligent or intentional acts or omissions of indemnifying party, its officers, agents, or employees.</p>
<p><b>Example of language allowing institutions that have state laws to limit liability. As an instrumentality of the State of California, UC's liability is limited by its Standing Orders.</b></p>	<p>If a Responsible Institution, as an instrumentality of a state/federal government, is further limited in substance by <b>the applicable law of the state or federal jurisdiction</b> in which such Responsible Institution serves as an instrumentality to the extent that <b>such applicable law</b> is designed to protect and limit the liability of such Responsible Institution as an instrumentality of such state/federal government, then the Responsible Institution's obligations to the Other Institution and/or the Other Institutional Representatives pursuant to this paragraph shall be limited <b>to the extent of such applicable law.</b></p>	<p>If a Responsible Institution, as an instrumentality of a state/federal government, is further limited in substance by <b>its regulations, policies or the applicable law of the state or federal jurisdiction</b> in which such Responsible Institution serves as an instrumentality to the extent that <b>such regulations, policies or applicable law</b> are designed to protect and limit the liability of such Responsible Institution as an instrumentality of such state/federal government, then the Responsible Institution's obligations to the Other Institution and/or the Other Institutional Representatives pursuant to this paragraph shall be limited <b>to the extent of such regulations, policies or applicable law.</b></p>

Similarly, some institutions may seek to limit their liability in a Reliance Agreement with a "limitation of liability" provision. For example, "ABC shall not be responsible for any consequential damages," or "ABC shall not be responsible for any claims of bodily injury."

Silence on indemnification may be acceptable. Aside from seeking the protections of indemnification when appropriate, another critical issue is ensuring that the Reliance Agreement language does not require UC to take on liability for any actions that are not its own. While a suitable agreement provision makes this explicit, silence also ensures that the

Reliance Agreement does not conflict with UC policy, including most importantly the Standing Order prohibiting UC from taking on third party liability. It may be helpful to communicate with other parties that UC's Standing Orders are considered applicable law.

If an indemnification or "limitation of liability" clause appears in a Reliance Agreement, and you are unsure if it is acceptable, or when you could remain silent, consult your campus counsel and/or risk management office.

## 2. Insurance

A Reliance Agreement may contain provisions relating to UC's and other party's insurance. Silence on insurance in the Reliance Agreement is an acceptable position.

### *UC's Insurance:*

Participating Institutions may require UC to carry certain insurance, at certain retention levels. UC's risk management coverage includes a variety of insurance programs, with various retentions. Refer to the following resources explaining UC's insurance programs and policies:

- [UC Insurance Programs](#),
- [Chapter 21-300 of the Contract and Grant Manual](#), and
- [Business and Finance Bulletin BUS-81](#).

Consult your local risk manager when there are questions about UC's coverage.

### *The Other Party's Insurance:*

Reliance Agreements may include provisions addressing the other party's insurance coverage. Refer to the [Certificates of Insurance/Self Insurance webpage](#) and consult your local risk manager for questions relating to specific requirements your location may have with respect to insurance. The types of insurance and retention levels UC may require in a particular agreement will depend upon location practices, as well as the considerations mentioned in the indemnification section of this guidance.

The following language may be acceptable, depending upon the study, UC's role, and the location:

*ABC will provide at its expense, and maintain throughout the term of this Agreement, general liability coverage in an amount no less than each claim/ annual aggregate, and officer and director liability coverage in an amount no less than each claim/ annual aggregate. Upon request, ABC agrees to provide Institution with Certificates of Insurance demonstrating this coverage.*

## 3. Governing Law

A governing law provision refers to the specific law that the court will apply when hearing and evaluating a dispute between the parties. In any Reliance Agreement to which UC is a party, the governing law should be California law. But, if the other Participating Institution will not agree to California law, UC may agree to silence on governing law; that is, the contract either may not reference a specific state law that would govern, or the parties may state in the Reliance Agreement that Governing Law is "Intentionally Omitted."

Deviations from either approach must be reviewed and approved by the campus counsel or UC Legal. Below is an example of what a governing law provision may look like within a Reliance Agreement.

*This Agreement shall be governed by the laws of the state of California without regard to the conflict of laws provisions thereof, regardless of the place of execution or performance.*

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