agreement regarding their respective roles within the scope of the research project.

Without fully knowing who is providing funding for the research, it is difficult to determine each institutions' specific responsibilities. Regulatory oversight hinges on answers to questions such as who is

the actual grantee and which institution owns the animals. According to its Rules of Accreditation, AAALAC International follows animal ownership to determine who is responsible for animals at an offsite program². The grantee institution in this case is Great Eastern; the animals are thus

owned by them. Assuming the funding is from the National Institutes of Health (NIH), the animal work is also covered by the Public Health Service (PHS) Policy.

As the work utilizes a recombinant mouse-adapted strain of SARS-CoV-2, an IBC must review Mayfield's proposed work for compliance with the NIH Guidelines (Section IV-B-2-b-(1))³. Coverage by NIH Guidelines "includes research collaboration or contractual agreements" (Section I-C-1-a [2]). The ABSL3 work constitutes a contractual agreement or subaward⁴; NIH Guidelines must be met at the CRO. An IBC may, based on its home institution's policies, allow oversight of the work by a second IBC (i.e., at the CRO).

We postulate that the difference in approvals between the CRO and Great Eastern IBC stems from differences in either institutional risk tolerance, a lack of knowledge regarding the CRO's ABSL3 biosafety features, or both. This risk is not without merit. Failure to adequately identify and mitigate biosafety risks at the CRO could jeopardize both human health (e.g., escaped mouse) and any further NIH funding for the grantee (Great Eastern). To reduce the university's institutional risk, Great Eastern's IO and its responsible official (often, but not always the same individual) should create a memorandum of understanding (MOU) between the university and CRO. Without such an MOU, Mayfield's research cannot proceed. The MOU should clearly state that the onus of all IACUC and IBC regulatory oversight and compliance lies with the CRO. In this way, we believe that University risk is mitigated while allowing Mayfield's valuable SARS-CoV-2 work to proceed.

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A WORD FROM OLAW

In response to the issues posed in this scenario, the National Institutes of Health – Office of Laboratory Animal Welfare (NIH-OLAW) provides the following clarification with the assumption that the research is funded by NIH:

In this scenario, two institutions are partnering to conduct SARS-CoV-2 coronavirus research. There are differences of opinion between the Institutional Biosafety Committees about the safety conditions necessary for conducting the research with infected mice. The question asked is what regulatory requirements must the IACUC follow.

As mentioned by other reviewers, NIH grants policy requires that when a grantee institution collaborates with another organization, the primary recipient of the grant funds is accountable for the performance of the project and all other obligations specified in the grants policy¹. It also states that the primary recipient is responsible for including these requirements in its agreements with collaborating organizations^{1,2}.

In addition to the NIH grants requirements above, the institution must adhere to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*. The Institutional Biosafety Committee (IBC) must ensure that research conducted at or sponsored by the institution is conducted in compliance with the *Guidelines* and applicable laboratory safety guidance^{3–5}.

In this case, assuming both institutions have an Animal Welfare Assurance with OLAW, there is no federal requirement for dual IACUC review^{1,6}. Agreement between the GEU IBC and the CRO's IBC is the key to resolving the situation. As highlighted in the *Guide for the Care and Use of Laboratory Animals*, "interinstitutional collaborations have the potential to create ambiguities about responsibility for animal care and use"⁷. An expanded written agreement describing IBC and IACUC oversight when disagreements arise would have both institutions well-positioned

to quickly resolve the issue. Absent that, the GEU IACUC should make it clear to Dr. Mayfield that work at the CRO may not proceed until the two IBCs agree on necessary safety conditions.

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