A Word from the USDA

In response to the issues raised in this scenario, the United States Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care (USDA, APHIS, AC) offers the following clarification and guidance:

The issue relevant to the Animal Welfare Act (AWA) is whether IACUC oversight is required to use blood and tissues obtained from an agricultural study in a biomedical pilot project.

The definition of an “animal” under the AWA and its regulations determines whether IACUC oversight is required. An animal is defined as any live or dead animal (warm-blooded) used or intended to be used for research, teaching, testing, research, or experimentation¹. An animal activity that meets any of these criteria requires IACUC oversight, unless other statutory and regulatory exclusions apply². With respect to the term “animal,” the definition excludes livestock or poultry, used or intended for use as food or fiber; improving animal nutrition, breeding, management, or production efficiency; or for improving the quality of food or fiber¹. An animal activity that meets any of these criteria does not require IACUC oversight under the AWA regulations³.

In this scenario, the animals on the milk quality study are not covered under the AWA regulations because the animals are livestock used for improving the quality of food (milk). For this reason, the sharing of tissue and blood obtained from this project with an investigator conducting biomedical research does not require IACUC oversight. However, IACUC oversight would be necessary if the animals on the milk quality study are subjected to additional collections or activities not otherwise required by the study and that are only performed to support the pilot biomedical project. Those additional activities would be covered under the AWA regulations and require IACUC review and approval².

1. 7 U.S.C. § 2132(g); 9 C.F.R. § 1.1 (Title 9, Chapter 1 Subchapter A § 1.1 –Definitions)
2. Title 9, Chapter 1 Subchapter A § 2.31(d)
3. Policy 17- Regulation of Agricultural Animals

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would be able to use any remaining fluids or tissues after Ramos has collected her samples, without IACUC review.

If Ramos will not be euthanizing the animals to collect her samples, will she be collecting additional types or quantities of blood, milk, or tissue to provide to Mason? If Ramos is collecting additional samples for Mason, then Mason will need to submit a protocol application to the IACUC for review. This protocol would need to identify Ramos’ animals as the tissue source. If Ramos did not collect extra samples, Mason can use any remaining fluid or tissue samples not used by Ramos, without IACUC review or approval.

Although Mason’s research is biomedical in nature and Ramos’ is agricultural, the two PIs could still use the same animals, even if a protocol is also required for Mason’s research. The experimental conditions of the protocol determine the housing conditions, not biomedical versus agricultural². Assuming the animals require no special housing requirements to be used for Mason’s study, the animals can continue to be housed as appropriate for Ramos’ study. Even though Mason’s project would be regulated by the USDA, Ramos’ is not because the goal of her research is to improve the quality of food (i.e., milk and meat) (§ 2132(g)(3); ref. 1).

- 1 Animal Welfare Act, 7 USC, § 2132(g)(3).
- 2 Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).

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This scenario is a good example of how Reduction (one of the 3Rs) can be applied to minimize the number of animals needed to complete both the agricultural and biomedical studies². The IACUC Chair is most likely correct in thinking that an IACUC

protocol is not necessary in this situation, but a couple questions do need to be addressed to confirm this.

Will Ramos be euthanizing the animals in order to obtain the blood, milk, and tissue samples for her project? If so, Mason