

“The most prudent approach is to study BSE prions at a minimum in a BSL-2 facility. When performing necropsies on large animals where there is an opportunity that the worker may be accidentally splashed or have contact with high-risk materials... personnel should wear full body coverage personal protective equipment... Although there is no evidence to suggest that aerosol transmission occurs in the natural disease, it is prudent to avoid the generation of aerosols or droplets during the manipulation of tissues or fluids and during the necropsy of experimental animals. It is further strongly recommended that impervious gloves be worn for activities that provide the opportunity for skin contact with infectious tissues and fluids.”⁷ The University should consider performing a risk assessment to ensure the safety of personnel.

1. Public Health Service. Policy on Humane Care and Use of Laboratory Animals (US Department of Health and Human Services, Washington, DC, 1986; amended 2015).
2. Animal Welfare Act and Animal Welfare Regulations. Institute for Laboratory Animal Research.
3. Guide for the Care and Use of Laboratory Animals (National Academies Press, Washington, DC, 2010).
4. Guide for the Care and Use of Agricultural Animals in Research and Teaching. (Federation of Animal Science Societies, Champaign, IL, 2010).
5. AAALAC International. Position Statements: Definition of “Laboratory Animals”. <http://aaalac.org/accreditation/positionstatements.cfm#labanimals>
6. The Center for Food Security & Public Health. Bovine Spongiform Encephalopathy. http://www.cfsph.iastate.edu/Factsheets/pdfs/bovine_spongiform_encephalopathy.pdf
7. Biosafety in Microbiological and Biomedical Laboratories (U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention and National Institutes of Health, US Government Printing Office, Washington, 2007).

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RESPONSE

IACUC approval for the sake of prudence, not welfare

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We believe that while there is no animal welfare issue to be addressed by including Mason’s biomedical research on an IACUC

protocol, it would be prudent from a regulatory standpoint to include it on one.

The Animal Welfare Regulations exclude farm animals used or intended for use for improving the quality of food or fiber¹. We assume Ramos’ work is not federally funded, so there is no regulatory requirement for this work to be included on an approved IACUC protocol through the PHS *Policy on Humane Care and Use of Laboratory Animals*². Based on the response of the IACUC chair, we further assume that the program of animal care and use at Great Eastern University excludes the use of agricultural animals in the improvement of food or fiber. Therefore, there is no institutional requirement for this work to be on an approved IACUC protocol. Further thoughts on this latter assumption will be discussed later in the response.

If the samples for Mason’s work were exclusively left over from the samples taken for Ramos’ work, then additional IACUC approval would not be necessary under the above assumptions. However, because Mason may require a specific number of samples under controlled circumstances or may require additional samples beyond those left over from the agricultural work, having an IACUC approved protocol for his work would be prudent to ensure regulatory compliance for the biomedical research as it moves forward. In addition, some journals require a statement that described animal work was covered under an IACUC protocol. The IACUC should establish that only biomedical personnel taking samples for use in Mason’s work (ie Mason and his staff) be included on an IACUC protocol. Under this condition, Ramos’ work should not be affected, but she would need to allow Mason to obtain his own samples.

With respect to the institutional exclusion of Ramos’ work from an IACUC protocol in the first place, we had two additional thoughts. First, we wondered whether Great Eastern University is AAALAC accredited or not. AAALAC follows the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (the *Ag Guide*) as one of its primary references. The *Ag Guide* states that an active IACUC is a critical component of an effective institutional program of agricultural animal care and use³. *The IACUC Handbook* states that “In order to preserve relations with the USDA and a good reputation and to obtain and maintain AAALAC accreditation,

any institution doing agricultural research with food and fiber species should endorse the principles in the agricultural guide.”⁴ Second, if Ramos’ work includes instruction of trainees or students, this teaching component might fall under the Animal Welfare Regulations. If Great Eastern is AAALAC accredited, or if Ramos’ use of these animals includes teaching, then we would expect her work to be described in an IACUC protocol.

1. United States Department of Agriculture. *Animal Welfare Act and Animal Welfare Regulations*. November 2013.
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals*. (US Department of Health and Human Services, Washington, DC, 1986; revised 2015).
3. Federation of Animal Science Societies. *Guide for the Care and Use of Agricultural Animals in Research and Teaching*, 3rd edition. (FASS, Champaign, IL, January 2010).
4. Silverman J, Suckow M, Murthy S, eds. *The IACUC Handbook*, 3rd edition. (CRC Press, New York, NY, 2014).

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RESPONSE

Sample Sharing

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One question this scenario raises is why Ramos had never interacted with an IACUC if she was conducting research using vertebrate animals. While Ramos’ project doesn’t require IACUC review (§ 2132(g)(3); ref. 1), it is good practice to communicate to the IACUC all of the activities using animals or animal tissues and let the Committee determine if it needs to be reviewed. This helps to ensure that no animals are used without prior approval from the IACUC. Additionally, the IACUC may have had specific recommendations for the sampling procedures or for the husbandry and care of these hybrid animals. Depending on the types of tissues collected, it may be necessary to have the institute’s Biosafety Officer perform a risk assessment for possible transmission of bovine spongiform encephalopathy. It would be helpful for Great Eastern to develop a policy to address tissue sharing if these sorts of collaborations are common.