

Jerald Silverman, DVM, Column Coordinator

## Managing a pending IBC approval

“I don’t know how many times I’ve said this, but I’ll say it again. There is no such thing as a conditional or limited approval. We can’t approve a protocol based on something that may happen in the future, even if we’re almost sure it’s going to happen.” With that, Dr. Larry Covelli, chairman of the Great Eastern University IACUC, began to discuss the next protocol on his list.

“Hold on, Larry,” said Seth Gordon, “I think we used the wrong wording, but the concept isn’t wrong. We want to approve this protocol in its entirety. We’re saying that Dr. Francis can’t start her biocontainment work with rats until her IBC [Institutional Biosafety Committee] approval comes through, but she can start all of her non-biocontainment mouse work in the meantime.”

“I’m not worried about the wording, Seth,” said Covelli. “It’s the concept of a limited approval that you and the others are promoting that I think is plainly wrong, but I can easily check that.” Covelli went online to the OLAW website, and under ‘Frequently Asked Questions’ he found the following statement:

“If the IACUC determines that a protocol is approvable, contingent on receipt of a

very specific administrative modification or clarification (e.g., a contact telephone number), the Committee may handle the issue as an administrative detail that an individual (e.g., IACUC Chair or Administrator) may verify. Requests for substantive modifications should result in the protocol coming back to the Committee. Protocols that lack substantive information necessary for the IACUC to make a judgment (e.g., justification for withholding analgesics in a painful procedure) should be considered incomplete and the IACUC should defer review until the requisite information is provided by the investigator.”

“So I’m right,” said Gordon. “The IBC approval is just an administrative detail we’re waiting for, and whenever it arrives, the rat part of the research can start because we’ve already approved all of the actual animal work.”

“No, I don’t think so,” said Covelli. “The IBC approval is a substantive piece of information that’s missing. Even though the work with rats has been approved by us, we can’t give Dr. Francis approval for moving ahead with only part of her study. But I have an idea. What if we ask her to delete the rat segment of the study, and we can approve

the protocol for the mouse work only? When we get the IBC approval, Dr. Francis can amend her protocol to add the rats. Is that a good compromise for everybody?”

“Not really,” Seth Gordon replied. “The IBC is slow enough, and now you’re suggesting a major amendment to add a new species. That can delay things at least a couple of weeks more. I have a better idea. Since the IACUC has already discussed and approved all the rat work, why can’t the addition of the rats be a minor amendment and you can give it immediate IACUC approval when Francis submits it? Is that okay with you?” Covelli thought about it for a few moments and agreed with Gordon’s suggestion. With that understanding in place, Covelli finally moved on to the discussion of the next protocol.

Was Covelli right when he said that the IACUC could not let Dr. Francis begin any work on her protocol until the IBC approval arrived for the segment that used rats? Was he right in agreeing with Gordon that amending the protocol with an additional species of animals can be considered a minor amendment if the IACUC had already discussed and approved the use of the animals? Would you have done anything differently?

### RESPONSE

#### Communicate with the PI

Shan Yan, PhD & Yvette Huet, PhD

The PHS *Policy on Humane Care and Use of Laboratory Animals* (PHS Policy)<sup>1</sup> allows an IACUC to review protocols with three possible outcomes: approval, requiring modifications in (to secure approval) and withholding approval. Covelli’s initial point that there is no option for conditional or limited approval is consistent with the PHS Policy. In our opinion, the IBC approval is an administrative approval as long as

the IBC approves the protocol without modifications. Francis, the Principal Investigator (PI), cannot start to work on animals until the administrative approval from the IBC is provided and the protocol is officially approved by the IACUC. Allowing Francis to start her mouse work without an IACUC protocol approval, as suggested by Gordon, is an apparent violation of the PHS Policy<sup>1</sup> and the *Guide for the Care and Use of Laboratory Animals*<sup>2</sup>.

The compromise suggested by Covelli is a more practical approach. The IACUC can require the PI to remove the rat segment to secure the approval of mouse work. Then the PI can start her mouse work under the

approved IACUC protocol. Once the IBC approval is provided, the PI can submit the rat work as an amendment to the approved protocol. We believe that such an amendment should be considered a major amendment, not a minor one, and must be reviewed by the IACUC again. The IACUC can decide whether this amendment will receive Full Committee Review or Designated Member Review (DMR). The DMR method may allow the amendment to be approved more quickly, because it does not require a convened meeting of a quorum of the IACUC members.

When Covelli and the IACUC discussed how to proceed with this protocol, they did