**IACUC Training Exercise #4 – 2020 (Signatures)**

The following exercise may be useful in stimulating discussion regarding compliance with PHS Policy and VA Handbook 1200.07. To facilitate discussion, page 1 of the exercise may be distributed to the IACUC members prior to a meeting. After a few minutes of discussion about the exercise during the meeting, the remainder of the exercise may be distributed to provide ideas for the committee’s consideration.

Signatures! Signatures! Dr. Carmen Barbosa has been the new IACUC Chair for 2 whole weeks at the Hometown VAMC, and she has begun to think she is spending more time with Ann Marie, the IACUC Manager, than with her own family. Yesterday, the IACUC “met” (remotely, of course, this being 2020) for the first time with Dr. Barbosa as the Chair, and this afternoon, she is supposed to meet in person with Ann Marie to deal with a whole list of things that Ann Marie says Dr. Barbosa has to sign. Ann Marie mentioned something about signatures on the approved ACORPs, and also signatures on the latest semiannual report, which the IACUC voted to approve yesterday. Dr. Barbosa is worried about the time it will take away from her working on her MERIT application renewal, when she commutes to and from the VA, and goes through all the hassles of remembering her mask, going through screening to get into the building, and maintaining appropriate distances from others in the office. She knows that Ann Marie uses an electronic system to manage all the routing and tracking of IACUC documentation, and she believes that the system records every action it takes, including who initiated the action and when, so she wonders why signatures are even needed. Or if signatures are still needed, Dr. Barbosa wonders whether she can authorize Ann Marie to sign on her behalf? Even in her short time as Chair, it has become clear to Dr. Barbosa that Ann Marie really knows what needs to be done (far more than Dr. Barbosa herself does!), does not ask Dr. Barbosa to do anything Ann Marie can take care of, and is absolutely trustworthy!

What do you think Ann Marie will say about using the automatic electronic tracking of transactions in place of signatures, or finding a way to make it clear that Ann Marie is acting on behalf of Dr. Barbosa?

The key is understanding the functions of each signature, and determining whether the electronic system ensures that those functions are served. Think of some functions that each of the signatures serves, and bring those ideas to contribute to the discussion at the next IACUC meeting.

Ann Marie responded diplomatically that for the electronic system in use at Hometown VAMC, the answer, regrettably, is “no”. Then she explained to Dr. Barbosa what the functions are, of the signatures on the IACUC documents:

In general, a signature on a document shows that the signer takes some sort of responsibility for the document. This both encourages the signer to recognize that responsibility, and confirms for others that the signer has done so. For documents related to oversight of research with animals, the signatures must be an integral part of each document, as these documents are subject to FOIA requests, and it is important always to provide the public with the certification statements and signatures along with the documents. To be meaningful, those evaluating the document must have some confidence that the signer is the one who applied the signature. VA Handbook 6510 specifies that, “A … signature … allows the recipient to prove the origin of the document and to protect against forgery.”

More specifically, the significance of any signature depends on the statement and document that it is attached to.

The ACORP (<https://www.research.va.gov/programs/animal_research/documents.cfm>) -- Item Z contains specific certification statements to which each signatures applies. These commit the signer to meeting stated responsibilities and/or confirming that certain actions have been taken, and are more specific than what committee document management systems commonly do, recording the details of transactions in the system. For each signature to serve its function in Item Z then, there has to be some assurance that the signer has seen the corresponding certification statement and recognizes that the signature indicates agreement with it. It is not sufficient for the system to contain a separate note saying, for example, that the individual who submitted the document is understood to have agreed to the certification statement. Such a note could not be generally relied upon to reflect the signer’s conscious intent, and this mechanism does not make the signature an integral part of the document itself.

The Main Body of the ACORP requires the signatures of the PI (commits to conducting the work only as described in the signed version), and the Chair and AV (confirms that the signed version is the one that was reviewed and approved by the IACUC). The PI’s signature may be provided before or after IACUC approval is granted, as long as it is on the file copy of the version that the IACUC approved. The Chair’s and AV’s signatures must be provided after the IACUC grants approval. As discussed in Guidance Document AR2020-001 (<https://www.research.va.gov/programs/animal_research/guidance.cfm>), these signatures are now required by VA on every approved ACORP.

Other signatures in Item Z apply to the appendices of the ACORP, and the certification statements associated with them are for the benefit of the IACUC. As such, it is left to the discretion of the IACUC whether to require those signatures or to instead rely on other assurances that the matters in the certification statements have been satisfactorily addressed. If the IACUC requires those signatures, they are of course only meaningful if provided before the IACUC reviews the ACORP.

The semiannual report -- The signatures of the IACUC members are required by the Animal Welfare Regulations, and they document on the report that is presented to the Institutional Official that a majority of the voting membership of the IACUC has approved the report. VA policy requires presentation of the findings of the report to the Director, personally, so the personal signature of the Director is also required, to document receipt of (but not necessarily agreement with) the report. Here again, it is not sufficient for an administrator to add a note to the electronic system, certifying that enough IACUC members have approved and the Director has received the report.

Collecting signatures -- Although the signatures have to be provided personally by the required signers, and they have to be unambiguously associated with the certification statements in the documents, Ann Marie explained to Dr. Barbosa that there is some flexibility in how the required signatures are gathered. “Wet” signatures (handwritten in ink) below the certification statement on a hard copy of the document are of course always acceptable. When the IACUC members “meet” from different remote locations (as during pandemic conditions), it is also acceptable for the pages showing the certification statements and the wet signatures to be scanned and submitted electronically to the IACUC administrator. Signatures applied by digital signature technology that meets the requirements of VA Handbook 6510 are also acceptable. It is not even necessary to circulate the signature page(s) to collect all of the signatures on the same page – a collection of separate pages, each signed by a different individual signer, suffices as long as it is clearly designated on each page, which specific document the certification statement and signature apply to.