

**Carome, Michael A (HHS/OPHS)**

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**From:** Peter Iafrate [IAFRAR@shands.ufl.edu]  
**Sent:** Friday, October 03, 2008 12:29 PM  
**To:** PSC Humansubjectstraining  
**Cc:** Lin, Melody (HHS/OPHS)  
**Subject:** Required Human Subjects Training

To the Reader,

I have been on the IRB at the University of Florida for 24 years, I have been Chairman for the last 11 years. At UF over the years, investigators are required to have HIPAA training, billing compliance training, training for submissions to the IACUC, and most recently research billing compliance. All these were mandated due to outside influences (either regulatory based or as a result of compliance issues). However, there is no requirement for human subjects protection training. Although the IRB provides many educational events, and I feel we run a tight ship (AAHRPP accredited, etc.) attendance is voluntary, and usually attended by research coordinator types and not the investigators.

For the most part, Universities react to crises. So if you have had an OHRP crisis, then you probably have mandatory training. With the push back many IRB's are getting regarding turn-around-time, mission creep, etc., unless it is mandated that Human Subjects training is required, there will always be many who think they need no training. I feel we do a great job at monitoring and resolving issues, but a lot of time is wasted on resolving compliance issues that investigators were not aware, or don't appreciate the impact.

My recommendation is for OHRP to mandate training for all investigators prior to submitting their first protocol to their IRB. I think OHRP should include a general list of the topics to be covered, and that should include training on the local IRB process, forms, etc. In addition, study coordinators must be included in the training. There should also be an annual training update, where items can be reviewed, for example new regulations, updates on how OHRP and others might be surveying regulations, and reviewing local IRB issues (eg. common compliance issues, new forms, etc.). Thanks for the opportunity to comment.

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10/6/2008

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## Carome, Michael A (HHS/OPHS)

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**From:** Bolton, Laurie [laurie.bolton@seattlechildrens.org]  
**Sent:** Tuesday, October 07, 2008 12:28 AM  
**To:** PSC Humansubjectstraining  
**Subject:** Human Subjects Protection Training and Education

Captain Michael A. Carome, M.D.:

Thank you on behalf of Seattle Children's Hospital for the opportunity to provide comment about the following: (a) whether OHRP should issue additional guidance recommending that institutions engaged in human subjects research conducted or supported by the Department of Health and Human Services (HHS) implement training and education programs for certain individuals involved in the conduct, review, or oversight of human subjects research; or (b) whether HHS should develop a regulation requiring the implementation of such training and education programs.

Seattle Children's Hospital respectfully requests OHRP to consider issuing guidance recommending that institutions implement human subjects training and education programs rather than developing regulation requiring the same. We believe that it would be important to afford institutions freedom to develop human subjects training and education programs that are tailored to and that will be effective in their local research contexts. The most effective programs would likely involve a variety of means and approaches that take into account the uniqueness of local settings to ensure that those individuals involved in human subjects research on a variety of levels are adequately educated about human subjects protections. It would be difficult and far less effective to prescribe specific human subjects training and education requirements through either regulation or guidance.

Thank you again for this opportunity. Please contact me if you have any questions about this comment.

Laurie J. Bolton, J.D.  
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