IRB members find it very helpful to have copies of all instruments to be used to be submitted as appendices to the application. Reading the instruments is essential to the board's assessment of participant risk and burden and the adequacy of the study description in the informed consent. Occasionally, however, investigators do not include all or full copies of instruments on the grounds that the instrument is copyrighted and in the belief that making copies to submit with an IRB application is a violation of copyright law. However, instrument developers and publishers are surely aware that instrument users must obtain IRB approval of their research and that approval requires review of all study materials. Therefore, the instrument developers can be said to have given implied consent to making copies of their instrument for IRB review. Providing copies to the IRB is also likely to be considered a fair use of the instruments under copyright law. IRB members are well aware of their own ethical responsibility to honor copyright and purchase contracts by investigators and to refrain from use of copyrighted material for purposes other than those related to their IRB obligations.

On the advice of University Legal Counsel, investigators are requested to include copies of all instruments, even if copyrighted or purchased, for IRB review. If you have any questions or concerns about this issue, please contact the Director of Research Compliance, Ms. Tanta Myles, at 348-8461.