

IRB Board Member/Reviewer Guidance for Limited and Expedited Review

Exempt Limited Review

- Can be used when 1) there are possible identifiers (such as in questions or in a recording), and 2) there is possible risk to employment, etc.
- Must be low risk
- In this case, there must be additional review of the security of the data.
- Two Board members will review these issues in an Expedited Review manner, while the RERC will complete the rest of the Exempt review.
- The Board members will be given 7 business days to complete this review.
- The Board members may request additional safeguards for the confidentiality of the participants and the security of the data.
- This will help bring us into alignment with OHRP in terms of video and audio recording, in cases of minimal risk.

Expedited Review

- The New Common Rule includes details about use of deception (when the participant is not aware that there will be possible deception) and audio and video recording where participants may be identified.
- We may be able to review some recordings through Limited IRB Exempt Review as discussed above.
 - Use of video recording, if it meets the requirements above, may be reviewed as Limited Review for example.
 - Audio recordings with the use of pseudonyms may still fall under Exempt review especially if minimal risk.
- Any deception that is not already agreed to by the participant must be reviewed through Expedited Review (two Board members – not the RERC—must review these).
 - Specifically, the reviewer must see that there is a discussion of what the deception was and why it was used in a written debriefing at the end of the study.

Summary

- **The Board will see more reviews in between Full Board meetings as we come into alignment with the Common Rule on these issues.**
- **This also helps to lighten administrative burden on the Full Board, while making sure that the responsibilities of review are not mainly on one person (the RERC).**

- **There have been concerns voiced that most protocols are only reviewed by one person, this will help with that issue as well. Fully Exempt Protocols will still be reviewed by the RERC as is appropriate.**