

APPENDIX 3: Request for an Exemption from 15 C.F.R. Part 27 for Research Involving Human Subjects in Information Technology, Manufacturing, or Non-clinical Imaging Studies

Responses to the following questions must be supplied along with the initial proposal submission or when a request for exemption is made during a current ATP award, to allow NIST and ATP to perform an independent determination of whether the use of human subjects qualifies for an exemption from the requirements of 15 C.F.R. Part 27. Keep in mind that the term data includes collection of data from voice, video, digital or non-clinical image recordings made for research purposes. To request exemptions for research activities contained in proposals or current ATP awards involving biological studies, complete the form attached as Appendix 4. If a question is not applicable, please indicate "NA."

1. What is the time frame (start and end dates) for human subject/data/image involvement?
2. How is the project planning to use human subjects in the research?
3. State the technical justification for human subject/data/image involvement. Is there a way to achieve an equivalent technical outcome without this involvement? Explain.
4. Is any of the data preexisting?
 - a. For the preexisting data, describe the data and how it is being obtained. Is it being obtained through a purchase, a donation from a source outside the project, or a project participant or collaborator?
 - b. Are the data/images stripped of any identifiable information (e.g., personal identifiers such as names or codes that can be traced back to the human donor or source)? Explain.
 - c. Are the data/images publicly available from a named source? Explain and name the source(s) being considered or planned, if appropriate.
 - d. Please explain the terms under which you are obtaining the data.

NOTE: An answer of "yes" to question 6 may disqualify the research activity from exemption under 15 C.F.R. Part 27. In these cases, the proposal protocol/ task descriptions MUST be reviewed and approved by an IRB that possesses a current assurance appropriate for the research in question, on file with the OHRP, and approved by OHRP for federalwide use. This IRB approval will be requested if the proposal is selected as a semifinalist. Ongoing projects with IRB reviews should submit documentation as outlined in Chapter 1 Section F.

5. Are any data and images being collected for the express purpose of this research? Or is any of the data being collected during the project primarily for purposes other than this project?
 - a. Please explain the source of the data/image/recording (e.g., video archives, proprietary database, security systems/records, medical records, video conference records).
 - b. What entity and/or individuals are collecting this data? What is their relationship to the project?
 - c. What is the extent of contact by these entities or individuals with the subjects?

- d. What is the extent of control by these entities or individuals over the environment in which the human subjects will be monitored?
 - e. What is the extent of contact by anyone on the project or connected to an institution that is involved in the project.
6. Do the data/images/recording come from individuals (e.g., children or prisoners) who may need special safeguards?

NOTE: An answer of "yes" to question 6 may disqualify the research activity from exemption under 15 C.F.R. Part 27. In these cases, the proposal protocol/ task descriptions MUST be reviewed and approved by an IRB that possesses a current assurance appropriate for the research in question, on file with the OHRP, and approved by OHRP for federalwide use. This IRB approval will be requested if the proposal is selected as a semifinalist. Ongoing projects with IRB reviews should submit documentation as outlined in Chapter 1 Section F.

7. Is the image/recording in fact "public behavior"? Some indicators of public behavior are the following:
- a. The image of behavior does not give rise to any cause of action under any legal theory protecting personal privacy.
 - b. There are no trade secrets or other confidential information pertaining to any person contained in the image or recording.
 - c. There are no copyright restrictions, or the copyright holder has granted written permission to the proposer.
 - d. The image of behavior contains any other matter the proposer deems germane to this issue.
8. If the answer to question 7 is "yes":
- a. Can the human subjects be identified directly or through identifiers?
 - b. If the human subject can be identified, would any disclosure reasonably place the subject at risk of criminal or civil liability, or would it jeopardize standing, employability, or reputation?
9. Has the research been reviewed by an IRB? If yes, attach a copy of the review. (See Chapter 1, Section F)

The following signed statement must accompany the answers to the above questions:

This is an accurate description of the proposed research involving human subjects. Any changes in protocol or task descriptions will be submitted in advance to the IRB as appropriate and to ATP before notification for an ATP award or current project decisions.

Signature of Principal Investigator

Date