APPENDIX 3

Request for an Exemption From 15 C.F.R. Part 27 for Research Involving Human Subjects in Information Technology, Manufacturing, or Imaging Studies

If the research may be exempt under 15 C.F.R. § 27.101(b), as indicated by your responses to the questions in The Human Subjects Determination Checklist (Appendix 2), then responses to the following questions must be supplied along with the initial proposal submission (Gate 1) to allow NIST and ATP to perform an independent determination of whether the use of human subjects qualifies for an exemption from 15 C.F.R. Part 27. Proposers are reminded that the term *data* includes collection of data from voice, video, digital, or image recordings made for research purposes. For proposals involving biological studies, please complete 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. State the technical justification for human subject/data/image involvement (i.e., Is there no other way to achieve an equivalent technical outcome? Why?).

3. 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.

4. Are the data/images publicly available from a named source? Explain and name the source(s) being considered or planned, if appropriate.

   NOTE: An answer of "no" to either question 3 or question 4 may disqualify the project from an exemption. In those cases, an appropriate IRB approval may be required and should accompany the proposal if the work is within the first year of the project.

5. Are the data/images/recording preexisting, being collected for the express purpose of the research, or being obtained by some combination of the two?

6. What is the source of the data/images/recording (e.g., video archives, proprietary database, security systems/records, medical records, video conference records)?

7. What is the extent of data/images/recording handling by the Principal Investigator: collecting, receiving, and/or sending data/images?

8. What is the extent of contact by the Principal Investigator with human subjects: personal observation, image recording, survey questions?

9. What is the extent of control by the Principal Investigator of the environment in which the human subjects will be monitored?

10. Do the data/images/recording come from individuals (e.g., minor children or prisoners) who may need special safeguards? NOTE: An answer of "yes" to question 10 disqualifies the project 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. The assurance must be on file with the OHRP, and approved by OHRP for federalwide use. This IRB approval MUST be submitted by the time of oral review (Gate 3).

11. 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. No trade secrets or other confidential information pertaining to any person are in the image or recording.

    c. No copyright restrictions exist, or the copyright holder has granted written permission to the proposer.

    d. The image of behavior contains other matter the proposer deems germane to this issue.

12. If the answer to question 11 is "yes":

    a. Can the human subjects be identified directly or through identifiers?

    b. If the human subjects can be identified, would any disclosure reasonably place the subjects at risk of criminal or civil liability, or would it jeopardize standing, employability, or reputation?

13. Has the research been reviewed by an IRB? If yes, attach a copy of the review.

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 of ATP award decisions.

_____ _____

Name of Principal Investigator Date