APPENDIX 2

Human Subjects Determination Checklist

This checklist should be used to determine whether human subjects are involved in the research project and whether the research is exempt under the Department of Commerce regulations for the protection of human subjects found at 15 C.F.R. Part 27. A proposal may contain more than one research activity involving human subjects that requires different levels of review. This checklist should be used for each potential use of human subjects.

1. Is there an intervention or an interaction with a living person that would not be occurring or would be occurring in some other fashion but for this research? Examples: videotaping people, observing children using software, surveying manufacturing personnel during a pilot test of new equipment, gathering tissue or cells from human donors.

   ☐ Yes—Human subjects are involved. Go to question 3.

   ☐ No—Go to question 2.

2. a. Will data/information/specimens collected originally from people or about people be used in this research? Examples: broadcast video, Web-use logs, medical information, cells or tissues, survey questions.

      ☐ Yes—Identifiable human subjects may be involved. Go to question 2.b.

      ☐ No—Go to question 6. It appears that human subjects may not be involved in the project. However, an exemption determination may be required. Please review question 3 for additional information about research that may require an exemption determination.

   b. Does that information contain private information in a form in which the identity of the subject is or may readily be ascertained from the information? Examples: medical records, donor name or address, sales transaction records.

      ☐ Yes—Identifiable human subjects are involved. Go to question 3 to see if an exemption may apply. If you know that an exemption does not apply, proceed to question 5.

      ☐ No—Go to question 3. The research may not be within the scope of 15 C.F.R. Part 27; however, it may require an exemption determination to be made due to the use of data, recordings, or specimens that could be linked to humans without appropriate safeguards.

3. Do you think the research may either not be within the scope of 15 C.F.R. Part 27 or qualify for an exemption under 15 C.F.R. § 27.101(b)? The following questions will help you evaluate whether to request an exemption determination by ATP or provide documentation that the research may not be within the scope of 15 C.F.R. Part 27:

   a. Will the task involving human subjects use only existing data, recordings (audio or visual), or specimens? Examples: patient records, a company's customer data, Web-use logs, cells, or tissue.

      ☐ Yes—Go to question 3.d.

      ☐ No—Go to question 3.b.

   b. Will the research plan involve normal educational practices such as instructional strategies or comparison of instructional techniques, curricula, or classroom management methods? Examples: observation of student-teacher interactions, video of instruction.

      ☐ Yes—Go to question 3.d.

      ☐ No—Go to question 3.c.

   c. Will the research plan involve educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior? Examples: broadcast video, software usage testing.

      ☐ Yes—Go to question 3.d.

      ☐ No—Go to question 5. This research is probably not exempt and will require Institutional Review Board (IRB) review and approval.

   d. Do any of the data, recordings, specimens, or practices/procedures involve or come from a protected class? Protected classes include prisoners, children, pregnant women, human in vitro fertilization, fetuses, and nonviable fetuses or fetal sources of data, cells, or tissue. Examples: testing educational software with children, surveys of obstetric patients.

      ☐ Yes—Go to question 5. This research is probably not exempt and will require IRB review and approval.

      ☐ No—Go to question 3.e.

   e. Are the data, recordings (audio or visual), or specimens publicly available? NOTE: Publicly available may include items for sale, items that are freely available to the public, or items that reside in the public domain. Examples: customer data sets, catalog orders of cells or tissues, donations of pathological specimens, shareware.

☐ Yes—Go to question 4. This research may be exempt under 15 C.F.R. § 27.101(b).

☐ No—Go to question 3.f.

f. Will the data, recordings (audio or visual), or specimens be stripped of all identifiable information that could be linked to a human subject prior to being received by the investigator?

☐ Yes—Go to question 4. This research may not be within the scope of 15 C.F.R. Part 27, or this research may be exempt under 15 C.F.R. § 27.101(b).

☐ No—Go to question 3.g.

g. Will information be recorded by the investigator in such a way that it can be linked to the human subject? Examples: Web-use logs tied to e-mail address, patient records, or specimens that include patient identifiers.

☐ Yes—Go to question 5. This research is probably not exempt and will need an IRB review.

☐ No—Go to question 4. This research may be exempt under 15 C.F.R. § 27.101(b).

4. An exemption under 15 C.F.R. § 27.101(b) may apply to the task, or the task may not be within the scope of 15 C.F.R. Part 27. In order to complete the necessary requirements for research considered exempt under 15 C.F.R § 27.101(b), please review this booklet. Complete Appendix 3 and/or Appendix 4 in this booklet as required and submit with Gate 1 proposal.

5. An exemption probably does not apply to the proposed research and further documentation is required. Please review this ATP booklet. See Appendix 5 for required documentation list.

6. It appears that human subjects are not involved in this project. This checklist is only a tool for general guidance and does not constitute a final legal opinion from NIST on whether human subjects are involved, or whether an exemption determination under the regulations is needed. If, upon NIST/ATP review of your proposal, it is determined that additional documentation is needed to reach a final determination, and your proposal is selected as a semifinalist (Gate 3), you will be asked to provide the additional documentation prior to an oral review.