APPENDIX 4

Request for an Exemption From 15 C.F.R. Part 27 for Research Involving Human Subjects in Biological 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. For proposals involving the collection of data from voice, video, or digital sources or involving other uses of informatics, please complete Appendix 3.

1. What is the time frame (start and end dates) for human tissue/subject involvement?
2. State the technical justification for human tissue/subject involvement (i.e., Is there no other way to achieve an equivalent technical outcome? Why?).
3. Are the samples 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. Is the tissue 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. What is the anatomical source of the cell or tissue (e.g., liver, skin)?
6. What is the extent of tissue handling by the Principal Investigator: collecting, receiving, and/or sending specimens?
7. Are the samples preexisting, being collected for the express purpose of the research, or being obtained by some combination of the two?
8. Are the samples "custom collected" from individuals who may need special safeguards (i.e., minor children, pregnant women, human in vitro fertilization, fetuses, or prisoners)?

   NOTE: An answer of "yes" to question 8 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).

9. 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/tissues. 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