Appendix H
Language to be Included for Tissue and/or Blood Banking

The following language was adopted as policy by the USA IRB for all protocols when blood or tissue is to be stored. This section should be included exactly as written within the body of the consent form (see STANDARD CONSENT FORM FORMAT #1 BIOMEDICAL STUDY for example).

Tissue and/or blood banking or storage

1. Stored samples have been used in research activities for many years. These samples allow investigators to make important new measurements that were not possible at the time that the original research was planned and conducted. It is possible that some of the biological material (for example: blood, urine or tissue) collected to diagnose your condition or to conduct this research project may remain unused when the research is completed. Normally such samples would be destroyed. We ask your permission to retain and store this for an indefinite period of time so that it might be used for future, as yet undefined, purposes. Future uses may include, but may not be limited to, research, education and commercial development.

IF YOU DO NOT WISH TO HAVE YOUR MATERIAL STORED FOR FUTURE USE YOU MAY STILL PARTICIPATE IN THIS STUDY.

If you agree to allow storage, the samples will be stored by:
(name/location of site)
Security will be provided by:
(Responsible person/agency and methodology)

Do you wish to allow storage of your remaining biological material?
Yes _____ No _____

2. If you agree to storage of your samples, you may choose how this material is to be used or you may limit its use.

Do you wish to limit the use of your stored biological material?
Yes _____ No _____
If “yes” specify the limitations:
___________________________________________________________

3. If you agree to allow your samples to be stored, they will initially be identified with you (for example, your name, your initials, or a number) that could lead back to you. You may choose to have information that could identify you removed. If such identification is removed it will be impossible for you to be contacted in the future regarding any important new or additional information which may be of benefit to you or your family and might lead to further research.

Do you wish to have all information that could identify you removed from the stored material?
Yes _____ No _____

4. If you agree to allow your samples to be stored with identifying information, you may choose to allow someone to contact you in the future to ask you questions about your health, to ask you to participate in more research or for any other reason

Do you wish to allow personal contact in the future regarding the stored material?
Yes _____ No _____
If “Yes,” specify any limitations you wish to impose: