IRB REQUEST FOR WAIVER OF HIPAA AUTHORIZATION/CONSENT

Principal Investigator:_____

Protocol Title/IRB #: _____

Please respond to each item using protocol-specific language to provide justification (you may reference IRB application for simplification).

1. Provide a brief explanation of why the research activity to be permitted by this waiver involves no more than minimal risk to the subjects: _____

   _____

   _____

2. Demonstrate that the research involves no more than minimal risk to the privacy of subjects by describing the plan to protect the identifiers from improper use and disclosure; and indicate where/if the identifiable private information will be stored and who will have access:_____

   _____

   _____

3. Explain why this waiver will not adversely affect the rights and welfare of the subjects:

   _____

   _____

4. Explain why the research could not practicably be carried out without this waiver:

   _____

   _____

   _____

Principal Investigator's Assurance: I assure the ETCH IRB that the information provided in the application and on this form is accurate and complete, and the PHI I request is the minimum amount of identifiable private information necessary for my research. I also assure that the PHI will not be reused or disclosed to any other person or entity, except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research which the use or disclosure of protected health information would be permitted by the HIPAA Privacy Rule.

Signature of PI/Date: _____