Request for Partial Waiver of Authorization for Recruitment Purposes Form

Header Information: Protocol/Project Title: The title should be the complete and full title of the research protocol.

Investigator Information: The name of the local Principal Investigator should be placed here.

1) Describe your screening/recruitment method: We want to know how you intend to find subjects/tissues that may be suitable for your research. This could be a review of medical records, review of laboratory/pathology clinical database (CoPath), review of billing records, etc.

2) Summarize what protected health information (PHI) is needed: Provide a list of what is required to assess eligibility. For example, name, date of birth, diagnosis, etc.

3) Please explain how your method meets the following four criteria. (The following text in italics are examples of possible answers to these questions and are meant as guidance to assist investigators in completing this form.)

   a. The use of PHI for identifying eligibility and contacting potential subjects will involve no more than minimal risk to the individual’s privacy: No PHI will be kept for subjects who do not fit the eligibility criteria. Those subjects who are eligible will be contacted by someone with a treating relationship specific to the disease type. For tissue protocols that do not require subsequent medical chart review, once the appropriate blocks are identified the PHI is no longer necessary and will be destroyed.

   b. The Waiver of Authorization will not adversely affect the rights and welfare of the participants: No PHI will be kept for subjects who do not fit the eligibility criteria. Those subjects who are eligible will be contacted by someone who has a treating relationship specific to the disease type. For tissue protocols that do not require subsequent medical chart review, once the appropriate blocks are identified, the PHI is no longer necessary and will be destroyed.
c. Recruitment cannot be practicably carried out without the Partial Waiver of Authorization: For retrospective tissue studies, it would not be possible to obtain authorization from all potential subjects. FAHC does have a standard form authorizing use of tissues for research.

d. Recruitment cannot practicably be conducted without the participant's PHI: Without the PHI mentioned above, we would not be able to identify suitable subjects/tissue and therefore the research could not be done.