USE OF EXISTING PATHOLOGICAL OR DIAGNOSTIC SPECIMENS

The “XT” (existing tissue) application may only be used when (1) specimens obtained by the Principal Investigator are totally anonymous, i.e., no identifiers linking the material back to the subject, no “log accession number” from Pathology, (2) prospective collection of biological specimens are for research purposes by noninvasive means.

OPRR (Office for Protection from Research Risks) Title 45 Code of Federal Regulations Part 46

46.101(b)(4) Research involving the collection or study of…pathological specimens, or diagnostic specimens,…if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Research involving human subjects not meeting this criteria should submit a full IRB application. If there are any questions, please do not hesitate to contact the Human Subjects Program Office at x44520 for assistance.
APPLICATION FOR THE USE OF EXISTING PATHOLOGICAL OR DIAGNOSTIC SPECIMENS

COMMITTEE ON INVESTIGATIONS INVOLVING HUMAN SUBJECTS
UNIVERSITY OF CALIFORNIA - SAN DIEGO

PRINCIPAL INVESTIGATOR____________________________

__________________________________________________

Signature of P.I.

Department_________________ Salaried: Yes_____ No_____ 

Mailcode:_________ Phone:_____________

Fax:_____________

e-mail:_________________________________________

Contact Person:________________________

Phone:_____________

Other Investigators:

PROJECT TITLE: 

Investigators obtaining human material for research purposes should insure that the requirements of informed consent are met by checking with the agency from which the materials are to be obtained. If there are questions about this, appropriate informed consent must be obtained and a standard application will be needed. If there are no questions, the following information should suffice for Human Subject Committee review.

1. Where will the study be carried out?

2. Describe the tissue (fluid) to be used - the type, the amount, the patients from whom it will be obtained, and the source (pathologist or other).

3. What will be done with the tissue (fluid) for purposes of this research?

PROJECT NUMBER________________________

(Leave Blank)

Date Received_______________________

(Leave Blank)

___________________________________

Approval of Department Chair

_______________________________

Date

PREVIOUS HISTORY OF THIS PROJECT

New_______ IF NOT NEW, please provide:

Previous Project Number_________________

FUNDING SUPPORT

Do you plan to solicit extramural funds?

Yes___ No___

UCSD Proposal Number__________________________

SUBMIT 1 COPY OF THIS APPLICATION TO:

Human Research Protections Program, 0052
University of California, San Diego
9500 Gilman Drive
La Jolla, California 92093-0052

Call (858) 455-5050 for assistance.

NOTE: IF YOUR STUDY INVOLVES DNA AND THE SUBJECT’S SPECIMEN IS NOT COMPLETELY ANONYMOUS A STANDARD APPLICATION AND CONSENT WILL BE NEEDED.

Yes          No

Will Study be done at the VAMC? _____        _____

UCSDMC? _____        _____