



LTRC DATA COORDINATING CENTER
CLINICAL TRIALS & SURVEYS CORP. (C-TASC)
10065 RED RUN BLVD., SUITE 250
OWINGS MILLS, MARYLAND 21117

410-435-0663 (TELEPHONE)
410-435-0689 (FAX)
LTRCPUBLIC.COM

[INSERT DATE]

MEMORANDUM

TO: Institutional Review Board
FROM: [INSERT INVESTIGATOR NAME]
SUBJECT: Exemption Letter for an LTRC Study

The Lung Tissue Research Consortium (LTRC) was formed by the National Heart, Lung, and Blood Institute in 2004 to collect lung tissues and clinical data from patients with lung diseases. The primary patient groups being studied are Chronic Obstructive Pulmonary Disease (COPD) and Interstitial Lung Disease (ILD). I have requested specimens and clinical data from the LTRC for a research project.

The clinical data and specimens have been de-identified as part of their normal processing in the LTRC. As this institution is not participating as an LTRC Clinical Center (**University of Colorado, University of Michigan, Mayo Clinic or University of Pittsburgh**), I have **no access to direct identifiers associated with the LTRC patients**. The LTRC Investigators review of OHRP guidelines indicates there is guidance that my analysis of these data is "not human research" and therefore not subject to IRB review, or IRB approval can be accomplished with an expedited review (see www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf).

If the IRB representative agrees with this position, the LTRC document entitled "Appendix IV, Investigator and Institutional Certifications," should be checked under the first heading of "1. Human Subjects" as "The proposed study does not involve human subjects." The IRB representative should sign the document and return it to me as soon as possible. I will not be able to receive specimens or data until I have submitted this form.

If you have any questions concerning this process, please contact Bruce Thompson, PhD at the LTRC Data Coordinating Center at (410) 435-0663.

Thank you for your attention to this matter.

Enclosures