



The University of Toledo  
Department for Human Research Protections  
Institutional Review Board Offices  
CCE Building – Room 0106  
Mail Stop # 1035  
3000 Arlington Avenue, Toledo, Ohio 43614-2570  
Phone: 419-383-6796 Fax: 419-383-3248  
(FWA00010686)

## MEMORANDUM

DATE: February 25, 2014

TO: Justus Philip  
Pre-Clinical Student Fellow  
Department of Pathology

FROM: Carolyn Pinkston, MPH, RN, CIP  
DHRP Director of Operations

RE: Single Case Study - Institutional Review Board Approval Not Required

CC: Roland Skeel, MD, Chair, Biomedical IRB  
Susan Mates, CMA-C, Biomedical IRB Coordinator II

---

This memorandum is in response to your inquiry regarding a single case study and it's publication in the UT Translation journal.

**Research** is defined by federal regulations for the protection of human subjects (45 CFR 46) as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge”.

A single case study does not meet the definition of “research” under federal regulations and therefore IRB review is not required. If your plans change and you would like to study more than one patient, please submit additional information to our office as a separate determination regarding IRB review and approval will be required.

Please be aware that HIPAA regulations permit case studies provided patient confidentiality is protected. This means your case study cannot contain any information that would identify the patient. Any information that might easily allow identification should never be used in publications or external presentations. Thank you in advance for adhering to those requirements.

Please write the IRB at [IRB.Biomed@utoledo.edu](mailto:IRB.Biomed@utoledo.edu) with any additional questions you may have.