Knoedler, Ruth

From: Tait, Alan
Sent: Tuesday, October 30, 2012 2:04 PM
To: Knoedler, Ruth
Subject: IRB approval letter

IRB approval letter

From: eresearch@umich.edu [mailto:eresearch@umich.edu]
Sent: Monday, September 24, 2012 8:40 AM
To: atait@umich.edu
Subject: eResearch Notification: Scheduled Continuing Review Approved

Medical School Institutional Review Board (IRBMED) • 2800 Plymouth Rd., Building 200, Room 2086, Ann Arbor, MI 48109-2800 • phone (734) 763 4768 • fax (734) 763 9603 • irbmed@umich.edu

---

To: Dr. Alan Tait

From:

Michael	Geisser
Alan	Sugar

Cc:

Terri	Voepel-Lewis
Alan	Tait

Subject: Scheduled Continuing Review [CR00029836] Approved for [HUM00043187]

SUBMISSION INFORMATION:
Study Title: Interactive informed consent for pediatric clinical trials
Full Study Title (if applicable):
Study eResearch ID: HUM00043187

SCR eResearch ID: CR00029836
SCR Title: HUM00043187_Continuing Review - Tue Sep 11 08:40:13 EDT 2012
Date of this Notification from IRB:9/24/2012
Date Approval for this SCR: 9/23/2012
Current IRB Approval Period: 9/23/2012 - 9/22/2013
Expiration Date: Approval for this expires **at 11:59 p.m. on 9/22/2013**
UM Federalwide Assurance:FWA00004969 expiring on 6/13/2014
OHRP IRB Registration Number(s): IRB00001999

Approved Risk Level(s) as of this Continuing Report:

Name	Risk Level
HUM00043187	No more than minimal risk

NOTICE OF IRB APPROVAL AND CONDITIONS:
The IRBMED has reviewed and approved the scheduled continuing review (SCR) submitted for the study referenced above. The IRB determined that the proposed research continues to conform with applicable guidelines, State and federal regulations, and the University of Michigan's Federalwide Assurance (FWA) with the Department of Health and Human Services (HHS). You must conduct this study in accordance with the description and information provided in the approved application and associated documents.

APPROVAL PERIOD AND EXPIRATION DATE:
The updated approval period for this study is listed above. Please note the expiration date. If the approval lapses, you may not conduct work on this study until appropriate approval has been re-established, except as necessary to eliminate apparent immediate hazards to research subjects or others. Should the latter occur, you must notify the IRB Office as soon as possible.

IMPORTANT REMINDERS AND ADDITIONAL INFORMATION FOR INVESTIGATORS

APPROVED STUDY DOCUMENTS:
You must use any date-stamped versions of recruitment materials and informed consent documents available in the eResearch workspace (referenced above). Date-stamped materials are available in the "Currently Approved Documents" section on the "Documents" tab.

In accordance with 45 CFR 46.111 and IRB practice, consent document(s) and process are considered as part of Continuing Review to ensure accuracy and completeness. The dates on the consent documents, if applicable, have been updated to reflect the date of Continuing Review approval.

RENEWAL/TERMINATION:
At least two months prior to the expiration date, you should submit a continuing review application either to renew or terminate the study. Failure to allow sufficient time for IRB review may result in a lapse of approval that may also affect any funding associated with the study.

AMENDMENTS:
All proposed changes to the study (e.g., personnel, procedures, or documents), must be approved in advance by the IRB through the amendment process, except as necessary to eliminate apparent immediate hazards to research subjects or others. Should the latter occur, you must notify the IRB Office as soon as possible.

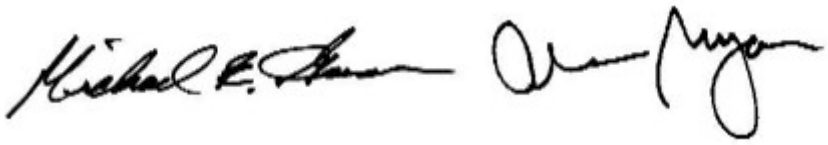
AEs/ORIOs:
You must continue to inform the IRB of all unanticipated events, adverse events (AEs), and other reportable information and occurrences (ORIOs). These include but are not limited to events and/or information that may have physical, psychological, social, legal, or economic impact on the research subjects or others.

Investigators and research staff are responsible for reporting information concerning the approved research to the IRB in a timely fashion, understanding and adhering to the reporting guidance (http://www.med.umich.edu/irbmed/ae_orio/index.htm), and not implementing any changes to the research without IRB approval of the change via an amendment submission. When changes are necessary to eliminate apparent immediate hazards to the subject, implement the change and report via an ORIO

and/or amendment submission within 7 days after the action is taken. This includes all information with the potential to impact the risk or benefit assessments of the research.

SUBMITTING VIA eRESEARCH:
You can access the online forms for continuing review, amendments, and AE/ORIO reporting in the eResearch workspace for this approved study, referenced above.

MORE INFORMATION:
You can find additional information about UM's Human Research Protection Program (HRPP) in the Operations Manual and other documents available at: www.research.umich.edu/hrpp.



Michael Geisser
Co-chair, IRBMED

Alan Sugar
Co-chair, IRBMED