

UNIVERSITY OF MISSOURI – COLUMBIA
HEALTH SCIENCES INSTITUTIONAL REVIEW BOARD

Waiver or Alteration of Health Information Portability and Accountability Act (HIPAA) Authorization for
the Use and/or Disclosure of Protected Health Information (PHI) Resulting from Participation in a
Research Study

FOR HS IRB USE ONLY	
APPROVED	
<i>Dan V. Muen</i>	<i>5/15/09</i>
HS IRB Authorized Representative	Date
The IRB has determined that all the criteria specified for a waiver or alteration of HIPAA authorization were met.	
Full Board	Expedited

PRINCIPAL INVESTIGATOR NAME: AARTI SARWAL
PROJECT #: CASE REPORT – ONE CASE
PROJECT TITLE: RABIES ENCEPHALITIS
Please provide a brief description of this project.

SUBMISSION OF CASE REPORT OF ONE CASE OF RABIES ENCEPHALITIS
TREATED WITH MILWAUKEE PROTOCOL

To obtain approval for a waiver or alteration of Health Information Portability and Accountability Act (HIPAA) authorization for the use and/or disclosure of Protected Health Information (PHI) resulting from participation in a research study, the project must meet the criteria listed below. Please explain how your study meets these criteria.

1. Describe the protected health information (PHI) to be collected and the source(s) of PHI.

PATIENT'S MRN WILL BE USED TO ACCESS MEDICAL RECORDS

2. Provide a brief explanation of why the research activity to be permitted by this waiver or alteration involves no more than minimal risk to the subjects.

NO IDENTIFYING DATA USED IN REPORT. EVENTS HAVE ALREADY TAKEN PLACE

3. Explain why this waiver or alteration will not adversely affect the privacy rights and welfare of the subjects.

CASE REPORT WILL HAVE NO IDENTIFYING INFORMATION

4. Demonstrate that the research involves no more than minimal risk to the privacy of subjects by describing the plans requested below.

a. Describe the plan to protect the identifiers from improper use and disclosure; and indicate where the PHI will be stored and who will have access to this information.

MRN WILL BE STORED IN PASSWORD PROTECTED FILE ACCESSIBLE ONLY TO PI

b. Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research (how and when identifiers will be destroyed). If there is a health or research justification for retaining the identifiers or such retention is otherwise required by law, provide the reason to retain identifiers.

MRN WILL BE DESTROYED AFTER SINGLE USE

5. Explain why this research could not practicably be conducted without the waiver or alteration [indicate why it is very difficult to obtain authorization from the participants (inconvenience, time, resources are not acceptable criteria)].

TAKING AUTHORIZATION FROM FAMILY WILL CREATE A DOCUMENT
CONTAINING IDENTIFYING INFORMATION

6. Indicate why the research could not practicably be conducted without access to and use of PHI.

NEED TO ACCESS MEDICAL RECORDS TO MAKE CLINICAL SUMMARY

I assure the HS IRB that the information that I have provided in this application is accurate and complete; that the PHI that I am requesting is the minimum amount of identifiable private information necessary for my research project; and that the PHI will not be reused or disclosed to any other person or entity, except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other permitted uses or disclosures according to federal regulations.

PI Signature Aarti Samuel

Date May 10, 2009