CASE REPORTS AND CASE STUDIES

I. General Summary

The IRB has provided helpful guidance to assist clinician investigators assess the differences between performing case reports and performing case studies on one's own patients. Each situation has separate reporting requirements.

a. Case reports, generally consist of three (3) or fewer patients, prepared for the purpose of illustrating some points in the care of a patient, to educate and formulate new research questions which may eventually lead to generalizable knowledge. Investigator/clinician should use a standard of care written consent when consenting each individual participant. For example, case reports may include but is not limited to:

- Report of a new condition, treatment and follow-up
- Report of a familiar condition with a proposed mode of inheritance
- A new theory
- Questions regarding a new theory
- Adverse responses to therapies

Case reports require IRB administrative approval. Submit the following documents to the IRB

- Complete the IRB Case Report Application
- Investigator/clinician should use a standard of care written consent when consenting each individual participant
- HIPPA consent /IRB waiver required (see case report application)
- Proof of researcher training/licenses'
- Letter of intent (cover sheet)

b. Case studies are considered qualitative research methods. It is the in-depth analysis, empirical inquiry, or investigation of a person or group in a natural, uncontrolled setting. This research method is done from the participants' perspective and studies how they make meaning of the world – not how researchers manipulate it. Qualitative researchers study things in their natural settings, attempting to make sense of, or to interpret, phenomena in terms of the meanings people bring to them. A case study includes multiple data sources such as interviews, documents, archival records, direct observations, and physical artifact.

The Office for Human Research Protection regulations (45 CFR 46.102(d)) defines "research" as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. In general, the review of medical, educational or private records for publication of "case reports" typically involves three (3) or less subjects. In such circumstances, they are NOT considered human subject research and may not require full IRB review since they do not formulate research hypothesis. However, administrative IRB approval is required.

Formal retrospective or prospective records review involving a larger subject population [greater than three (3) subjects] qualify for either Exempt (if data is existing and anonymous) or Expedited IRB review. In these circumstances, researchers are beginning to ask questions and collect data either prospectively or retrospectively to systematically analyze data, making the study closer to deriving generalizable knowledge

Please provide information about the Investigator and the Research Site. All fields on this form must be completed, failure to do so may result in a delay of IRB review. Please refer to the end of this form for a checklist of required documentation that must accompany your submission.	
A. GENERAL STUDY INFORMATION	
A1	Project Title:
A2	Brief Description:

B. **INVESTIGATOR AND RESEARCH STAFF INFORMATION**: **** Attach a CV and a license for the Principal Investigator***	
Principal Investigator Name and degree :	
Principal Investigator email address:	
Phone number	
Site Address	

C. Project Information			
C1.	Number of records to be examined: _____ ****if more than 3 records, the IRB may require expedited review***		
C2.	Are subjects or information about subjects selected from records gathered from a database or record search?	Yes ☐	No ☐

C3.	Start date: _____		
C4.	Completion date: _____		
C5.	Provide location where data records or information is stored or available:		
C6.	Will you record any direct identifiers, names, social security numbers, addresses, telephone numbers etc.	*Yes ☐	No ☐
C7.	If yes to question C6 please explain why it is necessary to record findings with identifiers. If there is a coding system which you will use to protect against disclosure of these identifiers, please describe the system. Also, describe the provisions you have taken to maintain confidentiality of data.		

_____ _____

Principal Investigator's Signature Date

Reviewed and approved as a Case Report or Case Study not requiring IRB approval.

_____ _____

Signature of Reviewer Date

Reviewed and disapproved as a case study. Submit as a research protocol.

_____ _____

Signature of Reviewer Date