

**ATTACHMENT TO THE NOVA SOUTHEASTERN UNIVERSITY
RESEARCH USES AND DISCLOSURES POLICY AND PROCEDURE:
IRB GUIDANCE ON RESEARCH VERSUS EDUCATIONAL ACTIVITY**

Case Studies

It is sometimes unclear whether the presentation of one or more case studies constitutes education or research. It is generally well accepted that case studies presentations made in classroom settings or in the on-line equivalent of a classroom setting constitute education. Such cases need to follow HIPAA privacy rules for consent and require use of the NSU Disclosure for Educational and Related Purposes. A form is not required if the case meets the HIPAA definition of being fully de-identified but is always necessary in cases where the client could be identified by data, pictures, voice recording, demographics, or other information which is presented to the class.

There are however other situations where the line between an educational use of case studies and a research use is less clear. This is important because both NSU and federal regulations require different procedures for educational or research uses. The HIPAA privacy rule defines research as a “systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge”. When research is also involved, IRB approval must be sought and consent forms must conform to research guidelines.

The difference between research use is often the intent of the user of the case information. When the intent is simply to present a single case or a series of cases without generalizing or studying results, this is usually considered an educational presentation whether it is presented in a classroom or at a workshop or conference. However, when the intent is to generalize beyond the case to general recommendations, procedures, or conclusions, the intent is usually considered to reflect research. In most cases, single case study presentations are classified as education, while presentations which aggregate data from multiples cases are research. However, there are significant exceptions to these rules and they cannot be seen as absolute. .

These cases do not deal with more organized research, where data is collected specifically to test a hypothesis or idea, but rather when data is collected after the fact from cases which follow the general clinical protocols for a specific practice area. In situations where additional measures or non-routine techniques are used with a client for the purposes of evaluation, then the case must be considered research no matter how many are involved. However, in all cases where there is any question we urge NSU personnel to contact their center IRB representative (who is listed on the IRB website) or to contact the IRB office directly.

Single Case Presentations:

In general, material collected from clients which are used only in classroom education (broadly defined to include traditional classrooms as well as distance and internet

learning sites) for the purpose of training students or attendees in specific clinical processes (diagnosis, recognition, treatment) is being used for clinical purposes. This material is usually case studies used for illustration rather than part of a desire to organize information in order to defend the efficacy of one technique over another although the teacher may share such conclusions with the students.

There are two primary exceptions to regarding single cases as educational presentations. The first exception is when a single case is used as its own control so that generalizable results can be granted. The second arises when a case is deliberately given additional measures to prove the efficacy of a technique or process.

Presentation at conferences outside of the educational setting tends to be a gray area, but the same reasoning applies: presentation of one or more individual case studies for the purposes of illustrating a specific diagnosis, diagnostic method, or treatment approach remains an educational pursuit.

Examples of single case determinations:

Presentation of a case (in class, a conference, or in print) where auditory steady-state evoked potentials were used to estimate threshold in order to illustrate how steady-state evoked potentials data are used clinically when conducting pediatric hearing aid fitting. (Education) However, if the case were presented to prove the superiority of the method at a conference or in a publication, then the case presentation would constitute research.

A Grand Rounds presentation where a patient with a specific diagnosis is presented to illustrate diagnostic and treatment techniques for such a case. (Education)

A case presented to illustrate a diagnostic or therapeutic method in a class, workshop, or conference. (Education)

The client is given the routine test for a given disorder. He is also given a new, experimental procedure which is faster and cheaper. The case presentation focuses on the comparison between the two techniques. (Research.)

The client is given a behavioral treatment for hair pulling. The treatment is given in alternate months to see if the hair pulling returns in the months when the treatment is not given. The case study focuses on the differences between the months on and off the treatment. (Research). However, if taking the patient on and off the treatment was part of the routine clinical treatment of the disorder (such as medications which are given in cycles, then the case presentation would be of a routine procedure and not represent research.)

Using a case study to teach peers at conference how to use a new type of splint. A case study is presented along with clinical data on functional outcomes with this splint when the data collected are those that are routinely collected in clinical practice.

Case study of the new splint with additional outcomes measurement data not typically collected in your clinical practice OR collected and reported in more depth than is typical in one's clinical practice. (Collecting additional data is research. While quoting client/patient response in normal documentation may be customary, systematic and in-depth collection of specific aspects of client/patient response is research.). (Research).

Multiple Cases

However, when cases are aggregated in order to prove the efficacy of a given method or procedure, to compare methods or procedure, or simply to describe certain demographic or therapeutic trends, the presentation is considered research. It should be noted that as long as de-identified data is used in such presentations, clinician / educators need only submit a basic application for center review rather than go through a more extensive IRB evaluation. Most studies where patient data is aggregated is research even if it is only descriptive becomes classified as research. Research is clearly conducted when a clinician exposes a client to experimental or altered techniques for the purposes of evaluation of those techniques or methodologies.

The general exception is when the individual presents multiple single case studies, which by themselves would be considered single case educational studies. In such a situation, the multiple cases are not being aggregated but rather presented sequentially to illustrate clinical points. However, if at the end, the cases taken together are used to reach a generalization (such as one procedure or one demographic characteristic leads to more success, then this becomes research when presented outside the classroom situation at a conference or in a publication.

Examples:

Aggregated case studies of the new splint as compared to a different type of splint. (The comparison implies efficacy research.) (Research)

Two case studies, one with the new splint and one with the traditional splint, presented to illustrate the two alternative approaches. (Education.)

Clients are randomly assigned to the new and traditional splint and evaluated for outcome. (Research.)

Comparison of cases of the steady-state evoked potentials results to tone-burst auditory brainstem response data or to behavioral threshold data (implies validation or comparative research). (Research).

Analysis of the efficacy of auditory steady-state evoked potential in aiding hearing aid fitting in three cases. (Research).

A teacher uses a series of case vignettes to illustrate the strengths, weaknesses, and pitfalls of alternate treatments in the field. The presentation is limited to classroom settings or the equivalent. (Education)

A teacher uses a series of case vignettes to illustrate the strengths, weaknesses, and pitfalls of alternate treatments in the field at a conference or in publication. The presentation reaches conclusions about what is the best approach to practice in the area. (Research.)

Presentation to a conference of how three different mental health cases were treated and the outcome, not involving additional measures not routinely used in the clinic. (Education)

Presentation to a conference of how three different mental health cases were treated using special outcome measures chosen for the presentation. (Research)

Presentation to a conference of how three different mental health cases were treated and the outcome, not involving additional measures not routinely used in the clinic. The clinician reaches conclusions about what demographic characteristics predict success in the clients. (Research).