Journal of Periodontology and *Clinical Advances in Periodontics*

Does My Case Series or Case Report Need IRB Approval?

Although the distinction between Case Series or Case Reports that are "observational" and those that meet the definition of "research" may seem like a minor distinction, most peer-reviewed medical journals including the *Journal of Periodontology* (JOP) and *Clinical Advances in Periodontics* (CAP) have clarified this distinction in recent years.

If a manuscript reports a study that should be classified as "research," we are compelled to require ethics board approval and compliance with the Helsinki Declaration. The challenge, of course, is determining when a clinical Case Series or Case Report should be classified as "research," as opposed to merely observations on a series of cases. In our experience, the decision is more complicated when authors are experienced clinical scientists who are knowledgeable in drafting manuscripts, because the papers are often written in the format of formal research reports.

The internal guidelines used by JOP and CAP to decide if ethics board approval is required are shown below. Please also see the Duke University Health System guidelines for Case Series/Case Reports, which has become one of the standards currently used by medical journals for decisions on what constitutes "research."

You will notice that many, but not all, of the Case Series and Case Reports published in the past year in JOP and CAP include ethics committee approval.

In general a Case Series or Case Report meets our criteria for "research" and the US Federal definition of "research" if it is a collection of cases that were selected based on specific criteria and analyzed to answer specific questions of whether the therapy had a predictable outcome and what factors contributed to success.

The fact that the cases were treated as part of routine clinical management of the cases or that the treatments were standard or FDA-cleared drugs or devices is not the determining factor, but rather that the investigators asked a specific question and collected and analyzed data on a specific population.

1. If ethics board approval has been received by the authors but is not explicitly stated in the manuscript, authors should revise the manuscript to include the statement: "This study was approved by **the human subjects ethics board of XXXXX** and was conducted in accordance with the Helsinki Declaration of 1975, as revised in 2000." The manuscript would then meet our human subjects ethical criteria for publication.

2. If ethics board approval has not been received, the authors may request a letter of exemption from their ethics board. The manuscript would then meet our human subjects ethical criteria for publication.

JOP and CAP Internal Guidelines for Classifying Manuscripts

The following applies to most Case Series and Case Reports. It should be noted that the editors will determine if specific Case Series or Case Reports require additional approvals beyond what is described below.

Requirement for ethics board approval

> Most Case Series and Case Reports are a retrospective description of clinical findings in a case or an observed course of events that document a new aspect of patient management during the normal course of clinical treatment. Since there is no hypothesis testing, no systematic data collection beyond that which is part of routine clinical practice, no data analysis, and the work has already been done, Case Series and Case Reports do not usually qualify as "research" requiring approval from ethics boards designed to protect humans involved in clinical research.

(US Federal definition) "RESEARCH is any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

> Example 1: Authors include a series of private practice implant cases in patients who have been taking bisphosphonates. They describe the findings in each case, which are collected and reported in a table format.
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> Example 2: Authors intentionally collect series of private practice implant cases in patients who have or have not been taking bisphosphonates. The sample size is sufficient for data analysis, and authors analyze and report the incidence of complications.
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> **Example 1 does not qualify as "research" but example 2 does qualify and requires ethics board approval.**