Case Reports and HSC approval

Faculty members often ask whether or not a case report or case series needs prior approval from the HSC. Below are the decision criteria outlined in the HSC SOPs:

A report of a small number of cases (generally not more than three), is not considered human subjects research, provided that:
1. the report is compiled by persons already involved in patient's care;
2. the information is presented/published in de-identified form;
3. no changes were made in the patient's care or diagnostic testing for the sake of reportability.

Case reports may become human subjects research, or may have other compliance requirements, if the above three stipulations are not met, or if multiple cases are analyzed in a manner that tests a hypothesis.