



TO: Whom It May Concern

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SUBJECT: Institutional Case Study Policy

A case study/series is an analysis of up to 3 clinical cases and usually examines a condition, treatment, presentation, or outcome. Case studies/case series submitted for publication do not strictly meet the criteria of research. Although a case study (defined as a retrospective analysis of one (1), two (2), or three (3) clinical cases) may be illustrative, it does not meet the Federal Regulation's definition of research at 45 CFR 46.102(d).

The Human Research Protection Program Standard Operating Procedures at Stony Brook University do not consider a case study/case series of up to three cases as human subject research that needs approval from the Institutional Review Board (IRB).

If the analysis involves more than 3 cases it would need to be reviewed by the Human Research Protection Program and an application would need to be completed in the electronic management system myResearch.