

TO:

Whom It May Concern

FROM:

Rebecca Dahl, PH.D.

Institutional Official
Stony Brook University

DATE:

February 13, 2020

SUBJECT:

Institutional Case Report Policy

Case reports/case series submitted for publication do not strictly meet the criteria as research. Although a case report (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 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 report/case series of up to three cases as human subject research that needs approval from the Institutional Review Board (IRB).