

OFFICE OF RESEARCH OVERSIGHT

IMPORTANCE OF STANDARD OPERATING PROCEDURES FOR FACILITY HUMAN RESEARCH PROTECTION PROGRAMS

January 12, 2015

The current version of VHA Handbook 1200.05 (issued November 12, 2014, for implementation no later than March 12, 2015) provides facilities with increased flexibility in operating their Human Research Protection Programs (HRPPs). As a result, the facility's local standard operating procedures (as required under VHA Handbook 1200.01 §§11.e & 14.d) will become ever more critical for ensuring HRPP effectiveness.

ORO strongly encourages facilities to evaluate carefully the effectiveness of their current HRPP procedures before making wholesale changes based solely on the recent revisions to VHA Handbook 1200.05. It is important to remember that the extant requirements of related regulations (e.g., FDA regulations at 21 CFR 312 and 812) and VHA Handbooks (e.g., 1200.01, 1200.12, 1058.01, 1605.1), remain in effect even in instances in which VHA Handbook 1200.05 no longer references them. In addition, local procedures that are working well need not be abandoned simply because the Handbook no longer requires them. Maintaining an effective local program of protections for human research subjects remains the responsibility of every VA research facility and every VA investigator.