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To: Institute and Center (IC) Clinical and Scientific Directors
All NIH Intramural Research Program (IRP) Investigators
IC Protocol Navigators

Subject: Compliance with Policy 801-Reporting Research Events

Effective July 1, 2019, all investigators will be required to follow the revised policy requirements for reporting research related events to the IRB, as described in [Policy 801-Reporting Research Events](#) and in the accompanying [implementation memo](#). These reporting requirements supersede *SOP 16*. The requirements of *Policy 801* also supersede any description of reporting requirements described in any currently approved protocol.

All investigators should follow the revised policy requirements as of July 1, 2019. Upon the investigator's next submission of an amendment to the IRB, the protocol should be amended to update the reporting section. We advise the investigator to simply refer to the policy itself in the protocol, rather than restate the policy in the protocol document.