

IND Safety Report Disseminating Info Procedure

Approval Date: 28MAY2015

Revision Date: 31OCT2017 Cosmetic Only

Revision Date: 11DEC2021

1. As IND Safety Reports come in, the Regulatory Specialist is responsible for notifying both the PI and Sub-I that a notification needs their review.
2. The PI is responsible for signing off on the IND Safety Report either in wet ink or electronically but not both so as to not duplicate work and so as to keep consistent with a single process for each protocol.
3. The Regulatory Specialist will review the IND Safety Information with the Sub-I on an as needed basis as the IND Safety Reports come in. This review will occur within a week of receiving the report.
4. The Regulatory Specialist will review the IND Safety Report with all staff at the next staff meeting.