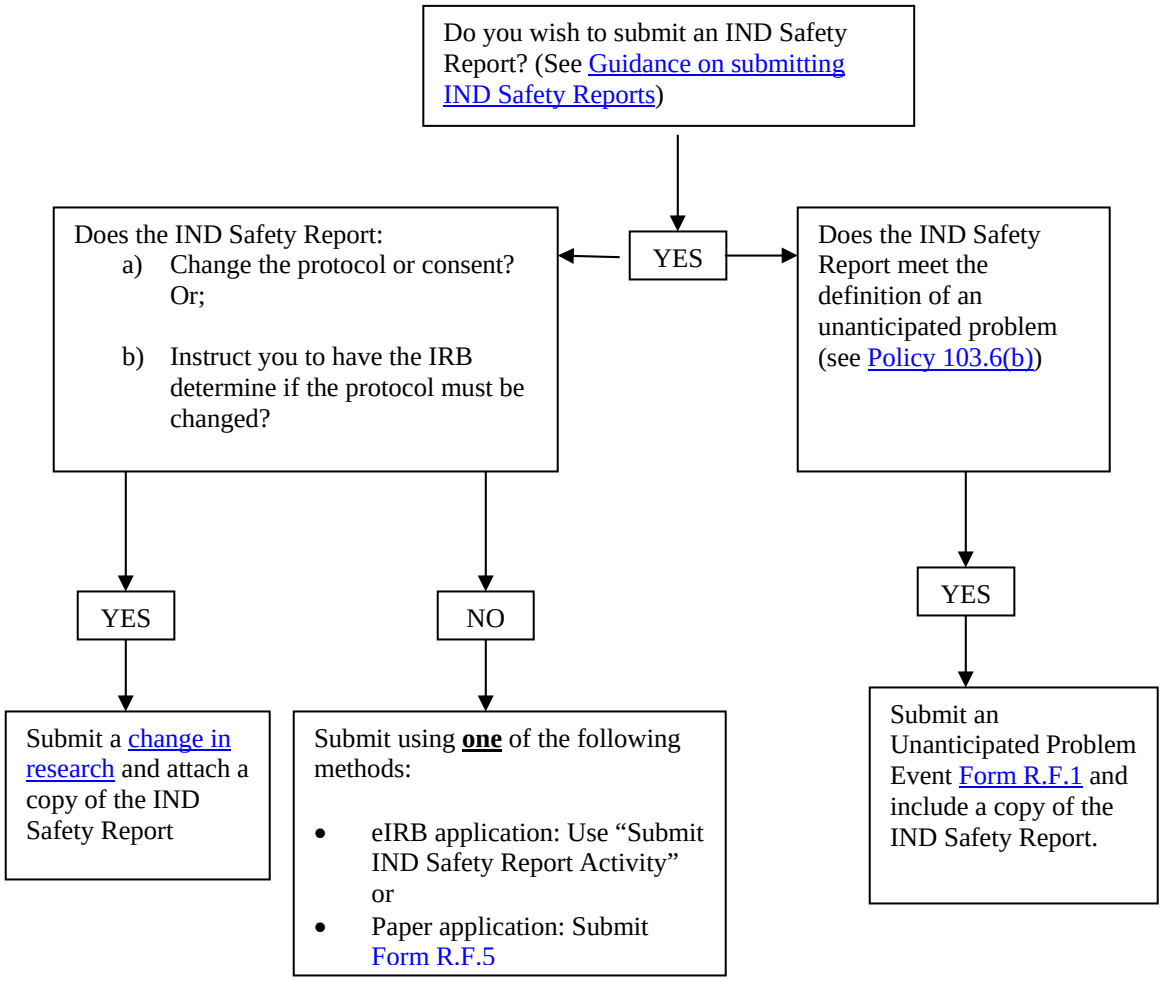III. IND Safety Reports