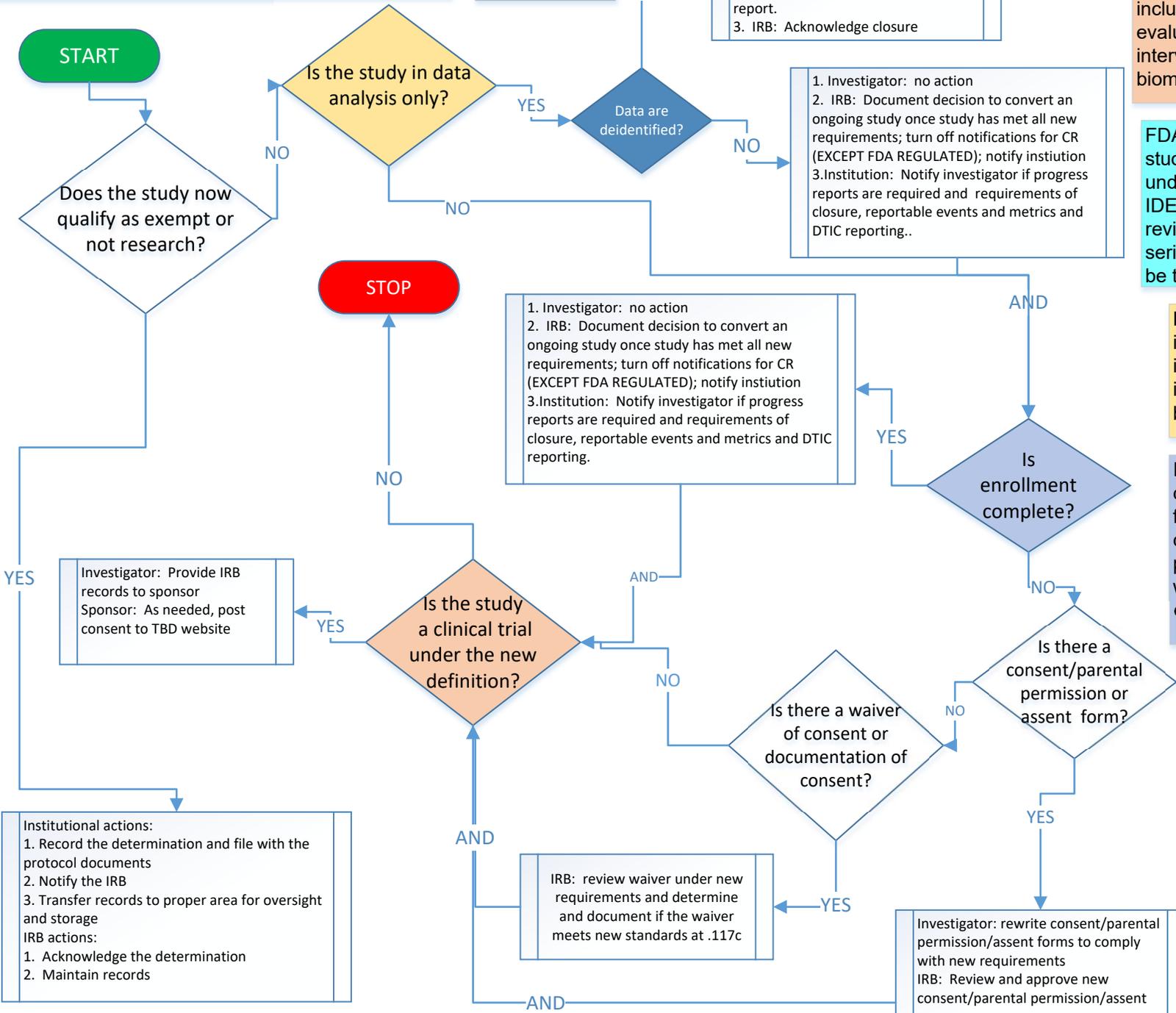


How to Document the Conversion of an Ongoing Study to the 2018 Requirements Starting 21 Jan 2019

V2 26 July 2019 mmk



Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

FDA regulated studies: If the study involve a drug or device under IND (exemption or not) or IDE (abbreviated or not), or was reviewed under any 21 CFR series regulations, CR cannot be turned off.

Data analysis only, including analysis of identifiable private information or identifiable biospecimens.

Is all enrollment and data collection complete except for accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care?

Institutional actions:
 1. Record the determination and file with the protocol documents
 2. Notify the IRB
 3. Transfer records to proper area for oversight and storage
IRB actions:
 1. Acknowledge the determination
 2. Maintain records