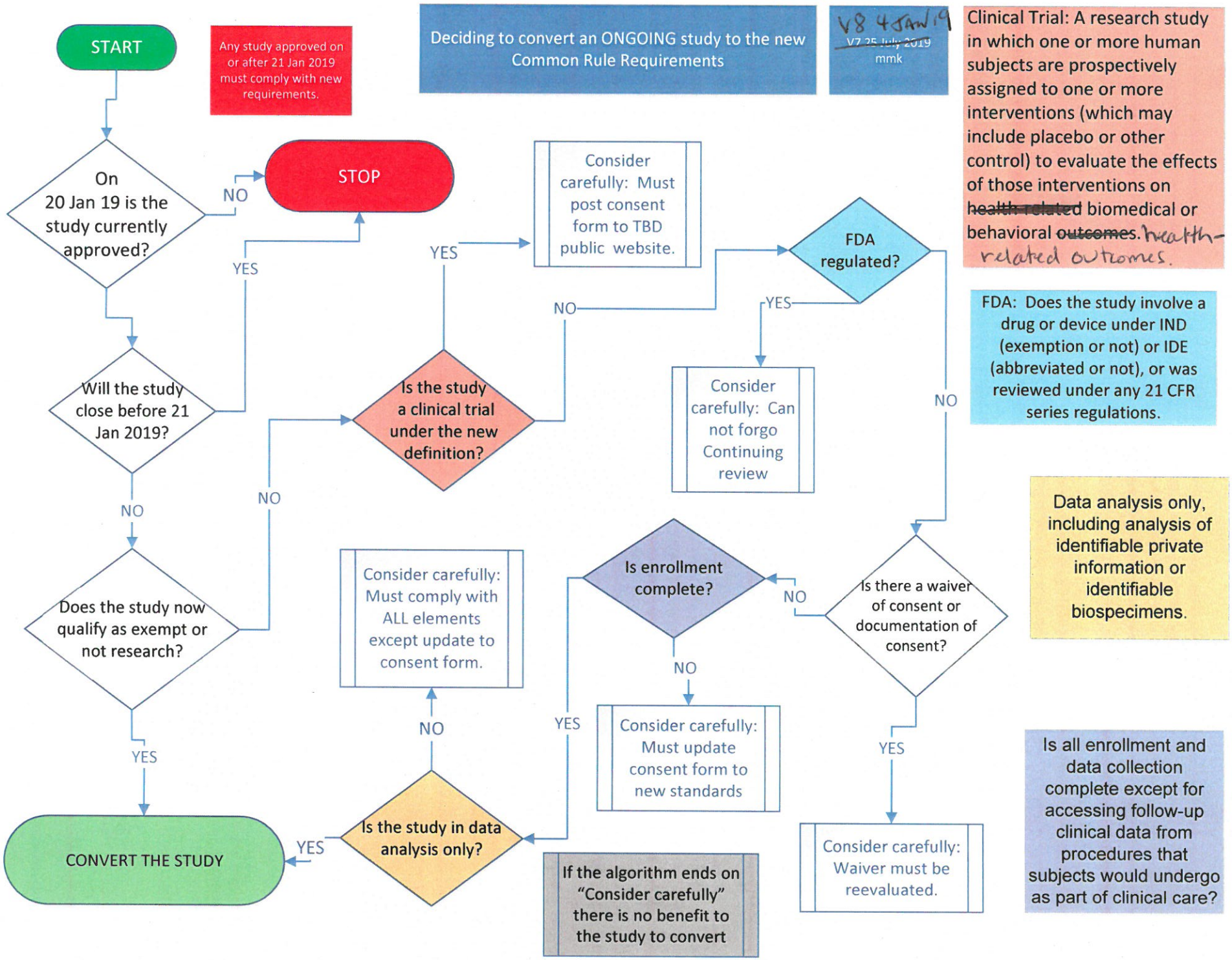
Deciding to convert an ONGOING study to the new Common Rule Requirements
V8 4JAN19
V7 25 July 2019
mmk
START
Any study approved on or after 21 Jan 2019 must comply with new requirements.
On 20 Jan 19 is the study currently approved?
NO
STOP
YES
Will the study close before 21 Jan 2019?
NO
YES
Does the study now qualify as exempt or not research?
NO
YES
CONVERT THE STUDY
Is the study a clinical trial under the new definition?
YES
Consider carefully: Must post consent form to TBD public website.
NO
FDA regulated?
YES
Consider carefully: Can not forgo Continuing review
NO
Is there a waiver of consent or documentation of consent?
NO
Is enrollment complete?
NO
Consider carefully: Must update consent form to new standards
YES
YES
Consider carefully: Waiver must be reevaluated.
Is the study in data analysis only?
YES
NO
Consider carefully: Must comply with ALL elements except update to consent form.
If the algorithm ends on "Consider carefully" there is no benefit to the study to convert
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~~. health-related outcomes.
FDA: Does 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.
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?