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

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mmk

START

Is the study in data analysis only?

YES

Data are deidentified?

YES

1. Investigator: file IRB closure report
2. Institution: Notify investigator if progress reports are required and requirements for closure of study report.
3. IRB: Acknowledge closure

NO

1. Investigator: no action
2. IRB: Document decision to convert an ongoing study once study has met all new requirements; turn off notifications for CR (EXCEPT FDA REGULATED); notify instiution
3.Institution: Notify investigator if progress reports are required and requirements of closure, reportable events and metrics and DTIC reporting..

NO

Does the study now qualify as exempt or not research?

NO

YES

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

STOP

NO

Is the study a clinical trial under the new definition?

YES

Investigator: Provide IRB records to sponsor
Sponsor: As needed, post consent to TBD website

AND

1. Investigator: no action
2. IRB: Document decision to convert an ongoing study once study has met all new requirements; turn off notifications for CR (EXCEPT FDA REGULATED); notify instiution
3.Institution: Notify investigator if progress reports are required and requirements of closure, reportable events and metrics and DTIC reporting.

AND

YES

Is enrollment complete?

NO

Is there a consent/parental permission or assent form?

NO

Is there a waiver of consent or documentation of consent?

NO

YES

IRB: review waiver under new requirements and determine and document if the waiver meets new standards at .117c

AND

YES

Investigator: rewrite consent/parental permission/assent forms to comply with new requirements
IRB: Review and approve new consent/parental permission/assent

AND

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?