Compliance Notice

Research Administration and Compliance
No. 17-003
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notably, this document includes definitions for essential terminology and timeframes for registration and results reporting.

2) Use of the Checklist for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial (ACT) is strongly encouraged to ensure early identification of ACTs. Note that ACTs have additional and different requirements, such as the required submission of Form FDA 3674 and the inclusion of specific language in informed consent forms.

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Registration

1)

b) However, the study record will not receive an NCT number until the QC

The protocol and statistical analysis plan must be submitted in a common electronic document format specified at _____ (42 CFR 11.48(a)(5))

Quality Control

13) All apparent errors,53(rRficierr)1rent and4oonsttr.

2) A responsible party who commits a prohibited act(s) as defined by the FDA may be the subject of an injunction action or criminal prosecution brought by the Department of Justice.

2) ICMJE Clinical Trial