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AAMC Statement on Clinical Trials Registration and Reporting of Results

In order to:

- Emphasize that research on human subjects is ethically justified only to promote generalizable knowledge
- Promote greater transparency in clinical and translational research
- Conform with emerging best practices promoted by the World Health Organization (WHO) and required for manuscript submission by the International Committee of Medical Journal Editors (ICMJE)
- Comply with applicable provisions of the 2007 Food and Drug Administration Amendments Act (FDAAA) and subsequent rulemaking, as authorized by the FDAAA

Recommendation: The AAMC urges every medical school and teaching hospital that conducts interventional studies on human research subjects to add to its institutional research policy the requirements that:

- All clinical trials (phase II-IV drug and device trials) must be registered at ClinicalTrials.gov within 21 days of enrollment of the first participant.
 - **Annotation:** Investigators should be mindful of the strong arguments in favor of registering observational studies, although to create such policy may require further consultation. The ICMJE defines a *clinical trial* as “any research project that prospectively assigns human subjects to interventional and comparison

groups to study the cause-and-effect relationship between a medical intervention and a health outcome” and thus already includes some observational studies.

- **Annotation:** Information provided on registration must include all of the data elements mandated by the FDAAA, many of which had been earlier promulgated as the WHO’s “Minimum Data Set” and subsequently required for manuscript submission by the ICMJE and for registration on ClinicalTrials.gov.
- o The principal investigator(s) must report or ensure that trial sponsors report to ClinicalTrials.gov the results of such trials for [FDA] approved drugs and devices, in the format and specificity required by ClinicalTrials.gov, as mandated by the FDAAA and subsequent rulemaking.
- o The principal investigator(s) must report, or ensure that trial sponsors report to ClinicalTrials.gov within 12 months of trial completion, or within 30 days of FDA approval, all serious or frequent adverse events as defined in the FDAAA.