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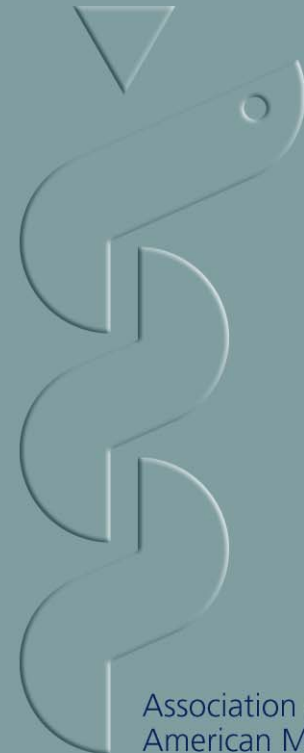
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Lead

# Principles for Strengthening Integrity in the Conduct and Reporting of Clinical Trials

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Association of  
American Medical Colleges

# Integrity in the Conduct and Reporting of Clinical Trials

- Public Concern about timely and complete reporting of clinical trial results, especially those sponsored by industry (VIOXX, antidepressants for teens)
- Academic institutions often play a prominent role in such trials
- Others have already responded (ICMJE, NIH.gov, legislation introduced in Congress)

# AAMC Project, Summer 2005

- Evidence that significant variation continues to exist within academic community on standards for active participation in analyzing and reporting clinical trials, especially multi-site industry-sponsored trials
- Need for reaffirmation that human subjects research can only be done with the intent to produce generalizable knowledge and therefore must be published
- The practice of evidence-based medicine is dependent on the quality of the available evidence

# Applicability of AAMC Principles for Access, Analysis, and Publication

- Principles should apply to all clinical trials\*, including post-marketing phase 4 trials, except for exploratory, phase 1 and early phase 2 trials
- Principles apply regardless of source of funding, but industry sponsored multi-site studies received most discussion

\* “Any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and- effect relationship between a medical intervention and a health outcome.”

# AAMC Principles – Publications and Public Availability of Results

1. Researchers and their institutions have an ethical obligation when conducting human research to seek to make results publicly available
2. Contracts should require a good faith effort to publish in a timely fashion in a peer-reviewed journal
3. Funding should be contractually committed to cover full costs of analysis and publication, including studies terminated “early”

# Publications and Public Availability of Results, cont'd.

4. Results must be made public, preferably via a results repository and link to peer reviewed publications
5. Sponsors, institutions, and investigators should adopt an NIH-like model for public data sharing, post publication (permits exceptions for proprietary info)

# Registration of Trials

6. Trials should be registered according to ICMJE standards in a public, non-profit registry [[clinicaltrials.gov](http://clinicaltrials.gov), PLoS (anticipated)], and updated to include links to publications

# Lead Investigator and Steering Committee

7. Multi site studies should identify, at the outset, a lead investigator and a steering committee to lead the analysis and interpretation of the data and to expedite publication

# Publication & Analysis (P&A) Committee

8. Multi site studies should establish at the outset an independent P&A committee, the majority of whom should be non-sponsor-employed investigators, with appropriate skills in analysis and interpretation of data
9. P&A committee should have access any data generated during the study that it deems necessary to assure integrity and validity and full reporting
10. Sponsor's analysis should be performed within a defined period of time, and P&A committee should have the right to conduct its own analyses, to the extent deemed necessary

## P&A Committee, cont'd.

11. Sponsor should share with P&A committee all analyses called for by the study that sponsor conducts on biological materials it obtains as part of study
12. P&A committee should make good faith effort to disseminate the results through peer reviewed mechanisms

# Individual Publication

13. Individual investigators should be free to analyze and publish, consistent with sound principles of science and analysis
14. But only after publication of the study as a whole and after review and comment by P&A committee

# Authorship

15. Ghost/guest authorship is unacceptable
16. Authorship standards of ICMJE should be followed
17. CONSORT principles should be followed, where applicable
18. Investigators should disclose all relevant financial interests, including consultancies, in any presentation of trial results

## Authorship, cont'd.

19. The role of each author in any manuscript submitted for publication or presentation of results must be accurately disclosed
20. Manuscripts must disclose whether there have been previous publications involving the same protocol or database
21. Manuscripts submitted for publication should be accompanied by the protocol and pre-specified analysis plan, and any deviations from it must be disclosed

# AAMC Principles – Next Steps

- <http://www.aamc.org/research/clinicaltrialsreporting/start.htm>
- Adoption as official AAMC policy, Sept. 2005; approval of minor amendments, January 2006
- Broad dissemination, including deans of medicine and research deans
- Endorsements from other scientific and professional groups
- Adoption and implementation by universities?