**Useful Links**

FDAAA 801 and the Final rule

 <https://clinicaltrials.gov/ct2/manage-recs/fdaaa>

NIH definition of a clinical trial

 <https://grants.nih.gov/policy/clinical-trials/definition.htm>

NIH clinical trial case studies

 <https://grants.nih.gov/policy/clinical-trials/case-studies.htm>

Clinicaltrials.gov History, Policies and Laws

 <https://clinicaltrials.gov/ct2/about-site/history>

International Committee of Medical Journal Editors: Recommendations

<http://www.icmje.org/news-and-editorials/icmje-recommendations_annotated_dec17.pdf>