Appendix C:
Elements of Legislation Requiring Clinical Trial Registries and Results Databases

Criteria	FDA Revitalization Act (S. 1082, Sec. 231)[1]	Food and Drug Administration Amendments Act of 2007 (H.R. 2900)[2]	Maine State Law (Title 22, 2700-A), Sec. 605[3]	California State Bill (SB606)[4]	Minnesota State Bill (HF2289)[5]	Hawaii State Bill (HB11)[6]	New Jersey State Bill (S2307)[7]	Rhode Island State Bill (H5955)[8]	Mississippi State Bill (SB2116)[9]	New York State Bill (A02274A)[10]	Pennsylvania State Bill (HR15/SB339)[11]
Clinical Trial Registries											
Clinical Trial Registry	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Accessible at No Charge*	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Open to All Registrants*	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Not-For-Profit*	✔	✔	✔				✔			✔	✔
Verification of Registration Data*	✔	✔	✔				✔				✔
Electronically Searchable*	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Includes All WHO Data Elements*	✔	✔	✔		✔		✔	✔		✔	✔
Conforms to ICMJE							✔				✔
Policy Currently In Effect?			✔								
Registration at Inception	✔	✔	✔		✔		✔	✔		✔	✔
Specifies Recruitment Status	✔	✔	✔				✔				✔
Protocol for the Lay Public		✔	✔				✔				
Funding Source	✔	✔	✔	✔	✔		✔	✔		✔	✔
Institutional Location	✔	✔	✔		✔	✔	✔	✔		✔	✔
Contact Information	✔	✔	✔	✔	✔		✔	✔		✔	✔
Title of Study	✔	✔	✔	✔			✔				✔
Technical or Lay Summary	✔	✔	✔				✔				✔
Research Ethics Review Disclosed	✔	✔					✔		✔		✔
Ethics Committee Named											
Study Hypothesis/Purpose of Study	✔	✔		✔	✔	✔	✔	✔		✔	✔
Key Inclusion and Exclusion Criteria (Eligibility Criteria)	✔	✔	✔	✔	✔		✔	✔		✔	✔
Study Design (e.g., Allocation to Intervention, Type of Masking, Group Assignment)	✔	✔	✔		✔		✔	✔		✔	✔
Study Type (e.g., Interventional vs. Observational, Randomized vs. on-Randomized)	✔	✔	✔				✔	✔		✔	✔
Study Phase	✔	✔			✔		✔	✔		✔	✔
Primary Outcome Variable	✔	✔	✔	✔	✔		✔	✔		✔	
Secondary Outcome Variable	✔	✔	✔	✔	✔		✔	✔		✔	
Phase I Trials Included *							✔	✔		✔	✔
Phase II Trials Included	✔	✔			✔		✔	✔		✔	✔
Observational Trials Included			✔		✔		✔	✔		✔	✔

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Publications Listed		✔	✔				✔				✔
Independent Verification of Results	✔	✔									
Text Search Specific to Clinical Trials											✔
Search by Recruitment Status	✔	✔									✔
Search by Sponsor/Institutional Location	✔	✔									✔
Search by Disease	✔	✔									✔
Results	✔ ‡	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Link to Results	✔	✔	✔								
Clinical Trial Results Databases											
Clinical Trial Results Database	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Open to All Registrants	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Results Disclosed	✔	✔	✔	✔	✔	✔	✔	✔		✔	✔
Results Posted Within 12 Months	n/a‡	✔					✔				
Results Reporting Standardized	✔	✔	✔								
Funding Source	n/a‡	✔	✔				✔	✔			✔
Institutional Location	n/a‡	✔	✔			✔	✔	✔			✔
Contact Information	n/a‡	✔					✔	✔			✔
Title of Study	n/a‡	✔	✔	✔			✔				✔
Technical or Lay Summary	n/a‡	✔	✔				✔				✔
Safety Data/Adverse Events	n/a‡	✔	✔	✔	✔	✔	✔	✔		✔	✔
Detailed Outcome Information§	n/a‡										
FDA Approval Status	✔	✔	✔							✔	
Attrition Rate	n/a‡	✔	✔	✔	✔		✔	✔			
Study Hypothesis/Purpose of Study	n/a‡	✔	✔			✔	✔	✔			✔
Study Design	n/a‡	✔	✔		✔		✔	✔		✔	✔
Publications	✔	✔	✔	✔			✔				✔
Link to FDA Label	n/a‡	✔	✔	✔							
Description of the Patient Population	n/a‡	✔	✔				✔	✔			✔
Stipulates Essential Data Elements	n/a‡	✔	✔	✔	✔	✔	✔	✔		✔	✔
Study Phase	n/a‡	✔	✔				✔	✔			✔
Phase I Trials Included							✔	✔			✔
Phase II Trials Included	✔	✔		✔			✔	✔			✔
Observational Trials Included			✔	✔			✔	✔			✔

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Independent Verification of Results	✔	✔									
Text Search Specific to Clinical Trials											
Search by FDA Approval		✔									
Search by Phase		✔									
Search by Name of the Drug		✔									
Search by Sponsor/Institutional Location		✔									
Search by Disease		✔									
Policy of Results Disclosure Timeframe Monitored	✔	✔	✔	✔	✔		✔	✔	✔	✔	✔

* Criteria required for ICMJE acceptance
‡ Depends on recommendations of feasibility study
§ The presence, in tabular format, of efficacy data in sufficient detail to permit the calculation of risk ratios

[1] Food and Drug Administration Revitalization Act, Title III, Subtitle C, S 1082 (2007).
[2] Food and Drug Administration Amendments Act of 2007, Title VIII, HR 2900 (2007).
[3] An Act Regarding Advertising by Drug Manufacturers and Disclosure of Clinical Trials, Maine State Law, 22 MRSA c605, §2700-A (2005).
[4] An act to add Division 112.6 (commencing with Section 130650) to the Health and Safety Code, relating to pharmaceutical information. 2007. (S.B. 606). California State Senate. Available at: http://www.leginfo.ca.gov. Accessed 7/16/07.
[5] A bill for an act relating to health; requiring disclosure of clinical trials for prescription drugs; proposing coding for new law in Minnesota Statutes, chapter 144. 2007. (H.F. 2289). Minnesota House of Representatives. Available at: http://www.leg.state.mn.us/. Accessed: 7/16/07.
[6] A bill for an act relating to advertising by manufacturers of prescription drugs and disclosure of clinical trials. 2007. (H.B. 11). Hawaii House of Representatives. Available at: http://www.capitol.hawaii.gov/. Accessed: 7/16/07.
[7] An act concerning public access to information 1 about clinical trials and supplementing Title 26 of the Revised Statutes. 2007. (S. 2307). New Jersey State Senate. Available at: http://www.njleg.state.nj.us/. Accessed: 7/16/07.
[8] An act relating to health and safety-patient safety and drug review transparency act. 2007. (H.5955). Rhode Island General Assembly. Available at: http://www.rilin.state.ri.us. Accessed: 7/16/07.
[9] An act to direct the board of trustees of state institutions of higher learning, acting through the appropriate institutional review board, to require the results of any clinical trials of a pharmaceutical drug or drug product which were conducted at the university of Mississippi medical center or at any state institution of higher learning to be registered with the state board of pharmacy and the state board of medical licensure and published on the internet; to prohibit any such clinical trial which does not comply with the provisions of this act; to amend section 41-9-17, Mississippi code of 1972, to direct the state board of health, as licensing agency for the state's hospitals, to require the results of any clinical trials of a pharmaceutical drug or drug product which were conducted at any licensed hospital to be registered with the state board of pharmacy and the state board of medical licensure and published on the internet; and for related purposes. 2007. (S.B. 2116). Mississippi State Senate. Available at: http://billstatus.ls.state.ms.us/. Accessed: 7/16/07.
[10] An act to amend the public health law, and part C of chapter 58 of the laws of 2005, amending the public health law and other laws relating to implementing the state fiscal plan for the 2005-2006 fiscal year, in relation to requiring all clinical trials and studies on pharmaceuticals to be posted for public access. 2007. (A02274A). New York State Assembly. Available at: http://public.leginfo.state.ny.us. Accessed: 7/16/07
[11] An act relating to the manufacture, sale and possession of controlled substances, other drugs, devices and cosmetics; conferring powers on the courts and the secretary and Department of Health, and a newly created Pennsylvania Drug, Device and Cosmetic Board; establishing schedules of controlled substances; providing penalties; requiring registration of persons engaged in the drug trade and for the revocation or suspension of certain licenses and registrations. 2007. (S.B. 339). General Assembly of the Commonwealth of Pennsylvania. Available at: http://www.legis.state.pa.us. Accessed: 7/16/07.