Clinical Trials Stewardship Resources

NIH INITIATIVES TO STRENGTHEN CLINICAL TRIALS:

Mike Lauer's Blog on "Building Better Clinical Trials through Stewardship and Transparency"	https://nexus.od.nih.gov/all/2016/09/16/clinical-trials-stewardship-and-transparency/
Mike Lauer's Email to the Extramural Community	https://grants.nih.gov/policy/clinical-trials/lauer-email.htm
Why Changes to Clinical Trial Policies	https://grants.nih.gov/policy/clinical-trials/why-changes.htm

NIH POWERPOINT SLIDES:

Presentation on Rationale: NIH Clinical Trials and Transparency Reforms. Why the Changes? **Brief Overview Presentation**: Doing Human Subject Research? Changing NIH Policies May Impact You. **Full length Presentation**: Doing Human Subject Research? Changing NIH Policies May Impact You.	https://grants.nih.gov/policy/clinical-trials/training-resources.htm

NIH CLINICAL TRIAL POLICY INFORMATION:

Overview of Clinical Trials Changes for Grants and Contracts	https://grants.nih.gov/policy/clinical-trials.htm
Good Clinical Practice Training Policy	https://grants.nih.gov/policy/clinical-trials/good-clinical-training.htm
Single IRB Policy	https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm
Certificates of Confidentiality Policy	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html

Clinical Trial-Specific Funding Opportunities Policy	https://grants.nih.gov/policy/clinical-trials/specific-funding-opportunities.htm
Requirements for Registering & Reporting NIH-funded Clinical Trials in ClinicalTrials.gov Policy	https://grants.nih.gov/policy/clinical-trials/reporting/index.htm
Updates to the Appendix Policy	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-098.html

TOOLS/GUIDANCE FOR RESEARCHERS:

2-Page Flyer Highlighting Definition of a Clinical Trial and a Summary of Policy Changes	https://grants.nih.gov/sites/default/files/CT-flyer.pdf
Tool to Determine if your research Meets NIH Definition of a Clinical Trial	https://grants.nih.gov/ct-decision/index.htm
How to Apply – Application Guide	https://grants.nih.gov/grants/how-to-apply-application-guide.html
New Human Subjects and Clinical Trial Information Form within FORM-E Packet	https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm Informational Walk-thru Video- https://www.youtube.com/watch?v=nz9NWFhYOG8