



Announcement: 16 October 2017

The NIH is introducing changes for research that involves human subjects. If you apply for NIH funding, you must be aware of these changes and make sure to follow any new rules.

You can find more information here - https://grants.nih.gov/policy/clinical-trials/tutorial/story_html5.html?utm. You can also contact the ORS if you have any questions.

The two tables below summarize the changes.

3 changes that apply to all research involving human subjects		
<i>Change</i>	<i>Details</i>	<i>Effective date</i>
New PHS Human Subjects Form	<ul style="list-style-type: none"> • Consolidates human subject information in one place • Has new fields • Asks for details of the protocol 	Applications with due dates on or after 25 January 2018
Single IRB for multi-site research	<ul style="list-style-type: none"> • To save time, only one IRB is needed for multi-site studies • BUT only applies to US based research • Doesn't apply to K, T or F grants 	Applications with due dates on or after 25 January 2018
Certificates of confidentiality	<ul style="list-style-type: none"> • These ensure the privacy of human subjects • Automatically applied to studies • The certificate maintains the subjects' privacy even if the data is passed to another team or institution not funded by NIH • Not an actual certificate (no document) 	Issued retrospectively to studies ongoing on or after 13 December 2016 Issued to all studies since 1 October 2017

4 changes that apply to clinical trials		
<i>Change</i>	<i>Details</i>	<i>Effective date</i>
Good Clinical Practice training	<ul style="list-style-type: none"> • Investigators must have GCP training • Must be renewed every 3 years • No specific course • NIH offers free training 	1 January 2017
Specific FOAs	<ul style="list-style-type: none"> • Must apply to specific clinical trial FOAs 	Applications with due dates on or after 25 January 2018
Review criteria	<ul style="list-style-type: none"> • New additional review criteria for clinical trials • Included in the FOA 	Applications with due dates on or after 25 January 2018
Reporting results	<ul style="list-style-type: none"> • Results must be added to clinicaltrials.gov within 1 year of the end of the study 	Applies to trials starting on or after 18 January 2017

The NIH announcement also included a reminder to carefully check if a study is a clinical trial under NIH definitions. The NIH tool for checking of a study is a clinical trial is here -- <https://grants.nih.gov/ct-decision/index.htm>