



September 19, 2016

NOT-OD-16-147 – Policy on Funding Opportunity Announcement (FOA) for Clinical Trials

NIH will require that all applications involving one or more clinical trials be submitted through a Funding Opportunity Announcement (FOA) specifically designed for clinical trials. This means that the NIH will no longer accept clinical trial applications through "parent" FOA announcements or through other FOAs that are not specifically designed to accept clinical trials.

The target effective date for the NIH Policy on Funding Opportunity Announcement (FOA) for Clinical Trials is September 27, 2017.

All applications with receipt dates on or after the effective date with plans to conduct clinical trials must be submitted in response to a clinical trial-specific FOA. After that date, applications planning a clinical trial that are submitted to a non-clinical trial FOA will be returned without review.

NOT-OD-16-148 – Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials

This policy establishes the expectation that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6 (R2).¹ GCP training may be achieved through a class or course, academic training program, or certification from a recognized clinical research professional organization. Completion of GCP training will demonstrate that individuals have attained the fundamental knowledge of clinical trial quality standards for designing, conducting, recording and reporting trials that involve human research participants. GCP training should be refreshed at least every three years in order remain current with regulations, standards and guidelines. Recipients of GCP training are expected to retain documentation of their training.

This policy is effective as of January 1, 2017.

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