

## Enrollment of Subjects into Clinical Trials Information Requested on Participant Availability at Clinical Sites

In accordance with the NIH Guide Announcement entitled “**NINDS Guidelines for Enrollment of Subjects into NINDS-Funded Clinical Trials**” (<http://grants.nih.gov/grants/guide/notice-files/NOT-NS-05-010.html>) NINDS requests that additional information be presented in research proposals of biomedical or behavioral interventions submitted as a NINDS pilot clinic trial or as a multi-center clinical trial, must include relevant information that addresses the feasibility of recruiting subjects who are eligible for the clinical trial. Specifically, potential applicants must provide evidence that each recruiting center in the trial has access to a sufficient number of study participants who meet the eligibility criteria as defined in the submitted protocol. For multi-site applications, information must be provided for each site participating in the trial.

Examples of relevant information may include (but are not limited to) data summarized from patient registries or chart reviews (including data within 2 years of the submitted application), prospectively collected data from patients presenting in the clinic, or enrollment of subjects into a previous study with a similar protocol. In addition the applicants should describe their experience in enrolling subjects in other clinical trials (including experience in enrolling minority populations) and their track record for meeting study enrollment goals in a timely fashion. The proposed application should provide specific information concerning the potential number of eligible subjects available at each participating site but this data should not have identifiers that could be linked to patients. These estimates should take into account any competing study(s) being performed at each clinical site that could impact the recruitment of subjects into the proposed trial. A plan for enrolling eligible participants into competing studies should be described in the application.

Below is an example of what information should be included in a grant application:

| <b>Site Name</b>      | <b>No. of participants seen yearly at this site with this condition</b> | <b>No. of participants seen yearly at this site that meet the inclusion/exclusion criteria</b> | <b>No. of participants expected to enroll per month/year</b> |
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| (total for all sites) |   |  |  |