# NIAMS Clinical Study Sample Size/Target Enrollment Number Change Request Form

{Submit this form and the accompanying requested attachment to Navitas Clinical Research, Inc. (NCR) at [NCR\_for\_NIAMS@navitaslifesciences.com](mailto:NCR_for_NIAMS@navitaslifesciences.com). These documents will be distributed to the NIAMS and the monitoring body, if applicable for review and approval of this request.}

**Before completing this form, are there are any budgetary implications of this proposed change?**

No (If no, continue completing this request)

Yes (If yes, **STOP** and contact your Program Officer before submitting this request)

|  |  |
| --- | --- |
| **Study Principal Investigator (PI) name** |  |
| **Grant number** |  |
| **Study title** |  |
| **Enrollment definition**  *[Insert how enrollment is defined as stated in your study protocol (i.e., enrolled = consented and randomized)]* |  |
| **What is the current target enrollment number?**  *[This is the total number of participants the study needs to enroll to reach the final evaluable number, taking into account attrition and dropouts. This number should be specified in the protocol]* |  |
| **What is the current sample size?**  *[This is the final evaluable number needed based on the study power. This number should be specified in the protocol]* |  |
| **What is the proposed revised target enrollment number and/or sample size?**  *[Revised target enrollment number: This should be the total number of participants needed to reach final evaluable number, taking into account attrition and dropouts.  Revised sample size: This should be the final evaluable number needed based on the study power]* |  |
| **Describe reason/rationale for change** |  |
| **Describe the power analysis implications of this proposed change** |  |
| **Describe any impact on target minority enrollment, if applicable** |  |
| **What is the current target enrollment end date?**  *[Insert planned date (i.e., mm/yyyy) for the last participant enrolled]* |  |
| **What is the proposed new target enrollment end date, if applicable**  *[Insert new planned date (i.e., mm/yyyy) for the last participant enrolled]* |  |
| **Has this request been submitted to the IRB?** | **No** (If no, what is the anticipated submission date? e.g. mm/dd/yyyy      )  **Yes** (If yes, what was the submission date? e.g. mm/dd/yyyy      ) |
| **Submission date to NCR**  *[Insert the date this form was submitted to NCR]* |  |
| **Name of study team member to be contacted regarding questions about this request** |  |
| **Email address of study team member to be contacted regarding questions about this request** |  |

Please submit a revised enrollment report to reflect this change.

The original expected enrollment numbers should be kept in the report for historical reference, and a new expected enrollment column should be added to reflect the updated projections based on the change in target enrollment. This template is located on the NIAMS [Clinical Study Tools and Templates](https://www.niams.nih.gov/grants-funding/conducting-clinical-research/trial-policies-guidelines-templates/data-safety-monitoring-guidelines-policies/clinical-study-templates-forms) webpage. (https://www.niams.nih.gov/grants-funding/conducting-clinical-research/trial-policies-guidelines-templates/data-safety-monitoring-guidelines-policies/clinical-study-templates-forms)

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