# NIAMS Clinical Study Site Addition Request Form

Submit this form and the accompanying requested attachments to Navitas Clinical Research, Inc. (NCR) at NCR\_for\_NIAMS@navitaslifesciences.com. If you are adding more than one new site, you must submit a separate request form for each new site. These documents will be distributed to the NIAMS and the monitoring body for review and approval of this request. The NIAMS may disapprove your request if your requested change is incomplete or inaccurate.

**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** |       |

*[The information below should be completed for the newly proposed site]*

|  |  |
| --- | --- |
| **What is the current number of sites?** |       |
| **What is the total number of sites if the new site is approved?** |       |
| **Is this a foreign site?** | **[ ]**  No **[ ]**  Yes (If yes, \*prior approval from the NIH is required) |
| **Will the new site replace an existing site?** | **[ ]**  No **[ ]**  Yes (If yes, describe which site is being replaced and reason) |
| **The name of institution where the new site is located** |       |
| **Name of new site PI and Study Personnel** |       |
| **Description of new facility** |       |
| **Describe the catchment area and any site specific recruitment plans at the new site**  |       |
| **Overall study target enrollment** |       |
| **Target enrollment for new site** |       |
| **Describe the expected minority population pool and enrollment at the new site** |       |
| **Describe how the new site is expected to enhance overall study enrollment**  |       |
| **Brief description of the training plan** for the new site *(i.e., a Manual of Operating Procedures [MOP] will be provided to the site and/or the Research Coordinator will be trained on study procedures)* |       |
| **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** |       |

In addition, once the NIAMS and the monitoring body review and approve of this request, please submit the following documentation to NCR once available:

[ ]  Institutional Review Board (IRB) approval letter(s) for new site

[ ]  Revised protocol, MOP, and any other applicable study materials

[ ]  Updated list of participating study sites

Lastly, any change in planned enrollment for the study must be approved by the NIAMS. If adding the new site changes the previously submitted planned enrollment figures or the racial/ethnic breakdown of participants who will be recruited, the Inclusion Enrollment Record (IER) must be updated by the PI Institution via eRA Commons.

\*Please note that the prior approval request for adding a foreign site must be approved by NIAMS Grants Management (GM) prior to submission of this form.

Version Date: November 2022