

Request for Change in Target Enrollment Number

{Submit this form and the accompanying requested attachment to KAI Research, Inc. at KAIforNIAMS@kai-research.com. These documents will be distributed to the NIAMS and the Monitoring Body for review and approval of this request.}

PI name	
Grant/contract number	
Study title	
Current target enrollment number <i>[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]</i>	
Proposed revised target enrollment number <i>[This should be the total number of participants needed to reach final evaluable number, taking into account attrition and dropouts]</i>	
Enrollment definition <i>[Insert how enrollment is defined as stated in your study protocol (i.e., enrolled = consented and randomized)]</i>	
Is the change an increase or a decrease from the original target? Describe reason/rationale for change	
Current target enrollment end date <i>[Insert planned date (i.e., mm/yyyy) for the last participant enrolled]</i>	
Proposed new target enrollment end date, if applicable <i>[Insert new planned date (i.e., mm/yyyy) for the last participant enrolled]</i>	
Describe the power analysis implications of this proposed change	
Describe any impact on target minority enrollment, if applicable	
Has this request been submitted to the IRB? Yes No If yes, what was the submission date? If no, what is the anticipated submission date?	

Submission date to KAI <i>[Insert the date this form was submitted to KAI]</i>	
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 Actual vs. Expected Enrollment graph and table to reflect this change. The template for this graph is located on the NIAMS Policies, Guidelines and Sample Templates for Clinical Trials webpage: <https://www.niams.nih.gov/Funding/Clinical Research/NIAMS guidelines.asp>.