The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) Clinical Trial Planning Milestone Checklist

To be completed by the applicant at the time of submitting a LOI or a LOR. Please submit to the NIAMS Scientific Research Contact listed in the U01 Funding Opportunity Announcement: NIAMSclinicaltrials@mail.nih.gov

Date:

Title of proposed study:

Principal Investigator:

Institution:

Applicant email:
Applicant phone number:

Form completed by:

Does the applicant have a currently active or completed NIAMS-funded U34/R34 related to the proposed U01 submission (Yes/No)?

- If yes, provide the U34/R34 grant number:

Has this U01 application been submitted previously (as an A0 application or under a different grant number)? (Yes/No)?

- If yes, provide the previous U01 grant number(s):

Proposed date of submission of this U01 application (see Table 2):

Note: If the budget is $500,000 or greater in direct costs in any given year, a separate Letter of Request (LOR) must be submitted by the appropriate deadline (10 weeks prior to the application due date). No exceptions. See due dates below.

Budgets under $500,000, are encouraged to submit a Letter of Intent (LOI). Instructions found here: https://www.niams.nih.gov/grants-funding/clinical-research/grants/letters-intent-less-than-500k

Proposed **Total** Clinical Trial (U01) Budget (total costs for all years – direct and indirect costs):
$_____

Table 1: Proposed Direct Costs per Year:

Year 1:	Year 2:	Year 3:	Year 4:	Year 5:

Due dates for a U01 application and Letter of Request (only for applications with budgets of $500,000 or greater in direct costs in any given year) LOR requirements found here: https://www.niams.nih.gov/grants-funding/clinical-research/grants/letters-request

Table 2: U01/LOR Application Due Dates

U01 Application Due Date	Letter of Request (LOR) Due Date (required 10-weeks prior to the application due date)
March 4, 2021	December 24, 2020
July 2, 2021	April 23, 2021
November 2, 2021	August 24, 2021
March 4, 2022	December 24, 2021
July 1, 2022	April 22, 2022
November 4, 2022	August 24, 2022
March 3, 2023	December 23, 2022
July 2, 2023	April 23, 2023
November 3, 2023	August 25, 2023

Instructions: The applicant should indicate a status by marking an "X" under the appropriate status heading for each planning activity with additional comment (s) to justify any item(s) that are not complete at the time the checklist is submitted to the NIAMS. The NIAMS reserves the right to not accept a LOR if the applicant does not demonstrate adequate readiness to submit the U01 application.

Table 3: LOR Planning Activity and Status

Planning Activity	**Status**				***Comments** (please include additional detail regarding the status of the activity including any anticipated dates of completion if the activity is not yet complete)	**NIAMS Internal Use Only**
	Completed (please provide dates of completion)	In process *	Not started *	Not applicable *		
Study protocol						
Budget proposal for U01 application						
Identification and qualifications of clinical trial sites, pharmacies and laboratories						
Intervention Documents						

Planning Activity	**Status**				***Comments** (please include additional detail regarding the status of the activity including any anticipated dates of completion if the activity is not yet complete)	**NIAMS Internal Use Only**
	Completed (please provide dates of completion)	In process *	Not started *	Not applicable *		
(Investigator's Brochure/Product Label/Package Insert or Intervention Monitoring Manual) *						
Manual of Operating Procedures (MOP)						
Data and safety monitoring plan (DSMP)*						
Clinical Monitoring and Data Management Plan*						
Finalize plans to obtain intervention related products (drugs, placebo, device)						
Develop Clinical Trial Agreement (CTA) and/or Cooperative Research and Development Agreement (CRADA)						
Develop template informed consent (and assent form, if applicable)						

Planning Activity	**Status**				***Comments** (please include additional detail regarding the status of the activity including any anticipated dates of completion if the activity is not yet complete)	**NIAMS Internal Use Only**
	Completed (please provide dates of completion)	In process *	Not started *	Not applicable *		
Develop case report forms (CRFs)						
Program study database						
Establish data collection system for primary and/or remote sites						
Submit/obtain approval for IND/IDE or documentation of IND/IDE exemption						
Develop materials and establish plans for training and site initiation						
Establish single-IRB arrangements (for multi-site trial) or other IRB (for single-site trials) Initiate IRB approval/request applicable waivers (e.g., HIPAA)						
Documentation of adequate co-funding, if applicable and necessary for completion of the trial						

Planning Activity	**Status**				***Comments** (please include additional detail regarding the status of the activity including any anticipated dates of completion if the activity is not yet complete)	**NIAMS Internal Use Only**
	Completed (please provide dates of completion)	In process *	Not started *	Not applicable *		
Other Milestone (to be added by Investigator):						
Other Milestone (to be added by Investigator):						

*See NIAMS U01 Funding Opportunity Announcement for description. This item is also a required attachment to the application and must be submitted with the U01 application.