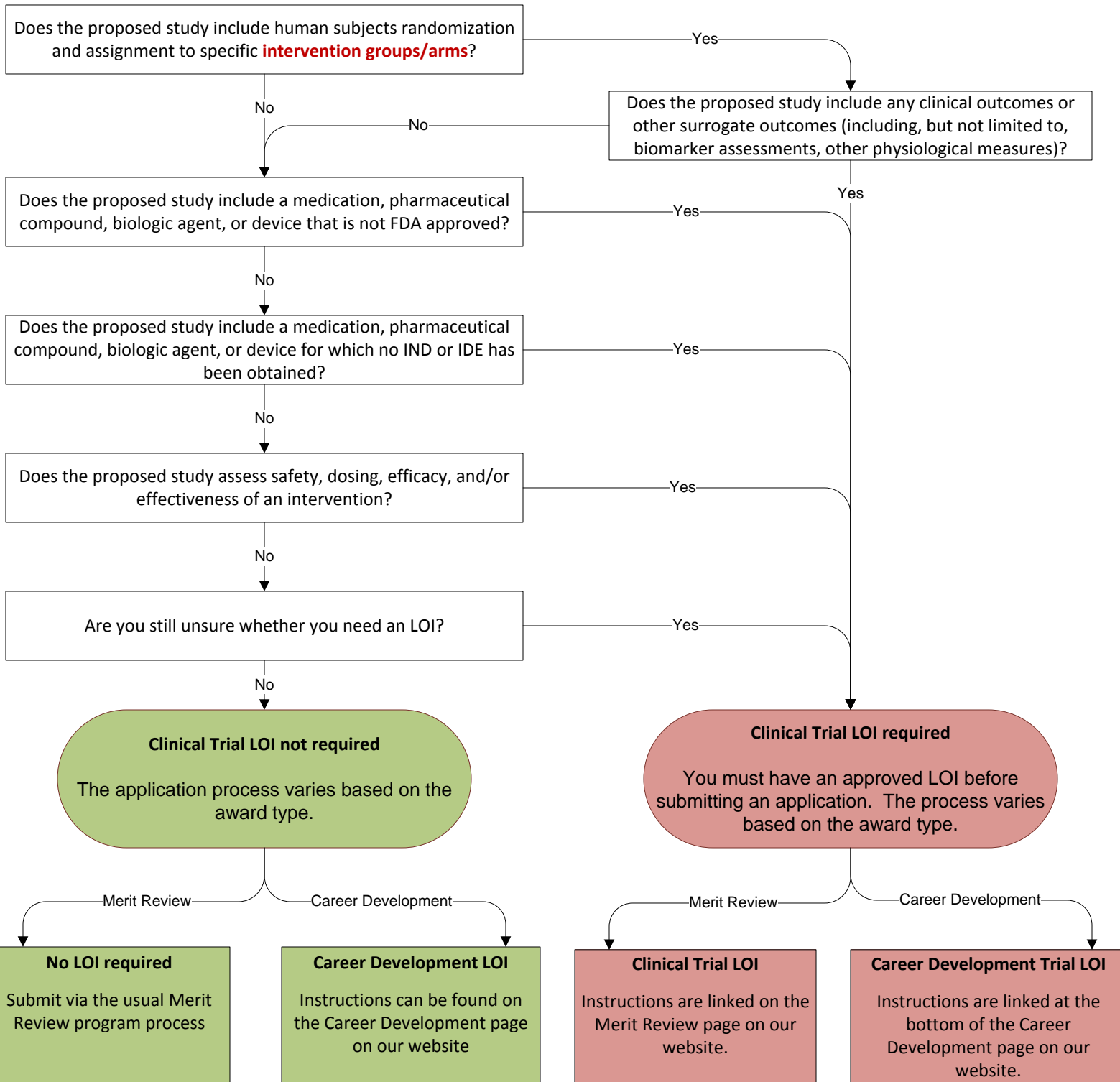


# CLINICAL TRIALS LETTER OF INTENT DECISION TOOL

Some research proposals submitted to Clinical Science Research & Development (CSR&D) must be pre-approved by Central Office staff. This includes most trials and early-phase intervention research. In these cases, the investigator(s) must submit a Letter of Intent (LOI) for review. Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. This flow chart will help applicants determine whether their proposals require a Clinical Trial LOI.

**Please note:** ALL Career Development (CADE) applications must be pre-approved via an LOI. CADE applicants can use this tool to determine which type of LOI to submit.

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