

**OFFICE OF HUMAN RESEARCH AFFAIRS (OHRA)**

**Closure Request Application**

PROTOCOL #:

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| The OHRA assesses the end of a project in two phases:  Phase 1 is Closure – A study is deemed Closed when regulatory oversight is no longer required. The OHRA requirements for closure are outlined in the form below.  Phase 2 is Completion – A study is deemed Complete when the future utilization plan outlined in the protocol has been achieved. The OHRA requirements for completion are outlined below.  The OHRA permits Closure of a research project independent from the assessment of Completion to reduce regulatory burden for studies that require annual renewal. If Completion is not appropriate at the time of the original closure submission, the OHRA will follow up periodically to request an update. |

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| 1. Please indicate the reason for closing the study and include any supporting details for context. |
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| 1. Please identify your study’s funding source (either direct funding or via any collaborating partners) |
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| **3. Requirements for Closure:** please respond to items A-E to determine if your project no longer requires regulatory oversight. **\*If your project does not expire / did not require annual renewal you are expected to submit your finalized issues log for review as part of the closure process.** | |
| **A.** Have all participants completed all study related visits and procedures?  ***\*If NO****, closure with the OHRA is not appropriate at this time.* | YES NO  NA *(Project had no participants)* |
| **B.** Is any further contact with participants needed for reasons related to gathering data for this research?  ***\*If YES****, closure with the OHRA is not appropriate at this time.* | YES NO  NA *(Project had no participants)* |
| **C.** Is any further access to identifiable subject data required for research purposes specific to this study?  ***\*If YES****, closure with the OHRA is not appropriate at this time.* | YES NO  NA *(Project had no identifiers)* |
| **D.** Are there any pending actions or other outstanding items for this research that have not been addressed that require OHRA review? (*This may include outstanding amendments, issues reports or other updates required by the OHRA.)*  ***\*If YES****, closure with the OHRA is not appropriate at this time.* | YES NO |
| **E.** Has OHRA approval of this project expired prior to OHRA receipt of the closure request? | YES NO  NA *(Project does not expire)* |
| **If approval expired**: No research related activities may occur after the protocol expiration date unless the PI contacts the OHRA in advance and it is determined that continuation during expiration is appropriate for participant safety. In the space below, please describe all activity that has occurred during the lapse in approval. | |
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| **Requirements for Completion:** please respond to items A-G. The OHRA will review your responses to determine if your project is complete. | |
| **A.** Have all participants been informed of research outcomes or has the participant engagement plan specific to this research been completed?  ***\*If NO****, project is not considered complete* | YES NO  NA *(Project had no participants)* |
| **B**. Please provide a summary of how the outcomes data was utilized (e.g., internal process improvement, policy updates, external publication) When applicable, please describe where will this data be reported within UHG for internal improvement and in what areas of UHG (Enterprise Level, Patient/Member Improvements, Provider Improvement). | |
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| **C.** Please summarize the status of publication of your results. Please identify journal names, status of publication submission, and confirm whether this aligns with your original research plan and research partners expectations. | |
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| **D.** Please summarize what was learned from the project and whether the primary objective was met. Please comment on whether this project has produced quality data (impactful data, verifiable/reproducible data, RWD, RWE or other patient experience information). | |
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| **E.** Please describe whether this project is linked to / coupled with any other ongoing or planned parallel projects. Please describe whether this is a pilot or early phase project that will inform development of a larger more complex project based on the outcomes. | |
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| **F.** Please comment on any other anticipated use of the data collected from the project (future use) or if the data will be stored / saved without a specific purpose for a defined period of time. | |
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| **G**. Are there any impactful research partnership(s) to consider for this individual project? If so, list the partner(s) and rationale for defining the partner as impactful. | |
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