PHACS ERP BUDGET REVIEW QUESTIONNAIRE

**PROJECT TITLE:**

**PRIMARY INSTITUTION:**

**PARTNER INSTUTIONS *(including partnership with Frontier Science (the PHACS Data Management Center) and Westat (the PHACS Operations Center))*:**

**SCOPE OF WORK (PRIMARY APPLICANT) *If there will be other institutions involved in addition to the primary applicant’s, including Frontier Science and Westat, please attach their Scopes of Work (SOWs) in separate documents:***

**PROJECT START DATE:**

**PROJECT END DATE:**

**WILL THIS PROJECT REQUIRE ANY OF THE FOLLOWING (CHECK ALL THAT APPLY):**

**Analysis of existing data**

**Existing PHACS specimens at the Central Repository (with Materials Transfer Agreement, or MTA)**

**Statistical analysis/report creation by Harvard**

**Other programming including identifying eligible participants**

**Limited dataset to be sent outside HSPH (with Data Use Agreement, or DUA)**

**Review and approval by the Harvard Longwood Campus (HLC) IRB?**

*Note, ERPs proposed after 12/31/23 may not involve PHACS clinical sites or the collection of new data or specimens.*

**IF ANY OF THE ABOVE ARE CHECKED, PLEASE SPECIFY:**

**WILL FRONTIER SCIENCE DATA MANAGEMENT WORK BE REQUIRED? (such as registering participants and having specific eligibility criteria, cataloguing specimens/executing specimen transfers/sending specimen results, CRF and/or survey creation, data QA and completeness monitoring, designing any specific site/participant utility, and data management planning and execution, etc.) IF YES, PLEASE SPECIFY DATA MANAGEMENT REQUIREMENTS:**

**WILL THE PROJECT REQUIRE REVISIONS TO A PROTOCOL AND/OR INFORMED CONSENTS, A CLARIFICATION MEMO (CM), SITE MONITORING, OR OTHER ADMINISTRATIVE MANAGEMENT NEEDS FROM WESTAT? IF YES, PLEASE SPECIFY:**

**DOES THE STUDY TEAM ANTICIPATE ENGAGING THE PHACS TASK FORCE/COMMUNITY ADVISORY BOARD/YOUNG ADULT COMMUNITY ADVISORY BOARD (PUG)/HEALTH EDUCATION AND COMMUNITY CORE TO PROVIDE ONGOING INPUT ON THEIR STUDY DESIGN AND IMPLEMENTATION NEEDS?**

**IS THERE ANY TRAVEL ASSOCIATED WITH THIS PROJECT, AND IF SO, HAVE TRAVEL EXPENSES BEEN INCLUDED IN THE BUDGET?**

**PLEASE COMMENT ON THE LENGTH OF TIME ALLOTED FOR THIS PROJECT AND WHETHER IT SEEMS ADEQUATE TO COMPLETE THE SCOPE (taking into consideration IRB, DUA/MTA, regulatory, protocol/protocol amendment development, data management and other required timelines):**