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| **Cover Letter** |  |
| A cover letter with a project title explaining the significance of the study and expected impact of the study on LIFE-Moms with justification for using the LIFE-Moms cohort and/or data and/or samples/specimens |  |
| **Participating Sites and Investigators** |  |
| * LIFE-Moms sites participating in the ancillary study (for studies using shared or core resources; must include at least one LIFE-Moms investigator) |  |
| * Other institutions that are participating |  |
| * Principal and Co-investigators of the ancillary study by name and institution |  |
| **Letter of Support** |  |
| Letters of support from **each** of the LIFE-Moms Co-Principal Investigators at each participating site. The letter must contain the statement that the PI has read and approved the proposal. |  |
| **A section describing the research design:** |  |
| * Background |  |
| * Specific aims |  |
| * Clear statement of the hypotheses to be tested |  |
| * Sample size justification for the primary hypothesis |  |
| * Outline of protocol clearly indicating procedures to be performed on and samples to be collected from participants.   + List of additional measurements to be obtained by the ancillary study including questionnaires, biologic samples, and physical measurements).   + Amount of participant time needed to complete each additional measurement.   + List of core and/or shared data or samples requested from LIFE-Moms to complete the study, with justification. |  |
| * + List of core and/or shared data or samples requested from LIFE-Moms to complete the study, with justification. |  |
| * Informative reference citation |  |
| **Resources and Budget:** |  |
| A description of the additional burden on LIFE-Moms staff and/or participants |  |
| A description of the study resources needed and the budget that will be provided to cover these. |  |