|  |  |
| --- | --- |
| **Date of Review:** [Date of Next Steering Committee Meeting] |  |
| **Full Proposal Title:** |  |
| **Initiating Principal Investigator:** |  |
| **BHS Co-Investigator(s):** |  |
| **Key Personnel and project roles:** |  |
| **External Collaborator:** |  |
| **Funding Agency:** |  |
| **Mechanism:** |  |
| **Anticipated budget for BHS Staff and resources:** |  |
| **Deadline:** |  |
| **Program Announcement:** |  |
| **Planned starting date:** |  |
| **Project timeline:** |  |
| Include as attachment:**Design and Methods*** **Background/Rationale**
* **Specific Aims**
* **Specific data collection methodology**

**Study Specifics*** **Participant burden, time burden, discomfort**
* **Targeted enrollment and expected participation rate**
* **BHS data needed, recent and historical**
* **Blood or other biologic sample needed (either fresh or from BHS repository), and quantity of specimens needed**
* **Planned collaboration with BHS investigators – with whom and have they approved this proposal?**
* **Follow-up time needed and events to be ascertained**
* **Number of participants required**
* **When data will be collected**
* **How the project will be funded**
* **Any additional work or personnel time expected of BHS staff**
* **How the new project budget will cover demands on BHS personnel time and resources**
* **Where data analyses will be conducted**
* **How confidentiality and protection of human subjects will be maintained**
* **Time frame and plan for merging data to main BHS repository**
* **Return of stored samples from ongoing study and those processed by new study**
* **Ongoing processes to merge new data collected as part of the proposed study as well as its conclusion**
 |  |

**Design and Methods**

* **Background/Rationale:**
* **Specific Aims:**
* **Specific data collection methodology:**

**Study Specifics**

* **Participant burden, time burden, discomfort:**

Questionnaires:

|  |  |  |  |
| --- | --- | --- | --- |
| Name of questionnaire | Time require to complete questionnaire? (in minutes) | Who completes questionnaire?(Participant, Study Coordinator, Other (specify) | Method of administration (mail, phone, in-person) |
|  |  |  |  |

If new project adds an additional procedure or an additional visit:

|  |  |  |
| --- | --- | --- |
| Name of procedure/Reason for added visit | Length of time needed to conduct procedure (in minutes) | Total number and timing of visits (e.g., “3 visits, 1 year apart”) |
|  |  |  |

* **Targeted enrollment and expected participation rate**
* **BHS data needed**
* **Blood or other biologic sample needed (either fresh or from BHS repository), and quantity of specimens needed**

If new project uses already stored biological samples:

|  |  |  |  |
| --- | --- | --- | --- |
| Test to be done on the specimens | Sample to be used(e.g., plasma, serum, urine) | Volume of specimen needed? | Which participants? (limitations by age, race, number of times participated, etc.) |
|  |  |  |  |

If new project needs additional biological samples please describe:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name(s) of test(s) to be done on the specimens | Type(s) of specimen(s) to be collected(Plasma? Serum? Urine? Other (specify)?) | Volume of each specimen needed. | Years of follow-up when test will be conducted. | When each specimen will be collected. (As part of existing protocol, or additional visit?) | Special processing specifications, if applicable |
|  |  |  |  |  |  |

* **Planned collaboration with BHS investigators – with whom and have they approved this proposal?**
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* **How confidentiality and protection of human subjects will be maintained**
* **Time frame and plan for merging data to main BHS repository**
* **Return of stored samples from main study and those processed by new study**
* **Ongoing processes to merge new data collected as part of the proposed study as well as its conclusion**