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| **Use for new proposals**  *(Make copies of pages as needed)* | | | | | | | | | | | | | | | |
| **HSPP (IRBNet) Number:** (if known) | | | | |  | | | | | | | | | | |
| **Protocol Name:** | | | | |  | | | | | | | | | | |
| **Principal Investigator:** | | | | |  | | | | | | | | | | |
| **Projected Completion Date:** | | | | |  | | | | | | | | | | |
| **Funding Sources** | | | | | | | | | | | | | | | |
| **Name of Funding Source** | | | | | | | **Funding Source ID** | | | | **Grant Office ID** | | | | |
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| **Names of all personnel involved in this protocol’s design, conduct, or reporting.**  **Include the principal investigator named above.** | | | | | | | | | | | | | | | |
| **Name** | | | | | | **Role** | | | | | | **Involved with human subjects?****\*** | | | |
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| **\*** Includes any of the following:  • obtaining information about living individuals by intervening or interacting with them for research purposes;  • obtaining identifiable private information about living individuals for research purposes;  • obtaining the voluntary informed consent of individuals to be subjects in research; and/or  • studying, interpreting, or analyzing identifiable private information or data for research purposes. | | | | | | | | | | | | | | | |
| **Financial Interest Declaration** | | | | | | | | | | | | | |
| * “Immediate Family” means spouse, domestic partner, children, and dependents. * “Related Financial Interest” means any of the following interests in the sponsor, product or service being tested, or competitor of the sponsor held by the individual or the individual’s immediate family:   + Ownership interest of any value including, but not limited to stocks and options, exclusive of interests in publicly-traded, diversified mutual funds.   + Compensation of any amount including, but not limited to honoraria, consultant fees, royalties, or other income.   + Proprietary interest of any value including, but not limited to patents, trademarks, copyrights, and licensing agreements.   + Board or executive relationship, regardless of compensation.   + Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center. | | | | | | | | | | | | | |
| **Yes  No** | **Do any personnel involved in the design, conduct, or reporting of the protocol have a Related Financial Interest?**  If yes, provide the organization’s evaluation of the financial interest. | | | | | | | | | | | | |
| **Provide an Investigator Protocol (***See HRP-503a TEMPLATE Social-Behavioral Protocol for guidance.)*  **Also include the following documents in your submission when they exist or are applicable:**   * All materials to be provided to or meant to be seen, read, or heard by subjects *(or potential subjects)*   + Recruitment materials and scripts, advertisements *(printed, audio, and video)*   + Consent documents: consent forms, written consent statements, or verbal scripts *(provide in MS Word format)*   + Study instruments and data collection forms *(e.g., surveys, questionnaires, interview or focus group questions, demographics, observation guides, assessments, etc.)*   + Foreign language versions of the above * Appendix A: External (non-MSU Denver) Sites information and approvals * Documentation of permission or support from internal or external organizations or entities where research activities will take place *(e.g., permission from school districts where procedures are taking place, permission from an organization that is providing access to potential participants, etc.)*. * Evaluation of any Related Financial Interest. * Grant application * Complete sponsor protocol * DHHS protocol and DHHS-approved sample consent document * Appendix B *(available from HSPP as needed)*: Drugs, Biologics, Dietary Supplements, and Foods, and Device and associated attachments * Appendix C *(available from HSPP as needed)*: Devices and associated attachments * For Department of Energy (DOE) research, a completed “Checklist for IRBs to Use in Verifying that HS Research Protocols are In Compliance with Department of Energy (DOE) Requirements” | | | | | | | | | | | | | |
| **Principal Investigator Acknowledgement** | | | | | | | | | | | | | | |
| **I will conduct this protocol in accordance with requirements in the INVESTIGATOR MANUAL (HRP-103).** | | | | | | | | | | | | | | |
| Principal Investigator (signature or typed name) | | | | | | | Date | | | | | | | |
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| **Appendix A: External Sites** | | | | | | | | | | | | | |
| **Complete for each external (non-MSU Denver) site at which the investigator will conduct or oversee the protocol** | | | | | | | | | | | | | |
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| **Site name** | | **Contact name** | | **Contact phone or email** | | | | **Will site’s IRB review the protocol?** | | | | **Will site rely on this institution’s IRB?** | |
|  | |  | |  | | | | **Yes** | **No** | | | **Yes** | **No** |
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