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| **Research Determination Worksheet** Version 6/13/2018 | **IRB Office & HRPP**  100 North Academy Avenue  Danville, PA 17822-3069  570-271-8663 |

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| ***For HRPP Use Only*** Does not meet definition of “research”  Does not meet the definition of “human subjects”  Requires submission of an IRB application for review **Signature HRPP Reviewer \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

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| **Email a PDF of this completed form to the IRB at** [IRB@geisinger.edu](mailto:IRB@geisinger.edu) **for IRB review and determination.**  The IRB will review your completed worksheet to determine if your proposed activity is human subject research and regulated by Health and Human Services (HHS) and/or Food and Drug Administration (FDA). Once a determination is made, you will receive an IRB Determination Letter with the outcome.  **PLEASE DO NOT** **USE THIS FORM** if drugs, devices or biologics are involved. You must submit a new study application to the IRB within iRIS. Contact the IRB at 570-271-8663 for assistance. |

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| **Project Title:** | | |
| **Principal Investigator (Name):**    MD  DO  PhD  EdD  Pharm D  DNP  Other (Specify): | | |
| Job Title: | Phone: | Fax: |
| Address: | Internal M.C.: | Pager: |
| E-mail: | |
|  | | |
| **Sub-or Co-Investigator (Name):**          MD  DO  PhD  EdD  Pharm D  DNP  Other (Specify): | | |
| Job Title: | Phone: | Fax: |
| Address: | Internal M.C.: | Pager: |
| E-mail: | |
|  | | |
| **Contact Person (Name):**    MD  DO  PhD  EdD  Pharm D  DNP  Other (Specify): | | |
| Job Title: | Phone: | Fax: |
| Address: | Internal M.C.: | Pager: |
| E-mail: | |
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| Are any research team members GSCOM students or GSCOM-paid faculty? Yes  No  If yes, enter the GCSOM Authorization Number:  It is critical for GCSOM administration to track faculty and student research involvement. Please submit a brief summary of your proposal to the GCSOM Office of Research Compliance to receive a tracking number that must be entered here. Please email your proposal summary to Laura Mayeski at [lmayeski@som.geisinger.edu](mailto:lmayeski@som.geisinger.edu). If you have questions, please call GCSOM ORC at 570-955-1308. Thank you. | | |

**Briefly describe your project below. This should include the purpose, description of the subjects, data and/or specimens to be studied.**

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**Please answer the following questions:**

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| Yes  No | 1. Is the activity a systematic investigation, including research development, testing and evaluation? |
| Yes  No | 1. Is the activity intentionally designed to develop **OR** contribute to generalizable knowledge? |
| Yes  No | 1. Is the data the investigator planning to obtain, whether directly from individuals or from their records, about living individuals? |

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| If you answered **NO to ANY** of the questions (A, B, or C) above, this form is completed. Sign the last page and submit.  If you answered **YES to ALL** of the questions (A, B, or C) above, please complete the questions on the next page. |

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| **1. The investigator plans to obtain data through one or more of the following (Check all that apply):** |
| Physical procedures performed on individuals |
| Manipulation of individuals |
| Manipulation of individuals’ environments |
| Communication with individuals |
| Interpersonal contact with individuals |
| **2. Are any of the following true? (Please check all that apply):** |
| The information is about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. |
| The individual has provided the information for specific purposes and can reasonably expect that the information will not be made public. This could include, for example, medical records or school records. |
| The identity of the individual is **or** may readily be ascertained by the investigator from the information received. |
| The identity of the individual is **or** may readily be associated with the information received. |
| **3. Will the PI and/or study team receive any of the following elements (PHI)? (Check all that apply):** |
| Names  Geographic subdivisions smaller than a state (e.g., street address, city, county, zip code, geocodes)  Dates (except ‘year’ alone) directly related to an individual (e.g., date of birth, admission, discharge, test, etc.) or elements of date (including ‘year’ for persons ≥ 90 years old)  Telephone numbers  Fax numbers  E-mail addresses  Social security numbers  Medical record numbers  Health plan beneficiary numbers  Account numbers  Certificate/license numbers  Vehicle identifiers and serial numbers, including license plate numbers  Device identifiers and serial numbers  Web addresses – universal resource locators (“URLs”)  Internet protocol (“IP”) address numbers  Biometric identifiers, including fingerprints and voice prints  Full face photographic images and any comparable images  Other unique identifying number, characteristic, or code  Describe: |
| **PI Signature**        **Date** |