

THE GEORGE WASHINGTON UNIVERSITY & MEDICAL CENTER
OFFICE OF HUMAN RESEARCH
INSTITUTIONAL REVIEW BOARD

EXEMPT FROM IRB REVIEW REQUEST FORM
THIS FORM IS FOR INSTRUCTIONAL USE ONLY!
ALL INSTRUCTIONS ARE PROVIDED IN GREEN ITALICS.

Before completing this form, complete the Human Subject Research Determination worksheet to ensure that you are in fact required to submit your new study to the Office of Human Research. The OHR will only review studies deemed "human subject research."

INVESTIGATOR AND TEAM CONTACT INFORMATION			
IRB# <i>ADMIN USE ONLY—(INCLUDE IF ONE HAS BEEN ASSIGNED TO THIS STUDY)</i>		VERSION DATE: <i>This must be included on all documents.</i>	<i>Date range must be updated if there is a requested change from OHR.</i>
TYPE OF HIPAA AUTHORIZATION REQUESTED:		- choose one - <i>Required for the collection of Protected Health Information (PHI) from a covered entity.</i>	
PROTOCOL TITLE AND SPONSOR:			
TITLE : <i>Name of study: As listed on the grant or protocol if one. Please be consistent across <u>all</u> documents.</i>			
SPONSOR : <i>List any external funding associated with this research</i>			
PRINCIPAL INVESTIGATOR INFORMATION <i>PI must be a Full Time GW Faculty Member. Please complete all fields with current information.</i>			
LAST NAME:	<i>Smith</i>	FIRST NAME:	<i>John</i>
DEPARTMENT	<i>Psychology</i>	SCHOOL:	<i>CCAS</i>
CAMPUS ADDRESS: <i>As applicable</i>			
PHONE:	<i>Provide PI phone # , not a general #.</i>	EMAIL: <i>Please use a <u>GWU, GWUMC, GWUH OR MFA</u> address. Other outside servers may not work with GroupWise</i>	
PRINCIPAL CONTACT IF OTHER THAN PI: <i>THIS MAY BE THE STUDY COORDINATOR, STUDENT, RESEARCHER, ETC.</i>			
LAST NAME:	<i>Researcher</i>	FIRST NAME:	<i>Sally</i>
CAMPUS ADDRESS: <i>As applicable</i>			

Recommendation:

- Study Registered as Exempt. Category: _____
- A HIPAA waiver of research subject authorization is justified for this study under 45 CFR 46 164.512 based on the following criteria:
 1. The proposed uses and disclosures of protected health information (PHI) involve no more than minimal risk to the privacy of individuals.
 2. The research could not practicably be conducted without the waiver.
 3. The research could not practicably be conducted without access to and use of the PHI.

Please obtain permission from the privacy officer of the health care organization in which you will access protected health information before beginning your research.
- This research does **NOT** meet the regulatory/institutional requirements for exemption from IRB review. To conduct this research you must complete an IRB submission package for IRB review. For more information on completing a research submission, contact OHR at 202-994-2715.

Authorized Designee

Signature

Date

This Exempt Registration does not expire nor does it require renewal.

Reporting Proposed Changes in Research

This exempt from IRB review determination only applies to this form/protocol, as currently proposed. Therefore, if there are any changes that increase the risk to subjects (e.g., methodology, data gathering instruments, type of information being accessed or disclosed, etc.) the changes must be submitted to the IRB/OHR for approval PRIOR TO implementation.

PHONE:

EMAIL:

Campus email

Select the category that describes the proposed research activity:

The exemptions outlined below do not apply to ANY research involving prisoners. Research involving children may be exempt with specific restrictions. See below: **PLEASE CHOOSE ONE OR MORE CATEGORIES OF RESEARCH BELOW**

- 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on instructional strategies; **or** research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
The information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
This category may not be applied to children, except in the observation of public behavior.
- 3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement tests), survey procedures, interview procedures or observation of public behavior:
Of human subjects that are elected or appointed public officials or candidates for public office; or Conducted under a Federal statute requiring that the confidentiality of the personally identifiable information be maintained throughout the research and thereafter.
- 4. Research involving the collection or study of pre-existing data sets, documents, records, or specimens, but only if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, either directly or through identifiers linked to subjects [i.e. through use of a key]. If research team does not receive, view or handle identifiable *original source data* at any point, study may be “not human subject research” (see link above to determine).
Research involving one of more of these existing data sets may require you to obtain, prior to using and/or disclosing identifiable health information from the existing data set, either HIPAA research subject authorization integrated into the consent form (see “HIPAA” section of [Medical Consent Guidance](#)) or a [waiver of a research subject authorization](#) granted by the GWU IRB.
***Entire date range must be prior to the date of the application submission.**
Pre-existing= Retrospective data collection: Information that has already been collected
- 5. Research/demonstration projects conducted by other federal departments designed to study or evaluate public programs, procedures for obtaining benefits or services under those programs, possible changes or alternatives to those programs, or possible changes in methods or levels of payment for benefits under those programs.
- 6. Taste and food quality and evaluation / consumer acceptance studies, as long as safe, normal foods are being consumed, and federal guidelines regarding acceptable levels of agricultural chemical or environmental contaminants are adhered to.

RESEARCH SUMMARY (Indicate in **each section below** how this research is consistent with the selected category. Please refer to the provided instruction sheet to ensure all required information is submitted to OHR):

***This application should be in language understandable to OHR reviewers/IRB committee members. Please spell-out any acronyms and abbreviations and use lay-terms, where appropriate.**

Research Purpose

Give a brief summary of the proposed research:

- Describe the specific scientific objectives/aims of the study, including hypotheses where applicable.
- Include background information, rationale/significance for the proposed

	research.
Study Population	<p>Identify the subject population that your research will target for enrollment:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Give the maximum number of subjects that will be needed to achieve the objectives listed. <input type="checkbox"/> Describe the subject population [females/males, age, children, groups, etc], or type of data/specimen(s) [medical records, deidentified tissue, etc.], that will be studied or reviewed. Provide justification for the exclusion of individuals/groups. (The IRB must follow specific guidance and regulations for certain populations). <input type="checkbox"/> Describe if there are any other specific enrollment criteria that persons may need to have/cannot have in order to participate.[Expertise, occupation, diagnosis, etc]. <p><i>NOTE: Research involving prisoners does not qualify for exempt review. Research with children may only be exempted in certain situations (see the review categories above).</i></p>
Subject Recruitment Methods	<p>Describe the plan to recruit participants: “Recruitment” refers to communications and activities with potential participants that support enrollment in the study, prior to consent.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Describe how you will identify potential participants. Explain where/how information regarding inclusion criteria will be accessed and/or obtained. (i.e., medical/student records review, public/private databases, existing contact list, etc). <input type="checkbox"/> Describe plans and methods for the recruitment of participants; indicate where and how they will be used. <input type="checkbox"/> If advertisements will be used for recruitment purposes, specify method(s) that will be used (flyers, posters, websites, radio, newspaper ads, telephone, television, mass e-mails, subject pool, etc.). <p><i>Examples: Email sent by point of contact, calling current patients, posted flyer in store, online ad- website, verbal announcement in a classroom, medical records review from (place) for condition(x).</i></p> <p>*NOTE: A copy of all recruitment/advertising materials including ads, emails, letters and telephone scripts, must be submitted with this application.</p>
Methodology (Be specific)	<p>Provide a step-by-step (1, 2, 3...) description of your research study design, with an emphasis on the collection of human subjects data (see Sample Exempt form for examples):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Identify the type of study (i.e. survey, questionnaires, interview, observational, record review, etc.). <input type="checkbox"/> Describe how informed consent will be obtained. (see information sheet http://www.gwumc.edu/research/human/inside/forms/exempt.html) <input type="checkbox"/> If obtaining verbal, scanned or online consent, (i.e., “agree by clicking here”), indicate that an information sheet will be made available to subjects. <input type="checkbox"/> Describe any procedures, surveys, interviews, or questionnaires used in this study. Indicate the following: <ul style="list-style-type: none"> ▪ All information you will collect for research, pertaining to the subject. Who will conduct each of the research procedures? ▪ How many procedures will there be? How long will each take? ▪ Describe mode of administering all instruments/procedures(e.g., by telephone, in person, one-on-one, group, etc.). Include location of research procedures. (Private, public, etc). <input type="checkbox"/> If data/specimen(s) are <u>not</u> publicly available: <ul style="list-style-type: none"> ▪ Describe how prior approval will be obtained for accessing information for your research (sites other than GWU, GWUH, or the MFA). ▪ Obtain authorizations site permissions to conduct research, as needed to access files/databases, enter private areas, etc. Include these as attachments. <input type="checkbox"/> Specify actions of and interactions with human subjects. If the research involves the viewing, receiving, collecting or recording of information, list all data points
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	<p>you intend to receive/extract from the subject's files (i.e. name, age, email, zip code, etc.).</p> <ul style="list-style-type: none"> <input type="checkbox"/> Indicate if study will involve collection of Protected Health Information (PHI). Please list PHI that will be collected, and submit applicable HIPAA forms. <p><i>Retrospective data collection: Information that has already been collected</i> <i>Prospective data collection: Information currently being or not yet collected.</i></p>
<i>Research Specific Risks</i>	<p>List all known risks of the procedures to be used, and how you will minimize risks. Include psychological, physical, privacy and/or confidentiality risks:</p> <ul style="list-style-type: none"> <input type="checkbox"/> When collecting private information from/about individuals there is always a risk of loss of privacy or confidentiality. This applies to internet surveys due to the nature of the internet and email, and privacy cannot be guaranteed. <input type="checkbox"/> Describe plans to decrease the likelihood of all risks that are listed. <input type="checkbox"/> Identify if data to be collected is of a "sensitive" nature to the participant. <input type="checkbox"/> Discuss briefly how the benefits of the results of this research will outweigh the risk to subjects.
<i>Benefits (to subject and society)</i>	<p>Discuss briefly any potential benefits of this research:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Describe the individual benefits to the participant, if applicable. (payment is not a benefit). <input type="checkbox"/> Explain how will the results of this research contribute to the body of knowledge/ field of study, and to society.
<i>Data Analysis and Justification of Sample Size</i>	<p>State specific scientific data analysis plan:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Provide justification to support the planned sample size indicated above. <input type="checkbox"/> Explain methods for analyzing data and obtaining statistical conclusions.
<i>Confidentiality and privacy (Include plan for data storage, deidentification, and destruction)</i>	<p>Outline how you intend to store the data, private information, and/or identifiable information:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Explain how data will be protected during the research (e.g., locked cabinets, password protection, etc.) by providing a detailed description of data-entry, data transfer, and data storage procedures (How; when, etc.). <input type="checkbox"/> Indicate who will have access to the research data/specimens <input type="checkbox"/> If study involves the collection of existing records or data, (Exempt Category 4), explain how data will be collected, recorded, and stored without identifiers. Information collected from existing records cannot contain any direct identifiers, codes or links to the subject's identification. <input type="checkbox"/> Explain what will be done with the data/specimen(s) once the research is complete <ul style="list-style-type: none"> ▪ If data will be maintained after the completion of the study, describe data use, protection, and storage plans. ▪ Describe data destruction procedures if applicable.
<i>Use of results/findings (plan for dissemination of information)</i>	<p>Describe how study results will be made generalizable:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Explain your intent to publish, present or otherwise share data/results outside of the research entity. (i.e., Journal, book, conference, internet, dissertation, etc). <input type="checkbox"/> Describe if data will be aggregated/ summarized such that <u>no</u> individual data will be communicated, or some individual results will be communicated. <input type="checkbox"/> Indicate any future research use of data or results.

ATTESTATIONS AND REQUIRED SIGNATURES

INVESTIGATIVE TEAM SIGNATURES: My signature indicates that I will respect and protect the rights and welfare of individuals enrolled in this research project. I will also carry out my responsibilities as Principal Investigator as is outlined in Federal-wide Assurance of Protection for Human Subjects, for which GWU is registered with OHRP/DHHS, and as detailed in GWU HRPP policies & procedures. I will be guided by the principles contained in the [Belmont Report](#) and The Code of Federal Regulations governing research with human subjects ([45 CFR 46](#)). I have queried all members of the research team to determine if they have an economic interest in this study as defined by GWU policies. ***These signatures must be originals and are required for submission.***

Principal Investigator (Print/Type) John Smith	Signature John Smith's original signature <i>(scanned or faxed ok, no electronic signatures)</i>	Date 1/11/2011
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Sub-Investigator (Print/Type) Sally Researcher <i>(signatures not required)</i>
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Sub-Investigator (Print/Type) James Resident <i>(signatures not required)</i>
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Student Investigator/Research Coordinator (Print/Type)
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DEPARTMENT CHAIR/DEAN SIGNATURE: My signature indicates that this project has been reviewed by the appropriate departmental parties, who have judged that 1) there is a scholarly and a scientific justification for the protocol, that the study is feasible, and that the proposed methods are scientifically valid, 2) that the department has made the space and time commitment necessary to carry out the project, 3) that the financial implications of the research have been considered and deemed acceptable to the department and 4) that all ethical principles have been appropriately addressed.

Medical, Alan G. Wasserman, MD or Gary Simon, MD, PhD Non-Medical, Name of Dean/Dept. Chair	Signature: Chair or Dean's original signature <i>(scanned or faxed ok, no electronic signatures)</i>
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Department Affiliation/Campus Location
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Phone	Fax	Email
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Please submit to OHR, Ross Hall, Room 613.