

# Sample

## IRB *Exempt* Packet

(Exempt Registration Form Instructions and Sample; Information Sheet Template; Sample Recruitment Flyer, Site Permission, Survey, and Research Protocol)

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

**EXEMPT FROM IRB REVIEW REQUEST FORM**

***ALL INSTRUCTIONS ARE PROVIDED IN BLUE ITALICS.***  
**DO NOT SUBMIT THIS VERSION TO OHR**  
**THIS FORM IS FOR INSTRUCTIONAL USE ONLY!**

**Section II. Investigator and Team Contact Information**

<b>IRB#</b>	-- - choose one - <i>PLEASE OBTAIN PRIOR TO SUBMISSION BY CALLING OR E-MAILING OHR WITH TITLE OF STUDY, NAME OF PI, AND FUNDING SOURCE</i>	<b>VERSION DATE:</b>	<i>This date must be updated if there is a requested change from OHR.</i>
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<b>TYPE OF HIPAA AUTHORIZATION REQUESTED:</b>	- choose one -
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**PRINCIPAL INVESTIGATOR INFORMATION - MUST HOLD FULL-TIME FACULTY STATUS**

<b>LAST NAME:</b>		<b>FIRST NAME:</b>	<b>Degree:</b> - choose one -
<b>DEPARTMENT</b>		<b>SCHOOL:</b>	
<b>CAMPUS ADDRESS:</b>			
<b>PHONE:</b>		<b>EMAIL:</b>	<i>(PLEASE USE A GWU, GWUMC, GWUH OR MFA ADDRESS. OFTEN AOL AND OTHER OUTSIDE SERVERS DO NOT WORK WITH GROUPWISE)</i>

**PRINCIPAL CONTACT IF OTHER THAN PI: (THIS MAY BE THE STUDENT/TRAINEE)**

<b>LAST NAME:</b>		<b>FIRST NAME:</b>	
<b>PHONE:</b>		<b>EMAIL:</b>	<i>(PLEASE USE A GWU, GWUMC, GWUH OR MFA ADDRESS. OFTEN AOL AND OTHER OUTSIDE SERVERS DO NOT WORK WITH GROUPWISE)</i>

**OHR OFFICE USE ONLY!**

OHR Trans: # \_\_\_\_\_

**Recommendations:**

- Study Registered as Exempt. Category: \_\_\_\_\_
- 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.
- This activity is **NOT human subject research**, and does not require exempt registration or IRB approval.*

\_\_\_\_\_  
IRB Chair/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 the protocol, as currently proposed. Therefore, if there are any proposed changes to this exempted study, e.g., protocol, data gathering instruments, type of information being accessed or disclosed, etc., the changes must be reviewed by the GWU IRB PRIOR TO implementation. Such a review will be limited to determining whether the proposed changes result in the study requiring IRB review and approval, or new exemption determination.

**SECTION III. EXEMPT RESEARCH CATEGORIES:**

**Select the category that describes the proposed research activity:**

*The exemptions outlined below do not apply to ANY research involving prisoners, fetuses, pregnant women, human in vitro fertilization or FDA regulated products. Research involving children may be exempt with specific restrictions. See below:*

- |                          |  |
|--------------------------|--|
| <input type="checkbox"/> | 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on instructional strategies; <b>or</b> research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.   |
| <input type="checkbox"/> | 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement tests), survey procedures, interview procedures or observation of public behavior if:<br><i>The information is gathered in such a manner that subjects cannot be identified, either directly (such as if you use photographs, video tapes, or voice recordings) or indirectly through identifiers (e.g., codes) linked to individuals; <u>and</u></i><br><i>Any disclosure of the subjects' responses outside of the research will not be damaging to the subject in any way (i.e., subject him/her to criminal or civil liability, damage financial standing, reputation, etc).</i> |
| <input type="checkbox"/> | 3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement tests), survey procedures, interview procedures or observation of public behavior: <b>This category may not be applied to children, except in the observation of public behavior.</b><br><i>Of human subjects that are elected or appointed public officials or candidates for public office; <u>or</u></i><br><i>Conducted under a Federal statute requiring that the confidentiality of the personally identifiable information be maintained throughout the research and thereafter.</i>  |
| <input type="checkbox"/> | 4. Research involving the collection or study of existing data sets, documents, records, or specimens, but <u>only</u> if these sources are <u>publicly available</u> or if the information is recorded by the investigator in such a manner that <u>subjects cannot be identified</u> , either directly or through identifiers linked to subjects.<br><i>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 a HIPAA research subject authorization or a waiver of a research subject authorization granted by the GWU IRB.</i>                   |
| <input type="checkbox"/> | 5. Research/demonstration projects <u>conducted by other federal departments</u> 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.   |
| <input type="checkbox"/> | 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.  |

**SECTION IV. 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):

**Purpose:**

*Give a brief summary of the proposed research describing the specific scientific objectives, including background information and rationale of the proposed research.*

*This summary should be in language understandable to the IRB committee members. Remember the IRB Committees are comprised of scientists with varied backgrounds, non-scientists, and community members. Many of them will not understand terms which are commonly used in your specialization.*

<p><i>Methodology:</i></p>	<p><i>List briefly the objective(s) of the study. Identify the type of study (i.e. survey, questionnaires, interview, observation, double-blind, open-label, etc.). Add significance of research.</i></p> <p><i><u>Describe any procedures, surveys, interviews, or questionnaires used in this study. Indicate who will conduct the survey(s), interview(s) or questionnaire(s). How long will they be? How many?</u></i></p> <p><i>In addition, describe the setting and mode of administering the instrument (e.g., by telephone, one-on-one, group, etc.) and attach a copy of all instruments. Indicate if any questions, or pictures shown, may be of a "sensitive" nature to the participant.</i></p> <p><i>How will consent be obtained? Will an information sheet be made available to subjects?</i></p> <p><i>If your study involves identifiable data collection please list all data points you intend to receive/extract from the subjects files (i.e. name, age, location of residence, zip code, etc.) Include all information you will receive pertaining to the subject. The IRB will use this list in order to ensure you are recording information in such a manner that subjects cannot be identified. {Exempt Category 4}</i></p>
<p><i>Study Population:</i></p>	<p><i>Describe the subject population or type of data/specimen(s) that will be studied or reviewed. It is important to identify who your research subjects will be, as the IRB must follow specific guidance and regulations for certain populations.</i></p> <p><i>Research involving prisoners does not qualify for exempt review. Also indicate the type of data or specimens.</i></p> <p><i>Give the approximate number of subjects that will be needed to achieve the objectives listed. Provide statistics to support the sample size.</i></p> <p><i>Describe inclusion/exclusion criteria. Justify exclusions.</i></p>
<p><i>Research Specific Risks:</i></p>	<p><i>List all known risks of the procedures to be used. Discuss briefly the benefits of the results of this research will out weigh the risk to subjects.</i></p> <p><i><u>Include all risks associated with privacy and/or confidentiality. If you are collecting private information from/about individuals there is always a risk of loss of privacy or confidentiality. However, there are steps you may take in order to decrease the likely hood of these risks. Those procedures should be outlined in the section entitled ‘Confidentiality and Privacy for the subjects’</u></i></p> <p><i>If you intend on using an internet survey this also applies. Due to the nature of the internet privacy cannot be guaranteed.</i></p>
<p><i>Uses of data:</i></p>	<p><i>Who will have access to the research information, what will be done with the data/specimen(s) once the research is complete.</i></p> <p><i>If the data/specimen(s) are not publicly available, describe how prior approval will be obtained for accessing this information (attach approval letter, if available). Provide a site permission letter as an attachment if</i></p>

	<i>you are intending on visiting sites other than GWU, GWUH, or the MFA for your research.</i>
<b>Subject Recruitment:</b>	<i>Describe the plan to recruit participants.  Identify if any advertisement for recruitment purposes will be used. If “yes”, identify the method(s) of advertisement that will be used (internet, letters, radio, newspaper ads, telephone, television, flyers, posters, mass e-mails). *NOTE: A copy of all advertising materials including ads, letters and telephone scripts, must be submitted with this application. If graphics will be used, the materials must be submitted for review and approval.</i>
<b>Justification of Sample Size:</b>	<i>Give the approximate number of subjects that will be needed to achieve the objectives listed. Provide statistics to support the sample size.</i>
<b>Confidentiality and privacy for the subjects:</b>	<i>Outline how you intend to store the data.  Indicate if this study involves the collection of existing records or data often referred to as "on-the-shelf" data [see 45 CFR 46.101 (b)(4)], and how this data is collected, stored and de-identified. In order to qualify for exempt category 45 CFR 46.101(b)(4), the information or data collected from the existing records must not contain any direct patient identifies. An "identifier" means any method or "code" that an Investigator assigns to the data so that he/she may link the data collected back to the individual's medical record or other identifying record.</i>
<i>Principal Investigator's Assurance Statement. Carefully read this entire statement prior to signing.</i>	

**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) <b>John Smith</b>	Signature <i>John Smith's original signature</i>	Date 1/1/2007
Sub-Investigator (Print/Type) <b>Erica Davis</b>	Signature <i>Erica Davis' original signature</i>	Date 1/1/2007
Sub-Investigator (Print/Type)	Signature	Date 1/1/2007
Student Investigator/Research Coordinator (Print/Type) <b>Sally Jones</b>	Signature <i>Sally Jones' original signature</i>	Date 1/1/2007

**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.

Chair/Dean Name (Print/Type) <b>Chair or Dean's Name</b>	Signature <i>Chair or Dean's original signature</i>	
Department Affiliation/Campus Location		
Phone	Fax	Email
<b>ADDITIONAL DEPARTMENT CHAIR SIGNATURES (IF APPLICABLE)</b>		
Chair/Dean Name (Print/Type)	Signature	
Phone	Fax	Email

**List attachments:** (CV/resume, site permission letter, flyer, etc.): [\*List all attachments here.\*](#)

**Please submit to OHR, Ross Hall, Room 613.**

SAMPLE



**SECTION III. EXEMPT RESEARCH CATEGORIES:**

**Select the category that describes the proposed research activity:**

*The exemptions outlined below do not apply to ANY research involving prisoners, fetuses, pregnant women, human in vitro fertilization or FDA regulated products. Research involving children may be exempt with specific restrictions. See below:*

- |                                     |   |
|-------------------------------------|---|
| <input type="checkbox"/>            | 7. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on instructional strategies; <b>or</b> research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.  |
| <input checked="" type="checkbox"/> | 8. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement tests), survey procedures, interview procedures or observation of public behavior if:<br><i>The information is gathered in such a manner that subjects cannot be identified, either directly (such as if you use photographs, video tapes, or voice recordings) or indirectly through identifiers (e.g., codes) linked to individuals; and</i><br><i>Any disclosure of the subjects' responses outside of the research will not be damaging to the subject in any way (i.e., subject him/her to criminal or civil liability, damage financial standing, reputation, etc).</i> |
| <input type="checkbox"/>            | 9. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement tests), survey procedures, interview procedures or observation of public behavior: <b>This category may not be applied to children, except in the observation of public behavior.</b><br><i>Of human subjects that are elected or appointed public officials or candidates for public office; or</i><br><i>Conducted under a Federal statute requiring that the confidentiality of the personally identifiable information be maintained throughout the research and thereafter.</i>  |
| <input type="checkbox"/>            | 10. Research involving the collection or study of existing data sets, documents, records, or specimens, but <u>only</u> if these sources are <u>publicly available</u> or if the information is recorded by the investigator in such a manner that <u>subjects cannot be identified</u> , either directly or through identifiers linked to subjects.<br><i>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 a HIPAA research subject authorization or a waiver of a research subject authorization granted by the GWU IRB.</i>           |
| <input type="checkbox"/>            | 11. Research/demonstration projects <u>conducted by other federal departments</u> 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.   |
| <input type="checkbox"/>            | 12. 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.  |

**SECTION IV. 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):

<b>Purpose:</b>	The purpose of this study is to evaluate the opinions of {XXXX} on {XXXX}.
<b>Methodology:</b>	<b>Example for survey research:</b> The objective of the study is to better understand student beliefs concerning {XXXX}. In order to do so I am going to administer a survey to students at GWU. The surveys will take approximately 20 minutes to complete and they will be passed out during classes taught within the psychology and sociology departments. They do not collect any sensitive information, they will only collect age, race, sex, major in school, and level within school (freshmen, sophomore, etc.) as well as answers to questions on a Likert scale regarding {XXXX}.

	<p>The professor will leave the room and I will read the attached recruitment script to the students prior to handing out the survey. An information sheet will be attached to the anonymous survey to inform the subjects of their rights as research participants. They will be instructed to not put their name on any of the materials in order for all answers to remain anonymous. I will then instruct them to drop the surveys in a box which will be located outside the classroom on their way out and I will inform them I will return in 2 hours to collect the surveys. I will also instruct them to drop their surveys in the box even if they choose not to participate, with the option to leave the survey blank or write “VOID” across the survey if they did not complete it, to ensure no one knows who did and who did not complete the survey. Permission letters are included in this submission from the teacher(s) who are allowing me to enter their class and conduct my research with their students.</p> <p><b>Example for retrospective data and records based research:</b>  The objective of this study is to better understand {XXXX}. In order to do so I will be reviewing data collected by {name of entity or organization} from {DATE} to {DATE}. There is a site permission letter attached which includes a list of all data points which will be released by the institution. (OR, if reviewing medical records – There is a waiver of research subject authorization included which has been signed by the privacy officer at the GW Hospital). I will receive the information and/or record the information in such a way that subjects cannot be identified. I will ensure this by only recording the following data points: {LIST}</p>
<p><i>Study Population:</i></p>	<p><b>*Research involving prisoners, research involving interaction with children (not observation only) AND research related to FDA drugs/devices DOES NOT qualify for exempt review.</b></p> <p><b>Example:</b>  My study population will include any student participating in the classes I have permission to recruit from. Both males and females will be included and no one will be excluded based on ethnicity or race, school status (freshmen, sophomore, etc.) or socioeconomic status.</p> <p><b>Example for retrospective data and records based research:</b>  My study population will include males who have undergone treatment for prostate cancer at GW Hospital between {GIVE DATES}. Because this study is focusing on prostate cancer, only males will be included in this study, and non one will be excluded based on race, ethnicity or socioeconomic status.</p>
<p><i>Research Specific Risks:</i></p>	<p><b>Example:</b>  There are no physical risks associated with this study, but there is a possible risk of loss of confidentiality or privacy of the subjects. However, since this is an anonymous survey, no identifiable information will be collected. The specific procedures for maintaining confidentiality and privacy are outlined below in that section.</p> <p><b>Example for retrospective data and records based research:</b>  There are no physical risks associated with this study, but there is a possible risk of loss of confidentiality or privacy of the subjects. However, no identifiable information will be collected or recorded from the medical record so all information will remain anonymous.</p>

	<p>-OR, if receiving data points from database: The only data points received from {name of organization or database} will be {LIST DATA POINTS}, therefore, no identifiable information will be released. Please see the attached site permission that also affirms that all data released will be de-identified and anonymous. The specific procedures for maintaining confidentiality and privacy are outlined below in that section.</p>
<i>Uses of data:</i>	<p><b>Example:</b> Only the researchers will have access to the data, and since no identifying information was collected in this study, there will not be any identifying information used in any publications, including GWU not being named as the institution where research took place. At the completion of the study, the surveys collected will be disposed of by shredding them.</p>
<i>Subject Recruitment:</i>	<p><b>Example for survey research:</b> I will use a recruitment script, which is attached, that will be read to the students in class. It will give a brief description of the study including purpose, time commitment and any risks. They will also receive an information sheet with the survey that will describe the study in more detail. Site permissions from the teachers of the classes I will be using are attached.</p> <p><b>-or-</b> Flyers will be posted around the GWU campus (see attached) which will list the general premise of the study as well as my contact information for interested individuals.</p> <p><b>Example for retrospective data and records based research:</b> I am using off-the-shelf data on 1000 subjects provided by {XXXX} on their webpage {XXXX}.</p> <p><b>-or-</b> I am receiving data from the University of Pennsylvania on 1,000 subjects. See attached permission letter which indicates what data will be provided.</p>
<i>Justification of Sample Size:</i>	<p><b>Example for survey research (NOT ONLINE):</b> I will recruit 100 subjects to take this survey from various psychology and sociology classes. This will be an adequate number of subjects to answer my research question. Any less than this number would invalidate the data, and more than that will not be necessary at this point in time to answer the research question. I intend to use the following statistical methods (if any): LIST.</p> <p><b>Example for survey research (ONLINE):</b> The target number of participants I will need in order to answer my research question is 100, however, since the survey will be conducted online more or less people may participate depending on the response rate and interest. The following statistical methods will be used to analyze the data (if any): LIST</p> <p><b>Example for retrospective data and records based research:</b> I will receive data on 1000 subjects provided by {XXXX}. This will be an adequate number of subjects to answer my research question. Any less than this number would invalidate the data but I believe that enrollment of more subjects would be unnecessary. I intend to use the following statistical methods: LIST.</p>
<i>Confidentiality and privacy for the subjects:</i>	<p><b>Example:</b> The data will be stored in a locked filing cabinet in the PI's office. It will then be transferred to my personal computer and password protected. The paper files will be destroyed once this procedure is complete. Once the research is complete the</p>

data set will be deleted.

**Example for retrospective data and records based research:**

The data will be collected in such manner that subjects cannot be identified. The only information I intend on extracting from the records is the subject's sex, age, race, number of hospitalizations and any treatment related information from the record (i.e., blood test results, x-rays, CT scans, etc.). This information is not enough to identify the research subject. There are no codes in existence which will allow the researcher to link the data back to the subject.

**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) <b>Jane Researcher, Phd</b>	Signature <i>Jane Researcher</i>	Date 9/12/2007
Sub-Investigator (Print/Type)	Signature	Date
Sub-Investigator (Print/Type)	Signature	Date
Student Investigator/Research Coordinator (Print/Type) <b>Joseph Research, Phd</b>	Signature <i>Joseph Researcher</i>	Date 9/12/2007

**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.

Chair/Dean Name (Print/Type) <b>Chair of Department</b>	Signature <i>Chair of Department</i>
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Department Affiliation/Campus Location		
Phone	Fax	Email

**ADDITIONAL DEPARTMENT CHAIR SIGNATURES (IF APPLICABLE)**

Chair/Dean Name (Print/Type)	Signature	
Phone	Fax	Email

**List attachments** (*site permission letter, flyer, etc.*): Information Sheet Version xx/xx/xxxx, Site Permission Letter Dated xx/xx/xxxx, Flyer Version xx/xx/xxxx, Survey Version xx/xx/xxxx, Waiver of Research Subject Authorization Dated xx/xx/xxxx

**Please submit to OHR, Ross Hall, Room 613.**

## Information about the Research Study

{Title}

{IRB #}

**Instruction: Investigators should use the following information sheet format. Non-highlighted language represents recommended language. Highlighted text represents instructions and must be deleted in the final version that will be submitted to the IRB. This form must be written using language understandable at an eighth-grade reading level.**

You are invited to participate in a research study under the direction of Dr. {name of Principal Investigator} of the Department of {name of Department}, George Washington University (GWU), and paid for by {Sponsor name, if any}. Taking part in this research is entirely voluntary. (If GW students are participants, include the following statement) Your academic standing (or) the status of your employment will not, in any way, be affected should you choose not to participate or if you decide to withdraw from the study at any time.

The purpose of this study is to (state the goals or objective of the research study)

The research will be conducted at the following location(s):

A total of {#} participants at approximately {#} institutions will be asked to take part in this study. You will be one of approximately {#} participants to be asked to take part at this location.

If you choose to take part in this study, you will (explain procedures, and designate which ones are research activities). The total amount of time you will spend in connection with this study is (specify amount of time, in hours, days or months)

There are no physical risks associated with this study. There is, however, the possible risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this can not be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

You will not benefit directly from your participation in the study. The benefits to science and humankind that might result from this study are: (state the benefit to science or mankind that you anticipate will result from this study)

You [will/will not] be paid for taking part in this study.

The investigator can decide to withdraw you from the study at any time. You could be taken off the study for reasons related solely to you (for example, not following study-related directions from the Investigator) or because the entire study is stopped.

If results of this research study are reported in journals or at scientific meetings, the people who participated in this study will not be named or identified. GW will not release any information about your research involvement without your written permission, unless required by law.

(Add a description of how the privacy of research subjects and the confidentiality of research records will be protected.)

The Office of Human Research of George Washington University, at telephone number (202) 994-2715, can provide further information about your rights as a research participant. If you think you have been harmed in this study, please report this to the Principal Investigator of this study or call the Office of Human Research immediately. Further information regarding this study may be obtained by contacting \_\_\_\_\_ (explain person's relationship to study) \_\_\_\_\_, at telephone number ( ) \_\_\_\_\_.

To ensure anonymity, your signature is not required in this document unless you prefer to sign it. Your willingness to participate in this research study is implied if you proceed with completing the survey/interview.

\*Please keep a copy of this document in case you want to read it again.

# GWU Research

## Research Title

Call Jane Researcher, PhD, for more information: XXX-XXX-XXXX

FDA suggested information for advertisements from the IRB information sheet available at the following link:

<http://www.fda.gov/oc/ohrt/irbs/toc4.html#recruiting>

1. the name and address of the clinical investigator and/or research facility;
2. the condition under study and/or the purpose of the research;
3. in summary form, the criteria that will be used to determine eligibility for the study;
4. a brief list of participation benefits, if any (e.g., a no-cost health examination);
5. the time or other commitment required of the subjects; and
6. the location of the research and the person or office to contact for further information.

\* Remember you can be creative but be careful not to be minimize the risks or exaggerate the benefits.

*This is a sample site permission letter. The format and language is entirely optional and may be generated by either GWU and sent to the site for signature or generated by the site, signed and sent to the GWU investigator. This letter must be signed by an appropriate official from the intended location and submitted with the application.*

---

**Date:** XXXX/XXXX

**To:** GWU Research Staff (insert name here)

**From:** Outside Research Location or Holder of Data to be Released to GWU (insert name here)

**Re:** Site Permission for GWU Off-Site Research Activities

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The following data points will be released to {insert researchers name} and the George Washington University:

{list} or {see attached}

The codes associated with these data will not be released to the researcher.

-or-

The officials at the {insert institutions name} have reviewed the research proposal entitled {insert title}. We hereby grant permission to {Insert Researcher Name} to visit our site to conduct this research.

Sincerely,

(type name here)



## General Patient Information

In general, what is the quality of your health?

- Outstanding     Good     Some chronic issues     Poor

How often have you visited [Healthcare Facility Name] within the past year?

- First Visit     2-5 Visits     More than 6

## Scheduling Your Appointment

Did you schedule an appointment by phone or did you drop in?

- Scheduled by phone     Dropped in

If you scheduled an appointment, did you have to wait longer than expected to get scheduled?

- Yes     No

How easy was it to make an appointment by telephone?

- Very easy                         Very difficult

How long did you wait to speak to a scheduling staff member?

- 0 to 2 minutes     3 to 5 minutes     5 to 7 minutes     Longer

Was the person who scheduled your appointment courteous and helpful?

- Very courteous                         Rude

## Day of Your Appointment

How long did you wait in the reception area beyond your scheduled appointment time?

- 0 to 5 minutes     5 to 20 minutes     20 to 40 minutes     Other \_\_\_\_\_

How long did you wait in the exam room before the physician appeared?

- 0 to 5 minutes     5 to 20 minutes     20 to 40 minutes     Other \_\_\_\_\_

## The Nursing Staff

How would you rate the competence of the nurse who helped you?

- Outstanding     Good     Adequate     Needs improvement     Poor     N/A

How would characterize the concern that the nurse showed for your problem?

- Outstanding     Good     Adequate     Needs improvement     Poor     N/A

Did the nurse respond to your requests within a reasonable period?

- Yes     No

## The Doctor

Were you able to see the doctor of your choice?

- Yes     No     N/A

Did you feel that your doctor spent an adequate amount of time with you?

- Yes     No     N/A

Mark the boxes that characterize the demeanor of your doctor:

- Attentive     Concerned     Friendly     Distracted     Rushed     Inconsiderate

**Please rate the clarity of the doctor's explanation of your condition and treatment options:**

- Outstanding     Good     Adequate     Needs improvement     Poor     N/A

**How well did your doctor include you in healthcare decisions?**

- Outstanding     Good     Adequate     Needs improvement     Poor     N/A

**Were your questions answered to your satisfaction?**

- Yes     No     N/A

**Would you recommend this facility and its staff to your family and friends?**

- Yes     No     N/A

SAMPLE

# RESEARCH PROTOCOL

## Required Elements

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**TITLE:**

### **RESEARCH PLAN**

**A. Specific Aims**

List the broad, long-term objectives and describe concisely and realistically what the specific research described in your proposal is intended to accomplish, and the hypothesis to be tested.

**Hypothesis:**

**B. Background and Significance**

Briefly give the background to the present proposal, critically evaluate existing knowledge, and specifically identify the gaps which the project is intended to fill. Cite literature and include a list of references.

**C. Preliminary Studies**

Provide an account of the PI's preliminary studies pertinent to the protocol and/or any other information that will help to establish the experience and competence of the PI/IS to pursue the proposed project. The titles and complete references to appropriate publications and manuscripts submitted or accepted for publication may be listed.

**D. Research Design and Methods**

Describe the research design and the procedures to be used to accomplish the specific aims of the project. Include the means by which the data will be collected, analyzed, and interpreted.

1. Describe any new methodology and its advantage over existing methodologies.
2. Discuss potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.
3. Provide a tentative sequence or time table for the study.
4. Specify procedures, situations, or materials that may be hazardous to personnel and the precautions to be taken to ensure safety.
5. Provide justification of the sampling procedure and sample size. Gender and Minority Inclusion, it is required that all research involving human subjects and human materials include minorities and women, as well as males and females of all ages. If one gender and/or minorities are excluded or are inadequately represented in a protocol, particularly in proposed population-based studies, a clear compelling rationale for exclusion or inadequate representation should be provided.

The composition of the study population must be described in terms of gender and racial/ethnic group, together with a rationale for its choice (by age distribution, risk factors, incidence/prevalence, etc.)

6. Identify all drugs and devices to be used, if applicable,. If the drug or device is investigational under FDA policy, list the actual IND/IDE number and respective source, supplier, and/or sponsor. If an IND/IDE has been assigned provide the FDA stage status. Note the proposed dosage related information including instructions for administering, adverse effects, compatibility in infusions, and stability.
7. Identify all procedures that will be used for the purpose of this research. If blood is to be drawn, indicate amount to be withdrawn per single withdrawal, and the total amount of blood to be drawn. If transfusions are anticipated, include assurance that the volume of blood removed for research purposes will not necessitate a transfusion. [Refer to Section 1.5.5]

#### **E. Study Population –(Gender and Minority Inclusions):**

Describe the *characteristics of the subject population*, include the anticipated number of normal volunteers, age ranges, sex, ethnic background, and health status. Identify the criteria for inclusion or exclusion (especially women and/or minorities). Explain the rationale for the use of special classes of subjects, such as fetuses, pregnant women, or others who are likely to be vulnerable, especially those whose ability to give voluntary informed consent may be questionable.

#### **F. Human Subjects (Risks & Benefits)**

1. Identify *sources of research material* obtained from individually identifiable living human subjects in the form of specimens, records or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records or data. Subjects with specific diseases or conditions are often identified as potential subjects through some type of record (e.g., medical records, patient charts, registries for cancer cases, surgical or X-ray log books, school records). Controls may come from the same population as the subjects (which is always the case in a randomized clinical trial), be persons with unrelated conditions or be volunteers from the general population.
2. Describe *plans for recruitment of subjects and the consent procedures* to be followed; including the circumstances under which consent will be sought and obtained, who will seek it, who will give consent, the age range of the individual who will give consent, the nature of the information to be provided to prospective subjects, payment for participation (if applicable), the prospective subjects, and the method of documenting consent. (State if you are requesting a 'waiver of consent' from the IRB and why.) [Refer to Section 3.0]

#### **G. Risks and Side Effects:**

1. Describe any *potential risks--physical, psychological, social, legal, or other* and assess their likelihood and seriousness. Describe the alternative treatments and procedures that might be advantageous to the subjects.
2. Describe the *procedures for protecting against or minimizing any potential risks*, including risks to confidentiality, and assess their likely effectiveness. Discuss provisions for insuring necessary medical or professional intervention in the event of adverse effects to the subjects. Describe the provisions for monitoring the data to insure the safety of subjects.

3. Discuss *why the risks to subjects are reasonable in relation to the anticipated benefits* to subjects and in relation to the importance of the knowledge that may be reasonably expected to result.
4. List all risks that are more than minimal (no greater probability or magnitude than those ordinarily encountered in daily life or during routine medical tests). Include physical, psychological, social, economic, legal or other risks, where present.
5. Describe the severity and probability of all material risks, and the implications, in understandable terms. Use a table for Common (21-100/100), Occasional (5-20/100) and Rare (<5/100) risks sorted by Immediate (1-2 days of treatment), Prompt (within 2-3 weeks before next course), Delayed (any later time during treatment) and Late (after completion of treatment) onset wherever possible.

#### **H. Benefits:**

1. The risks must be reasonable in relation to anticipated benefits, if any, to subjects, and to the importance of the knowledge reasonably expected to result.
2. The use of modest compensation for the burdens imposed by the research may be permitted, especially if benefits are minimal, but should be incremental and not conditioned on completion of the entire study.
3. Explain the expected benefits, if any, and their likelihood. If none, say so.
4. You may mention general benefits for science, or for other persons, if any.

#### **I. Outside Consultants/Collaborators**

Attach a letter from the consultant(s) and/or their signature(s) on the Application (Sign-Off) Form confirming their role in the project.

#### **J. Contractual Agreements**

Describe the nature of these collaborations. Attach an appropriate letter from each individual/institution involved confirming the agreement. If the protocol originates at another institution, explain how CH will be involved and provide the name and department of the Institutional Sponsor. The assigned PI/IS must be a faculty/staff member of CH.

#### **K. Costs To Subjects:**

1. The Research Plan and the consent documents must describe the costs to such compensation plans in detail, including the provision of free care or medicines related to the study.

*Example:* Children's Hospital will give you the medicine used in this study for free. You will not be charged for anything else we do that is part of the study. You will still have to pay for any medical care that is not part of the study.

**L. Conflicts Of Interest:**

1. Describe any financial or other conflicts of interest as indicated. Any interests of the investigators or provider institutions in the outcome of the research, the study product, or the sponsoring entities, any support received by the researchers or provider institutions from same in excess of \$25,000 per year, and any other relationship to the sponsor or the research that could be material to any subject.
2. Where such interests exist, describe the disclosures that will be made to subjects in the consent process and consent documents and discuss the factors considered in selecting the appropriate disclosures. Consult §2.3 of the Manual for a discussion of materiality and appropriate disclosure to subjects, including disclosure of sponsor identity and source of funding where potentially material to subjects.
3. Review the *Financial Interest Disclosure* form submitted to the Office of Sponsored Programs to ensure that it is current and consistent with the *Application* disclosure.

**M. Confidentiality:**

Include appropriate provisions to protect the privacy of subjects and maintain the confidentiality of data, and include safeguards to protect the rights and welfare of vulnerable subjects.

**N. Subject Compensation:**

The Research Plan must describe such compensation plans in detail, including the provision of free care or medicines related to the study.

**O. Facilities and Equipment**

Describe the facilities and equipment to be used. Indicate the extent to which these facilities and equipment are available or will be obtained for the project.

**P. References & Literature Cited**

Compile a judicious list of relevant literature citations. Each literature citation must include the title, names of authors, book or journal, volume number, page numbers, and year of publication.

**Q. Appendix**

Attach the letters of confirmation from collaborating institutions, consultants, research documents (e.g., questionnaires, scales, tables, charts, diagrams, manufacturers brochures, etc.) in this section.

**PLEASE REMEMBER TO PAGE NUMBER THE ENTIRE DOCUMENT**