IRB Boards and Qualitative Research:
Bonus Handouts #5
GW Forms and Examples

Presented By: Jo Anne Schneider, PhD

Provided By:
Principal Investigators Association™

Principal Investigators Association
9990 Coconut Road, Ste 316
Bonita Springs, FL 34135
800-303-0129
www.principalinvestigators.org
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.

The George Washington University
Office of Human Research
Institutional Review Board

Exempt from IRB Review Request Form

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.”

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 risks 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.

<table>
<thead>
<tr>
<th>INVESTIGATOR AND TEAM CONTACT INFORMATION</th>
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<tr>
<td>IRB# (ADMIN USE ONLY--WILL BE ASSIGNED UPON SUBMISSION)</td>
<td>VERSION DATE:</td>
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<tr>
<td>TYPE OF HIPAA AUTHORIZATION REQUESTED:</td>
<td>- choose one -</td>
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<td>PROTOCOL TITLE AND SPONSOR:</td>
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<td>TITLE:</td>
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<td>SPONSOR:</td>
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<td>PRINCIPAL INVESTIGATOR INFORMATION (MUST BE GWU FACULTY)</td>
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<td>LAST NAME:</td>
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<td>PRINCIPAL CONTACT IF OTHER THAN PI: (THIS MAY BE THE STUDENT/TRAINEE)</td>
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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:

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.

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** *(Please see Exempt Instructions to ensure all required information is included in application)*

<table>
<thead>
<tr>
<th>Research Purpose</th>
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<tbody>
<tr>
<td>Study Population</td>
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<tr>
<td>Subject Recruitment Methods</td>
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<tr>
<td>Methodology <em>(Step-by-step 1,2,3 description of study design)</em></td>
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<tr>
<td>Research Specific Risks</td>
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<tr>
<td>Benefits <em>(to subject and society)</em></td>
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<tr>
<td>Data Analysis and Justification of Sample Size</td>
</tr>
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<td>Confidentiality and Privacy <em>(Include plan for data storage, deidentification, and destruction)</em></td>
</tr>
<tr>
<td>Use of results/findings <em>(plan for)</em></td>
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**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.*

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<td>Sub-Investigator (Print/Type)</td>
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<tr>
<td>Student Investigator/Research Coordinator (Print/Type)</td>
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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 Dept. Chair  
Department Affiliation/Campus Location

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<th>Phone</th>
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Please submit to OHR, 2030 M St. NW Suite 301 with all materials identified in the IRB Submission Checklist
Recommendation:

- Study Registered as Exempt. Category: _______.
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  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 (PHI) from a covered entity.

- 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: ___________________________

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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.
**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**

<p>| | |</p>
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| 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.** |
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   - *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.*

<table>
<thead>
<tr>
<th>Research Purpose</th>
<th>Give a brief summary of the proposed research:</th>
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</table>
|   | □ Describe the specific scientific objectives/aims of the study, including hypotheses where applicable.  
   □ Include background information, rationale/significance for the proposed... |
**Study Population**

Identify the subject population that your research will target for enrollment:

- Give the maximum number of subjects that will be needed to achieve the objectives listed.
- 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).
- 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].

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).

**Subject Recruitment Methods**

Describe the plan to recruit participants: “Recruitment” refers to communications and activities with potential participants that support enrollment in the study, prior to consent.

- 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).
- Describe plans and methods for the recruitment of participants; indicate where and how they will be used.
- 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.).
  
  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(s).

*NOTE: A copy of all recruitment/advertising materials including ads, emails, letters and telephone scripts, must be submitted with this application.

**Methodology (Be specific)**

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):

- Identify the type of study (i.e. survey, questionnaires, interview, observational, record review, etc.).
- Describe how informed consent will be obtained. (see information sheet http://www.gwumc.edu/researchhuman/inside/forms/exempt.html)
- If obtaining verbal, scanned or online consent, (i.e., “agree by clicking here”), indicate that an information sheet will be made available to subjects.
- Describe any procedures, surveys, interviews, or questionnaires used in this study. Indicate the following:
  - 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).
- If data/specimen(s) are not publicly available:
  - 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.
- Specify actions of and interactions with human subjects. If the research involves the viewing, receiving, collecting or recording of information, list all data points.
| **Research Specific Risks** | List all known risks of the procedures to be used, and how you will minimize risks. Include psychological, physical, privacy and/or confidentiality risks:
| | □ Indicate if study will involve collection of Protected Health Information (PHI). Please list PHI that will be collected, and submit applicable HIPAA forms.
| | Retrospective data collection: Information that has already been collected
| | Prospective data collection: Information currently being or not yet collected.
| | When collecting private information from/about individuals there is 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.
| | Describe plans to decrease the likelihood of all risks that are listed.
| | Identify if data to be collected is of a "sensitive" nature to the participant.
| | Discuss briefly how the benefits of the results of this research will outweigh the risk to subjects.

| **Benefits (to subject and society)** | Discuss briefly any potential benefits of this research:
| | □ Describe the individual benefits to the participant, if applicable. (payment is not a benefit).
| | □ Explain how will the results of this research contribute to the body of knowledge/field of study, and to society.

| **Data Analysis and Justification of Sample Size** | State specific scientific data analysis plan:
| | □ Provide justification to support the planned sample size indicated above.
| | □ Explain methods for analyzing data and obtaining statistical conclusions.

| **Confidentiality and privacy (Include plan for data storage, deindentification, and destruction)** | Outline how you intend to store the data, private information, and/or identifiable information:
| | □ 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.).
| | □ Indicate who will have access to the research data/specimens.
| | □ 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.
| | □ Explain what will be done with the data/specimen(s) once the research is complete
| | • If data will be maintained after the completion of the study, describe data use, protection, and storage plans.
| | • Describe data destruction procedures if applicable.

| **Use of results/findings (plan for dissemination of information)** | Describe how study results will be made generalizable:
| | □ Explain your intent to publish, present or otherwise share data/results outside of the research entity. (i.e., Journal, book, conference, internet, dissertation, etc).
| | □ Describe if data will be aggregated/summarized such that no individual data will be communicated, or some individual results will be communicated.
| | □ 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.**

<table>
<thead>
<tr>
<th>Principal Investigator (Print/Type)</th>
<th>John Smith</th>
<th>Signature</th>
<th>John Smith’s original signature (scanned or faxed ok, no electronic signatures)</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>Sub-Investigator (Print/Type)</td>
<td>Sally Researcher (signatures not required)</td>
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<tr>
<td>Sub-Investigator (Print/Type)</td>
<td>James Resident (signatures not required)</td>
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<tr>
<td>Student Investigator/Research Coordinator (Print/Type)</td>
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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.

<table>
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<tr>
<th>Medical, Alan G. Wasserman, MD or Gary Simon, MD, PhD</th>
<th>Signature: Chair or Dean's original signature (scanned or faxed ok, no electronic signatures)</th>
<th>Non-Medical, Name of Dean/Dept. Chair</th>
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</thead>
<tbody>
<tr>
<td>Department Affiliation/Campus Location</td>
<td>Phone</td>
<td>Fax</td>
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</table>

**Please submit to OHR, Ross Hall, Room 613.**
HUMAN RESEARCH STUDY SYNOPSIS (VERSION DATE: )

TITLE:
SPONSOR (FOR EXTERNAL FUNDING ONLY):
IRB # (if already assigned, otherwise leave blank--will be assigned upon submission):

PRINCIPAL INVESTIGATOR (MUST BE GWU FACULTY)
LAST NAME: FIRST NAME: DEGREE:
DEPARTMENT: SCHOOL:
ADDRESS: EMAIL:
PHONE (DAY):

PRINCIPAL CONTACT (IF OTHER THAN P.I.) □ STUDENT □ COORDINATOR □ OTHER:
LAST NAME: FIRST NAME: EMAIL:
PHONE (DAY):

RISK LEVEL
Indicate which of the categories below accurately describe this study, where “minimal risk means that “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” (45 CFR 46.102(h)(i))
□ Minimal risk
□ Greater than minimal risk

PRINCIPAL INVESTIGATOR SIGNATURE
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 outlined in Federalwide Assurance of Protection for Human Subjects, for which GW is registered with OHRP/DHHS, and as detailed in GW 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 verified that all members of the research team have agreed to accept the responsibilities required of their roles and I provide my assurance that all will be kept fully briefed on the details of the study. I have queried all members of the research team to determine if they have an economic interest in this study as defined by GW policies.

______________________________                      ____________________
Signature of Principal Investigator
Date

DEPARTMENT CHAIR OR MEDICAL CHAIR 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) the PI is sufficiently qualified by training and experience to conduct the research, 3) that the department has made the space and time commitment necessary to carry out the project, 4) that the financial implications of the research have been considered and deemed acceptable to the department and 5) that all ethical principles have been appropriately addressed.

______________________________                      ____________________
Medical Studies - If the PI is an MFA faculty, signature of
Alan G. Wasserman, MD, or Gary Simon, MD, PhD
-OR-

______________________________                      ____________________
Non-Medical Studies - Department Chair Signature

____________________________________________________________
Signature of Department Chair or Medical Chair
Date
GENERAL INSTRUCTIONS

1. Grey Fields indicate areas for response.
2. Write all responses in layman’s terms as reviewers may be from outside your field.
3. Do not copy/paste from the protocol-responses should not address issues outside of question domain.
4. Call the Office of Human Research for help filling out this form at 202-994-2715

Section I. Study Characteristics

1. Sites
   a. GW’s Role in the Project (select one):
      - Sole Site (GW is the only IRB involved in this study)
      - Lead Site (Lead Researcher is GW-based, other IRB’s are also evaluating)
      - Participating Site (Lead Researcher is not GW-based, other IRB’s also evaluating)
      - Data Collection Site (GW researcher role limited to data analysis, other IRB’s also evaluating)

   What other institutions are participating?

b. Research Locations (list locations where subjects participate in GW IRB-supervised activities or from which data is retrieved)

   Organization/Facility/Location (include city, state) | Research Activity (including recruitment, consenting, subject/researcher interaction or retrospective data retrieval)

   {CONTROL-TAB to cursor right}

2. a. Research Team

   Last Name, First (External Org if app.) | GW Faculty, GW Staff, GW Student or External? | Research Activities Performed
   (indicate subject recruitment, consenting, “prospective” or “retrospective” data collection, data analysis, other)

   {CONTROL-TAB to cursor right}

   b. Effort. What percentage of the PI’s total professional effort is devoted to the study and/or paid for by the Sponsor? **Note: This question applies to all research regardless of funding.** For student research, please estimate the amount of time that the PI will supervise the student.

   c. Curriculum Vitae (CV). If the Department Chair or Medical Chair has a conflict of interest with certifying the PI’s qualification (e.g., the Department Chair is the PI), please include a copy of the PI’s CV with the submission.  

      □ ATTACHED  □ NOT APPLICABLE

   d. Conflicts of Interest.  Do any members of the research team have any economic interest in or consulting relationship with a for-profit company that provides products or services that are a subject of the proposed study? □ No  □ Yes/explanation of how conflict of interest will be managed

Section II. Narrative

1. Background.
   a. What are the principal objectives of the study? (1-2 paragraphs)
b. (1) What is the justification for conducting this study in the context of field advancements and (2) How will the study contribute to generalizable knowledge outside of your research entity (publishing, establishing national standards, etc.)? (2-3 paragraphs)

- Note: If you have no intent to publish, be sure to complete the Human Subject Research Determination Worksheet to determine if your study requires submission to the Office of Human Research.

2. Subject Identification and Recruitment.
“Identification” refers to determination of potential participants for future recruitment activities. “Recruitment” refers to communication activities up until consent that support solicitation of participation.

a. Maximum number of subjects to be recruited (or number of retrospective records):
Give rationale for why/how this number was chosen. (1 paragraph)

b. Specify the age range of subjects to be recruited for the research:

c. Indicate any special populations to be involved in the research. □ N/A

- Pregnant Women, Fetuses or Neonates
- Prisoners
- Children
- Educationally Disadvantaged
- Economically Disadvantaged
- Mentally Ill
- Decisionally-Impaired
- Employees
- Students
- Illiterate
- Non-English speaking
- Other (specify):

 d. In the space below (2-4 paragraphs):
(1) List the inclusion and exclusion criteria for the identification of potential subjects (condition, ethnicity, employer/position, age, etc.), justifying any exclusion criteria.
(2) Indicate where, how and from whom information regarding these criteria will be accessed, obtained or otherwise determined (i.e. “medical records review from GWU-Hospital for presence of condition xyz”)

 e. If obtaining, viewing or collecting records or data from medical or clinical settings to support subject selection, are all potential subjects currently under treatment by a member of the research team listed above? □ N/A □ No □ Yes/identify investigator(s) and explain treatment relationship:

 f. Explain how and from whom subjects’ contact information will be obtained for recruitment purposes?
□ N/A or Explain:
g. (1) Check all recruitment methods that apply:

- Email
- Phone
- Flyer
- Online Ad
- Verbal Announce
- Referral/Snowball
- Other

(2) Describe in detail how each of these methods will be utilized. Include:

- Who is executing each particular outreach method
- Locations (verbal announce in P.I. classroom, already-scheduled patient apt., location of flyers, etc.)
- How subjects may privately indicate interest in participating (prior to consent)
- Initial as well as follow-up recruitment activities


a. Indicate applicable consent procedure (check one):

- Standard subject consent (obtaining subject signature)
- Waiver of documentation of consent (verbal consent obtained from subject with no signature)
- Waiver of consent (subject unable to indicate consent)

*Justify:

*See Charts 10 & 11 at OHR Decision Charts for eligibility requirements

b. Give a detailed description of your informed consent process. Your narrative should include the following elements (3-5 paragraphs):

Required

- Who will consent/assent the subjects
- When consent will occur relative to recruitment and research activities
- Where or through what communication channels (telephone, email, etc) it will occur
- How privacy will be assured for the subject throughout
- How subjects will be given a chance to ask questions and opt out prior to research
- How subjects will receive a copy of signed consent form

If applicable

- Special considerations for children (assent procedures, etc.), pregnant women, new-borns, fetuses, prisoners, illiterate, non-English-speaking (see Federal Guidelines)
- Include an assent process for children aged 7 years or older, and include how parental permission will be obtained
- How undue influence will be minimized in authoritative relationships (professor-student, doctor-patient)
- Use of Evaluation to Consent or other measures for decisionally-impaired subjects
- Methods/amount of compensation
- Use of deceptive or withheld information and plan for subject debriefing
- Foreign-language translation measures

4. Research Design.

a. Provide a step-by-step (1, 2, 3...) description of your research study design, with an emphasis on the specific actions of and interactions with human subjects.

Your description should include the following elements as applicable:
Describe frequency, duration and location of activities in which subjects participate
Indicate all data sources and identify and attach all data collection instruments (surveys, tests, etc.)
Precisely describe experimental/control design groups
Distinguish between research-specific procedures and standard-of-care or other procedures that would occur even if the research wasn’t being conducted
Describe and justify any deceptive measures including use of placebo or withholding/alteration of specific information from subjects
Indicate if/when audio-recording or video-recording are used

b. How will the collected data be analyzed to answer the research question? (1-2 paragraphs)
   - Describe statistical tests and software, thematic analysis, what factors will be compared

5. Data Management & Security
   a. What personal/demographic data will be collected (check all that apply):

  ☐ Name                     ☐ Location of                      ☐ Employer/School Name
  ☐ SSN                      ☐ Residence or                       ☐ Department/Division
  ☐ Medical Record #         ☐ Employer/School including:
  ☐ Age or ☐ DOB             ☐ State/Other Region
  ☐ Ethnicity                ☐ Zip code/postal code
  ☐ Gender                   ☐ City
  ☐ Telephone #              ☐ Street address
   ☐ OTHER (list):

   b. (1) Describe primary research data collected (i.e. “attitudes regarding alcohol use”, “biomarkers related to pregnancy”, etc.) and (2) either list specific data points or reference attached collection instruments (i.e. “see ER Survey and Data Sheet #1”):

   (2) When this primary research data is recorded (written-down or entered) by investigator or subject, will it be (check all that apply):
   (a) ☐ Identified directly with any personal/demographic data points listed in 5.a.?
      Which data points or “all”?
      Justification (data and identifiers should be recorded separately per (b) unless impracticable):
   (b) ☐ Identified indirectly, through use of a unique alphanumeric code that links to any personal/demographic data points listed in 5.a using a key stored securely and separately?
      Which data points or “all”?
   (c) ☐ Maintain data anonymity by not doing (2.a.) or (2.b.)

c. Is the research team viewing or collecting Protected Health Information (i.e., medical records)? ☐ No  ☐ Yes
   - See Protected Health Information Determination Worksheet, attach appropriate documents and integrate proper text in Consent Form (see Consent Guidance documents).
d. Provide a detailed description of data-entry, transfer, storage and destruction procedures. (3-6 paragraphs)
   Your description should include **all** of the following elements:
   - **Methods to minimize risk of breach of confidentiality** including anonymous data collection, use of coding and identity key, sealed envelopes, lock-boxes, digital firewalls b/w data & identity, etc.
   - **Specify digital vs. hard copy and locations for data, key and/or subject roster** (data and key should be separate, secured locations; indicate if research data are stored in medical records).
   - **How and when measures will be taken to remove identifying data and codes as soon as possible.**
   - **Use of encryption (above minimal risk) and/or password-protection (minimal risk) on computers.**
   - **When hard copy or digital versions of data, key, recordings and roster will be destroyed. How long they will otherwise be stored and for what purposes.**

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**e. Publication and presentation.**

1. Results will be published, presented or otherwise shared outside of my research entity in the following manner (check one):
   - [ ] Data will be aggregated or summarized such that **no** individual data will be communicated
   - [ ] Some individual results will be communicated.
     - (a) How will individual results be attributed, specifying use of descriptors from 5.a. (i.e. “one employee of company abc said ____”)?
     - (b) What is the range of the number of subjects in the study who are associated with each of these attributing descriptors (i.e. “5-6 subjects are employees of the company that will be named”)?

2. Will recordings be used in presentations or for any other reasons other than data analysis?
   - [ ] No  [ ] Yes
   *If yes, explain and submit Audio/Video Release Form:*

---

**6. Risks & Benefits.**

a. Describe all risks to the subject. **Include physical, psychological/emotional, cognitive, privacy, social/cultural stigma, financial, and legal risks.** Confidentiality risks should already be addressed above at Question 5.d.

   **Common risks that should be acknowledged include:**
   - **Emotional discomfort, anxiety or other affective risk from survey questions**
   - **Breach of privacy from other people observing consenting or research participation**

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b. **Radiation.** Will subjects be exposed to radiation during the research?  [ ] No  [ ] Yes

   - If yes, please explain use of radiation in detail including maximum number of subject exposures over 12 months, distinguishing between standard of care and research. For research, please specify the type of device and make/model.
c. What steps will be taken and research procedures implemented to minimize all risks?

➢ Describe additional precautions for special populations as defined at 2.b.(2) (see HHS 45 CFR 46 Subparts B-D for considerations specifically regarding children, pregnant women, new-borns, fetuses and prisoners)


d. Describe the potential benefits of the research.

➢ Please specify the direct benefits to subjects (if any) and the benefits to the class of research subjects.

Section III. Study details for medical or other therapeutic or diagnostic studies  □ N/A

1. Registered on the www.ClinicalTrials.gov? - choose one -

2. FDA-Regulated Studies:

a. Drug Studies (select one): □ N/A

□ Drug study requiring an IND

(ID Number: , or provide IND Letter from the FDA)

□ Study not requiring IND, involves off-label use of approved drug

Provide rationale or proof:

c. Device Studies (select one): □ N/A

1. Categorize the device: - choose one -

2. IDE/HDE# IDE/HDE Sponsor:
Complete sections I and II of this worksheet to determine if your research requires submission to the Office of Human Research (OHR). You do not have to submit this form to the OHR, but OHR will review completed forms upon request. If you are not the PI, you should first discuss your research with the PI before submitting this form.

This is a guide to help investigators determine if their project is considered human subjects research as defined by the Department of Health and Human Services (DHHS).

- Activities that do meet the definition of “human subject research” will require submission of either an Exempt from IRB Review Request form or Human Research Study Synopsis form (follow steps at Forms Page).
- Activities that do not meet this definition do not require IRB submission. Please note that you must still conduct all activities in an ethical manner. Please consult with your academic department regarding fulfillment of your ethical obligations.

### Section I. DETERMINATION OF RESEARCH

“Research” is defined as a systematic investigation designed to develop or contribute to generalizable knowledge.

**I.A. DOES THE PROPOSED ACTIVITY MEET ALL OF THE FOLLOWING CRITERIA TO BE DEFINED AS RESEARCH?**

1. **Y □ N □** Activities constitute a systematic investigation, (at least 4 subjects), that include research development, data collection and analysis, and evaluation.

2. **Y □ N □** Conclusions will contribute to generalizable knowledge (i.e. intent to publish, present, or otherwise apply knowledge gained to a population outside of the local research context/ entity).

   *(CE, course/ internal program evaluations, many QA/ QI programs, course requirements, or classroom exercises do not usually qualify as contributing to generalizable knowledge).*

- **IF YOU ANSWERED “No” TO (I.A.1) OR (I.A.2):** STOP HERE- DO NOT SUBMIT YOUR PROJECT TO THE OHR.
- **IF YOU ANSWERED “Yes” TO (I.A.1) AND (I.A.2):** CONTINUE TO SECTION II BELOW.

### Section II. DETERMINATION OF THE INVOLVEMENT OF HUMAN SUBJECTS

“Human subject” means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or the use of identifiable private information.

- Data which describe organizational dynamics, external trends, environmental factors or other non-human factors, even if collected from humans, does not itself constitute human subjects research, unless primarily opinion-based.
- “About whom” = The information being elicited for the research is about the [living] individual (the “Whom”). The focus on the investigation is the opinions, characteristics, or behavior of the individual(s).

**II.A. DOES THE PROPOSED ACTIVITY INVOLVE HUMAN SUBJECTS?**

1. **Y □ N □** Collect data through intervention\(^1\) or interaction\(^2\) with an individual, including interviews, surveys, physical procedures manipulations of the subject’s environment, and any other direct contact or communication with the subject (regardless of whether resulting data is identifiable or not).

   1. Intervention: Includes both physical procedures by which data are gathered, and manipulations of the subject or subject’s environment performed for research purposes.
   2. Interaction: Communication or interpersonal contact between investigator and subject.
(2) Y □ N □ Obtain, view or otherwise handle any private information\(^1\) which identifies individual subject(s) through the use of either direct identifiers\(^2\) (name, address, etc.), or indirect identifiers in the form of a code that links back to the identity of subject through an existing key.

1. Private information includes (but is not limited to)
   - Medical records and charts, specimens, data or tissue repositories
   - Employment or educational records, and observations of behavior which the subject could reasonably expect no observation to be taking place.
   - Personal thoughts, feelings, opinions, attitudes, beliefs, etc.
2. Direct identifiers include (but not limited to) name, street address, audio/video-recordings, telephone, fax, email, SSN, medical record # (other potential identifiers evaluated on a case by case basis).
   - If codes & key exist: check “N” here, and submit official correspondence from the holder of the key which states that researcher will not be given access to the key under any circumstances.

☐ IF YOU ANSWERED “No” TO (II.A.1) AND (II.A.2): STOP HERE- DO NOT SUBMIT YOUR PROJECT TO OHR.
☐ IF YOU ANSWERED "Yes" TO EITHER (II.A.1) OR (II.A.2.): YOU ARE CONDUCTING HUMAN SUBJECT RESEARCH- PLEASE SUBMIT YOUR STUDY TO THE OHR FOR IRB REVIEW.

IF YOU ARE STILL UNCERTAIN WHETHER OR NOT YOU ARE CONDUCTING HUMAN SUBJECTS RESEARCH AND WOULD LIKE VERIFICATION FROM THE OHR, PLEASE COMPLETE THE FOLLOWING SECTION III.

Section III. RESEARCH DESCRIPTION

III. A. APPLICANT INFORMATION

PROJECT TITLE:

<table>
<thead>
<tr>
<th>PRINCIPAL INVESTIGATOR</th>
<th>First Name:</th>
<th>Degree:</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Last Name:</td>
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<td>School:</td>
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<td>Phone:</td>
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</table>

Grant/Funding Source: [ ] N/A

<table>
<thead>
<tr>
<th>PRINCIPAL CONTACT</th>
<th>First Name:</th>
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<tbody>
<tr>
<td>Last Name:</td>
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<td>Phone:</td>
<td>Email:</td>
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</tbody>
</table>

Please indicate **YOUR** primary research role (check all that apply):

- [ ] Principal Investigator (must be full time GW faculty)
- [ ] GW Co-Investigator or Sub-Investigator
- [ ] Project/study coordinator
- [ ] Principal contact/administrator only
- [ ] Research Assistant/ Research team member
- [ ] GW Student
- [ ] Other _____________________________

Please indicate your type of research:

- [ ] GW Faculty/staff research
- [ ] GW Nursing Practicum/ Clinical Residency requirement
- [ ] GW Dissertation research
- [ ] GW Undergraduate student project
- [ ] GW Graduation- Thesis/fieldwork
- [ ] GW Class/Course/ Curriculum requirement only
- [ ] GW Culminating Experience (CE)/CE Practicum
- [ ] Non-GW research

This research involves: (check all that apply):

- [ ] All or some research activities are taking place at or through GW
- [ ] GW Collaborative research with another institution(s)
- [ ] No research activities will take place at or through GW
- [ ] Study has/will seek IRB approval at a non-GW institution

Form version 02/11/2011
### III. B. PROPOSED STUDY CHARACTERISTICS
(PLEASE COMPLETE THE FOLLOWING IN LAYPERSON TERMS).

1. Provide a 3-5 sentence, clear summary of the proposed research activity. Please include the purpose and aims of the research.

2. Briefly describe all research activities that will be performed by or conducted under the supervision of the GW faculty, staff, or students.

3. Briefly describe or list all study procedures to be conducted related to study participants (i.e., screening, recruitment, consenting, enrollment, procedures, etc), types of data being collected, anonymous/identifiable information, and how you will be obtaining data from or about study subjects.
   
   *(Please be sure to attach any survey, interview, or focus group questions, if applicable.)*
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/IS'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):

1. 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 that institution will be involved and provide the name and department of the Institutional Sponsor. The assigned PI/IS must be a faculty/staff member of that institution.

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 $10,000 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**