

**Georgetown University Institutional Review Board
Application (Protocol) for Committee C
Social and Behavioral Sciences IRB Review (C-1)**

Section One: Application Information

Principal Investigator:	
Department:	
Title:	
Phone/Pager:	
Fax:	
E-mail address:	
Mailing Address:	

Co-Investigator:	
Department:	
Title:	
Phone/Pager:	
Fax:	
E-mail address:	
Mailing Address:	

Responsible Participant (member of faculty or official or administrative unit)	
Title:	
Phone/Pager:	
E-mail address:	
Is this research for your thesis/dissertation?	<input type="checkbox"/> Yes
	<input type="checkbox"/> No

Title of Project	Purpose of Project (one or two sentences)

Additional Co-Investigators/Consultants, if any	Department or Institution

Estimated duration of total project	
Estimated total number of subjects (including control subjects)	
Age range of subjects	
Sex of subjects	
Where will study be conducted?	
Source of subjects	
Experience of Principal Investigator: Brief summary (also attach a CV or biosketch,)	

Source of Funding/Grant Support for Project (if any)	Commercial Support for Project (if any)

Section Two: Additional Georgetown University Regulatory Information

Please answer each specific question and use additional sheets as needed. A response of “See attached project description or grant application” is not sufficient.

2.1 Background. Provide a brief historical background of the project with reference to the investigator’s personal experience and to pertinent scientific literature. *Use additional sheets as needed.*

2.2 The plan of study. State the hypothesis or research question you intend to answer. Describe the research design, methods, interventions, and procedures (including standard or commonly used interventions or procedures) to be used in the research. Specifically, identify any interventions, procedures, or equipment that are innovative, unusual, or experimental. Where appropriate, provide statistical justification or power analysis for the number of subjects to be studied. *Use additional sheets as needed.*

2.3 Risks. Indicate what you consider to be the risks to subjects and indicate the precautions to be taken to minimize or eliminate these risks. If any data monitoring procedures are needed to ensure the safety of subjects, describe them. *Use additional sheets as needed.*

Section Three: Selection of Subjects and the Informed Consent Process

3.1 Indicate whether this project involves any of the following subject populations?

- Children (Children are defined by local law as anyone under age 18.)
- Prisoners
- Pregnant women
- Cognitively impaired or mentally disabled subjects
- Economically or educationally disadvantaged subjects

If you indicated any of the above, in the space below please describe what additional safeguards will be in place to protect these populations from coercion or undue influence to participate. (Use additional sheets as needed.)

3.2 Recruitment: Describe how subjects will be recruited and how informed consent will be sought from subjects or from the subjects' legally authorized representative. If children are subjects, discuss whether their assent will be sought and how the permission of their parents will be obtained. Use additional sheets as needed.

3.3 Compensation: Will subjects receive any compensation for participation in cash or in kind?

Yes

No

If subjects receive any compensation, please describe amount or kind of compensation in the space below.

3.4 Fees: Will any finder's fees be paid to others?

Yes *If so, please describe the amount below.*

No

Section Four: Privacy and Confidentiality of Data and Records

4.1 Sensitive Information. Will identifiable, private, or sensitive information be obtained about the subjects or other living individuals? Whether or not such information is obtained, describe the provisions to protect the privacy of subjects and to maintain the confidentiality of data. Use additional sheets as needed.

Section Five: Conflict of Interest

5.1 Conflict of Interest: Do any investigators or co-investigators have a conflict of interest as defined in the Georgetown University Faculty handbook?

<http://www.georgetown.edu/facultysenate/handbook.html#financial>

- Yes. If so, please explain below.
- No.

Note: A copy of each investigator’s and co-investigator’s current Georgetown University Financial Conflicts of Interest Disclosure Form must be attached to this application (original plus one copy)

Each “investigator” must submit a Georgetown University Study Specific Disclosure Form as part of this protocol application. “Investigator” includes the principal investigator and any other person who is responsible for the design, conduct, or reporting of research.

The Georgetown University Study Specific Disclosure Form is available for downloading from the IRB website: <http://ora.georgetown.edu/irb/irbDisclosure.htm>

Questions about the Georgetown University Study Specific Disclosure Form can be directed to the Office of Regulatory Affairs, Conflicts Regulation Office at 202-784-5313 or conflictsregulation@georgetown.edu

Guidance for Conflicts Disclosure in Publications and Presentations

Financial and/or Intellectual property interests (e.g. patents or patent applications) must also be disclosed in all related press releases, publications and presentations.

- I certify that the information furnished concerning the procedures to be taken for the protection of human subjects is correct. I will seek and obtain prior approval for any modification in the protocol or informed consent document and will report promptly any unexpected or otherwise significant adverse effects encountered in the course of this study.

- I certify that all individuals named as consultants or co-investigators have agreed to participate in this study.

- I assure that the protected health information identified on the “Medical Records Release and General Authorization to Use and Disclose Health Information for Research” and the persons and entities that may use, give and receive protected health information is accurate and reflective of the known use and disclosure for this human clinical study.

_____ Printed/Typed Name of Investigator	_____ Telephone number
_____ Signature of Investigator	_____ Date
_____ Printed/Typed Name	Department Chair: <input type="checkbox"/> Approved <input type="checkbox"/> Disapproved
_____ Signature of Department Chair	_____ Telephone Number
_____ Signature of Department Chair	_____ Date

If more than one department or administrative unit is participating in the research and/or if the facilities or support of another unit, e.g., nursing, pharmacy, or radiation therapy, are needed, then the chair or administrative official of each unit must also sign this application.

_____ Authorized Signature	<input type="checkbox"/> Approved <input type="checkbox"/> Disapproved
_____ Title and Department	_____ Date
_____ Authorized Signature and Title	<input type="checkbox"/> Approved <input type="checkbox"/> Disapproved
_____ Title and Department	_____ Date
_____ Authorized Signature and Title	<input type="checkbox"/> Approved <input type="checkbox"/> Disapproved
_____ Title and Department	_____ Date

Section Six: Attachments

Please attach the following items in order for the IRB-C to review your research:

Note: provide the original plus 15 copies of all materials for FULL REVIEW (ONLY). Provide the original only (of all materials) for EXEMPT and EXPEDITED reviews.

IRB-C Application forms (all forms are available on the IRB-C website at:
<http://ora.georgetown.edu/irb/irbC.htm>)

- Form C-1 (always required)
- Request for Expedited Review (Form C-3) and/or Request for Exemption (Form C-4)
Note: One or both, depending on nature of the research
- Study Specific Disclosure Forms for all Investigators
- Certificate of completion of education in the protection of human research subjects (required)
- Informed consent document
- Any recruitment notices or advertisements
- Any survey instruments, psychological tests (other than standard, commercially available instruments), interview forms, or scripts to be used in the research
- Investigator's qualifications (CV, biosketch, or Form 1572, if available)
- Formal research protocol, if available.
- Grant application, if applicable.

IRB-C forms may be delivered to the Social & Behavioral IRB drop-box location on the Main Campus located in the Graduate School of Arts and Science
ICC302

OR

IRB-C forms may be mailed or delivered to the following address:

Social & Behavioral Sciences IRB-C
Attention: Brandon Edmonds, Project Coordinator
Georgetown University
Med-Dent SW 104, 3900 Reservoir Road NW
Washington, DC 20057-1005
Fax: (202) 687-4847
Email: sjr33@georgetown.edu

For questions, please call the IRB office at (202) 687-6553