

IRB/PAS

Graduate Student

Manual

2006

The University of Maryland Hearing and Speech Sciences Department

Website for IRB application: <http://www.umresearch.umd.edu/ORAA/forms/umoraa.html#6>

Website for PAS: <http://pas.umd.edu/PAS/default.aspx>

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INTRODUCTION

This manual has been compiled for graduate students completing research in the Hearing and Speech Sciences Department at the University of Maryland. The contents of this manual will focus on the Institutional Review Board (IRB) process and the basic directions for using the Protocol Approval System (PAS).

What is the IRB?

An Institutional Review Board (IRB) is a committee designated by an institution to help assure the protection of the rights and welfare of human subjects. The IRB approves the initiation of and conducts periodic reviews of research involving human subjects. Investigators also share the responsibility for protecting human subjects. *IRB review is required for research involving human subjects.* Information can be found at: <http://www.umresearch.umd.edu/IRB/index.htm>.

What is a Human subject?

A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information (45 CFR 46).

What is Research?

Research is defined by the U.S. Department Health and Human Services as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” (45 CFR 46).

What is 45 CFR 46?

The Common Rule (Federal Policy for the Protection of Human Subjects) set forth the human subject protection requirements adopted by the following Federal agencies (Code of Federal Regulations). The University of Maryland, College Park Federal Wide Assurance assures that the University will apply "The Common Rule" to all human subject research regardless of the source of support. Title 45 (Public Welfare) Code of Federal Regulations Part 46 (Protection of Human Subjects) is what governs the IRB protocols followed by the University of Maryland.

45 CFR 46 can be found at the following website: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

What does all of this mean for the HESP graduate student?

Any time a student or faculty member plans to collect data from another person for purposes of reporting this data to others, the project is considered research and must first undergo IRB review. Some examples include: 1. bringing subjects to the lab for assessing listening behavior; 2. administering questionnaires to students in a class; 3. assessing the benefit of treatment for a group of patients in the clinical setting. Also, prior IRB approval is needed if a student or faculty member does not plan to interact or intervene with human subjects but plans to collect private identifiable information.

Students at the University of Maryland, College Park (UMCP) who are conducting research that involves human subjects must go through the same process as faculty members or other UMCP employees to secure IRB approval for their research. Master's theses projects and doctoral dissertation projects involving human subjects research require prior IRB approval.

The student cannot be the Principal Investigator. That role belongs to the student's faculty advisor or another faculty member. When filling out an IRB application form the student investigator is listed on the student investigator line; and the student's advisor or other faculty member is listed on the Principal Investigator line.

When research projects involve no more than minimal risks, the student may, in some cases, be listed as a co-investigator if the project is wholly generated and carried out by the student with little input or oversight by a faculty advisor. If the student wants to be listed as a co-investigator, he/she should provide a rationale for this role.

Important Message for Students Completing Dissertations or Theses

The Vice President for Research and Dean of the Graduate School issued a memo in 2000 that stated:

“Any research project using animals or humans must be approved by the appropriate Campus committees prior to the initiation of research. This applies not only to research conducted on campus but also to all research conducted under the auspices of the University of Maryland, that is by UM faculty, students, or staff at other sites anywhere in the world.

During the past several years both the IRB and IACUC have encountered a growing number of graduate students who seek protocol reviews well after research has started, and sometimes after it has been completed. This is in direct violation of all regulations. I have therefore instructed both committees to not approve such after the fact protocols in the future. Please be aware that this policy change could prevent a student's graduation.”

In essence, what this means is:

- All requests for permission to use human subjects in research must be obtained before beginning the research.
- Retroactive approval from the IRB will not be granted.
- The Graduate School will not clear a dissertation that involves human subjects without IRB approval.

OUTLINE OF IRB PROCESS

A. Initial Application (see page 10)

1. Meet with advisor.
2. Complete application form (can be found at <http://www.umresearch.umd.edu/ORAA/forms/umoraa.html#6>).
3. Submit 3 hard copies. Place them in the IRB Faculty Liaison's mailbox. Make sure each copy of the application has a cover sheet (mark the original cover sheet). The cover sheet is considered to be the first page of the application with all of your information on it. *If possible, please include a note containing the PAS # for your investigation.*
4. Simultaneously, submit an application on the Protocol Approval System (PAS) which can be accessed at <http://pas.umd.edu/PAS/default.aspx> (see page 14).

B. Departmental Review of Application

1. Members of the faculty review the research protocol for clarity, and for adherence to rules covering protection of human subjects. In most cases, they will request changes to the document.
2. You will receive notification via PAS of the questions and comments from the Departmental Human Subjects Review Committee, usually within two weeks following submission.

C. Response to Department Review

1. Make the appropriate modifications to your investigation via PAS.
2. Submit the changes to PAS.
3. Your faculty advisor must approve your changes prior to automatic routing to the Faculty Liaison.

D. Department Approval

1. You will receive a notice in PAS when the IRB Faculty Liaison has approved the proposal. The proposal is automatically sent to the University IRB. You may not collect data until you receive approval from the University IRB.

E. University IRB Approval

1. You will be notified via an automatic email from PAS or a letter from the IRB.
2. After you receive written approval and a stamped consent form (for research requiring informed consent), you may begin collecting data.

F. Modification Requests if necessary (i.e. adding another investigator, etc.)

1. If any aspect of your research project changes, you must submit an addendum or modification request to the IRB. Modification requests include: Changes to recruitment procedures, changes to subject selection or criteria, changes to investigators, and/or changes to procedures in any way.
2. If your investigation has been previously approved in PAS, you may make a modification request via PAS. (see page 18)
3. You may not implement modifications prior to IRB approval except when a change is necessary to eliminate apparent immediate hazards to the subjects.

G. Renewal of an investigation (see page 19)

1. Approximately 1-2 months before your investigation is due to expire, fill out a renewal application. You should be able to do so via PAS.
2. If your investigation was not previously approved via PAS, and PAS will not let you choose the renewal option, submit a hard copy application for renewal (can be found at <http://www.umresearch.umd.edu/ORAA/forms/umoraa.html#6>). You will then send the application for renewal to the University IRB. Once you receive a signed letter of approval to continue your investigation, please place a copy of that letter in the IRB Faculty Liaison's mailbox (Currently Dr. Gordon-Salant).
3. PAS is working on the capability of renewing applications online, even for applications that were previously approved in paper format. Check the PAS system to see if you can renew online, prior to preparing a renewal on paper.

** You may make modifications to your investigation at any time. Whenever you do so, be sure to follow modification protocol**

IRB/PAS APPLICATION REVIEW PROCESS

The first step in the whole entire process is to **submit three hard copies of the application**. They can be placed in the IRB Faculty Liaison's Department mailbox. Each copy should have the signed cover sheet. Please note which one is the original cover sheet. The cover sheet is considered to be the first page of the application with all of your information on it. ***If possible, please include a note containing the PAS # for your investigation.*** At the same time that you submit the hard copies, you should **also submit the application in the Protocol Approval System (PAS)**- see page 14. The hard copy form of the application can be found on the IRB website or at <http://www.umresearch.umd.edu/ORAA/forms/umoraa.html#6>.

The second step is Departmental review. Two copies of the application are routed to faculty members in the Department, with a request to return their comments to the IRB Faculty Liaison within one week. One copy is reviewed by the Department's Graduate Research Assistant, for formatting issues/compliance with IRB requirements; this is also the copy reviewed by the IRB Faculty Liaison. Once the IRB Faculty Liaison receives responses from the department reviewers, she will respond in PAS to the Principal Investigator (faculty advisor) and the student investigator with any questions. The Principal Investigator (faculty advisor) and the IRB Faculty Liaison continue to correspond via PAS (assuming that it is working correctly) until the application is approved. If PAS is not working for any reason, the IRB Faculty Liaison will correspond with the Principal Investigator (faculty advisor) using hard copy. Approval is submitted, by the IRB Faculty Liaison, directly to the IRB via PAS (or the hard copy is submitted if PAS is not working) for IRB review at the campus level.

The third step is the campus IRB application review. At this point the IRB decides whether the research is exempt or non-exempt. If the research is considered exempt it is sent to the IRB Manager or IRB Co-Chair who then reviews the application. If the research is considered non-exempt, the application is sent to the IRB Co-chair, who reviews the application and assigns it for expedited or full board review. Expedited review is conducted when the project is deemed "minimal risk" and where the only involvement of human subjects will be in one or more of the Expedited Review Categories (can be found [at http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm)). During an expedited review, one or two IRB members review the application for approval. Full Board review is conducted for projects involving more than minimal risk and those that do not qualify for expedited review. The Full Board review occurs monthly and is conducted by at least a quorum (one half of the IRB members plus one). Full Board review meeting dates can be found on the IRB website (<http://www.umresearch.umd.edu/IRB/IRBdates.html>).

IRB APPLICATION

An IRB "Application for Research Approval" form (<http://www.umresearch.umd.edu/ORAA/forms/umoraa.html#6>) must be submitted to obtain approval for all research activities on campus involving human subjects. Requests to modify active protocols (also called “addenda”) may be submitted at any time.

The form requires the signature of the Principal Investigator, Co-Principal Investigator (if applicable), Student Investigator, and the Faculty Liaison to the IRB, Dr. Gordon-Salant. For research involving UMCP students, **only UMCP faculty and staff can be listed as Principal Investigators.** For research involving investigators at other institutions, a UMCP faculty or staff must be listed as Principal Investigator or Co-Investigator.

Refer to the instructions on the IRB application and provide all of the information required in the 10 items in the instructions. Include all relevant supporting documents including consent forms, letters to recruit participants, questionnaires, the ORAA (See Appendix) Internal Routing Form for Proposals (if required), and any other material germane to human subjects review. If you submit an incomplete application, the review of your research will be delayed until all required information is received.

What information needs to be included on the IRB application form?

The application form must contain the following (see the actual application for more specific instructions):

1. Abstract - Up to 200 words describing the purpose of the research, summarizing strategies used to protect human subjects, and explaining why the benefits of the project are greater than the risk to the subjects.
2. Subject Selection - A description of the subjects and how they will be recruited.
3. Procedures - A detailed explanation of exactly what will be done to the subjects, methods and procedures to be used, and copies of the questionnaires or handouts used in the experiments and recruitment materials.
4. Risks and Benefits - An explanation of the risks and benefits that participating in the project would involve.
5. Confidentiality - A description of what will be done to protect the privacy of subjects and to maintain confidentiality of identifiable information. Information should be provided concerning data storage (including location and duration), the persons who will have access to the data, when or if the data will be destroyed, and how the data will be destroyed at the conclusion of the project.
6. Information and Consent Forms - Statement of what information will be provided to the subjects about the investigation and copies of all consent forms to be used, including parental permission forms and assent forms for minors (< 18 years old).
7. Conflict of Interest - A description of the potential conflict of interest.
8. HIPAA Compliance- Statement of whether HIPAA protected health information will be used.
9. Research Outside the United States – Responses to questions regarding research that will be conducted outside of United States.
10. Research Involving Prisoners – A statement of whether research involves prisoners. For research involving prisoners, responses to additional IRB criteria.

What do the possible outcomes of IRB application review process mean?

Exempt

If the application is declared exempt and approved by the IRB Manager or IRB Co-Chair no further IRB reviews are needed. The approval forms will be mailed to the address on the application. Exemption is granted for three years. Exemption categories can be found at http://www.umresearch.umd.edu/IRB/irb_Exemption_Categories.htm

Expedited Review

Certain types of research are eligible for an expedited review. The IRB may use an expedited review procedure when the research involves no more than minimal risk to the subjects and where the only involvement of human subjects will be in one or more of the Expedited Review Categories (can be found at <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>). In an expedited review, the application is forwarded to one or two IRB members for review. The IRB is kept informed of all protocols approved by expedited review at its monthly meetings.

Full Board Review

An application which involves more than minimal risk to human subjects and/or does not qualify for expedited review is reviewed by the members of the IRB at a convened monthly meeting. The IRB meeting dates for full Board review and deadlines for submitting applications are listed under IRB Full Board review meeting dates (<http://www.umresearch.umd.edu/IRB/IRBdates.html>). After the Full Board review, the principal investigator may need to revise the application to address concerns raised by the IRB. If the research is approved pending specific changes and clarification, the Principal Investigator's responses will be reviewed through expedited review. If the changes requested by the IRB are not minor, the Principal Investigator's responses will be reviewed by the full board at one of its monthly meetings.

What is "Minimal Risk?"

The Federal regulation for the protection of human subjects defines minimal risk as: "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 examination or tests." For research involving prisoners, minimal risk is defined as "the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons."

Protocol Approval System (PAS)

 IRB  Animal Care & Use  Hazardous Materials

The Protocol Approval System (PAS) has been set up by the University of Maryland as an efficient way of handling IRB applications and the review process. PAS is set up through a website and can be accessed through the university's internet or at your home computer. The website is: <http://pas.umd.edu/PAS/default.aspx>. When you are ready for your research to be reviewed, you must submit an application through PAS which will then be routed between you, your faculty advisor, and the department liaison to the IRB. At the end of that process, PAS will send the application directly onto the IRB for review. Notification of approval, renewal notifications, or requests for information are automatic via e-mail.

At this moment, the Hearing and Speech Sciences Department is involved in the pilot phase of PAS; therefore, please be patient if you experience problems with the PAS system, as there are still bugs to be worked out. If you experience any problems, please do not contact the IRB Manager, Roslyn Edson, directly since she may already be aware of the problem you are experiencing. Instead, you should contact Meggin Petronis (mpetronis@hesp.umd.edu) and Dr. Gordon-Salant (sgordon@hesp.umd.edu). Due to the problems that may occur with PAS, the Hearing and Speech Department asks that you still submit three hard copies of the application to the Department via Dr. Gordon-Salant, the IRB Liaison for the HESP Department.

Specific instructions for accessing and using PAS are presented on the following pages.

BASIC GUIDE TO USING THE PROTOCOL APPROVAL SYSTEM (PAS)

The website for PAS can be found at <http://pas.umd.edu/PAS/default.aspx>. The very first step in accessing the system is to sign in with your university directory ID and your directory password (this is the same information you use to login to Testudo or WebCT). Once you are logged in your PAS homepage will appear.

A. Starting a New Application

1. Expand the Sliding Menu, located on the left side of the screen, by placing the mouse over the blue Menu bar.
2. Click the "Getting Started Link". You will be taken to the Getting Started page.
3. Click "New" under Submission Type column.

B. Filling out the Request for Protocol Approval Form (RPAF) -This includes the description of the investigation. You will also need to upload consent forms and other documents as needed (see step C).

1. When you first open a RPAF, your name should automatically be filled in as the Student Investigator. You must select a Principal Investigator (your Faculty Advisor) by using the search button.
2. Specify Co-Investigators, if this applies to you, by clicking the search button under the Co-Investigator section.
3. Indicate which department you are in. PAS will automatically default to the department from which you have logged onto PAS, but this can be changed by using the pull down menu
4. Cut and paste your abstract, procedures, risks/benefits, etc. from Word into the RPAF.
5. Once you have filled in the other information on the form, click the save button at the bottom to save your work. You do not have to fill in all of the fields the first time you open the form. You only have to select a Principal Investigator and conflict of interest section the first time you open the form. The form can later be opened from the Protocol Information Page (see page 16) to be finished.

C. Uploading a Supporting Document (ex. signed consent form, advertisement, etc.) -You will need to upload Consent Forms, Recruitment flyers, test forms, etc. You should have all of these documents scanned into and/or saved onto your computer before you start this process.

1. Click the "Upload New Document" link on the Protocol Information Page. You can upload any .txt, .rtf, .doc, .pdf, or .xls file. If you try to upload a document that is a file type not supported by PAS, you will receive an error message.
2. To upload a document, click the browse button and select your file, then click on the upload file button.
3. All files that you upload are automatically converted to PDF format unless the file already is in that format. Since you are the Student Investigator, you will have access to the original file.

D. Deleting Documents

Documents can be deleted provided that they have not been submitted.

1. Go to your Protocol Information page.
2. Under the Documents section, click on the trashcan icon to delete the document.

Documents that have been added to a protocol after it has been submitted can be deleted before they are released. Use the trashcan icon in the Unreleased Documents section

D. Submitting Your Protocol

1. After completing the RPAF, and uploading all supporting documents, you will be ready to submit your application.
2. At the bottom of your Protocol Information Page you will see a box asking if you are ready to submit the protocol for approval.
3. Click on the "Please Submit this Application" button, and your application will be routed to your advisor for approval prior to being submitted to the Department IRB Faculty Liaison for Department level review.

RETURNING TO PAS AFTER INITIAL SUBMISSION

The Protocol Information Page

This is the page where you will find all information related to a specific protocol. It can be accessed via the homepage on your PAS account by clicking on the investigation you want to edit or submit listed under Unsubmitted Protocols. *It is generated in PAS the first time you save a RPAF with an associated PAS #.*

1. Sign into PAS. You will then see your homepage listing unsubmitted, pending, and active protocols.
2. You can open the RPAF for viewing or editing by clicking on the PAS number under the Unsubmitted or Pending Protocols section. You may also view already approved protocols under the Active Protocols section.
3. Once viewing the specific Protocol Information Page you can also open supporting documents for viewing by clicking on the name in the Document Title column of the Documents section. **Note:** Only the RPAF can be directly edited. You may upload new versions of documents with the same name. This will cause the new version to appear below the original and the version number will be increased by one.

Responding to Questions from the Faculty Liaison

Once your RPAF is reviewed, it is likely that your advisor, the Faculty IRB Liaison and/or fellow Department reviewers will have questions for you about your application, or suggested revisions. These will be listed as Questions for the Applicant (QA).

1. You will receive a To Do Item. Access to your To Do section is located in the sliding Menu on the left side of the screen. A reminder email should be sent to you when you have a QA.
2. You will find the link to open the QA under your Protocol Information Page. After clicking on the QA link you can fill in responses. Be sure to click Save after you type in your response. Then you can select the "Please Send this QA" button. QAs that you have not completed say "Pending Response" in the Status Column.
3. After you submit your answers to the QA, they will be routed to your advisor for approval prior to submission to the Faculty Liaison to the IRB. You may need to submit a revised RPAF at this time. Click on the original document in PAS, make your revisions, and save. This should automatically be saved with a new version number.
4. The revised application will be reviewed by the Faculty Liaison to the IRB and occasionally by members of the Department Review Committee. A dialog will continue with the student and faculty investigator(s) until the Faculty Liaison to the IRB approves the document

*****Tip for using PAS:** Do not rely on receiving emails from PAS to remind you to check the progress of your investigation. Check back to your PAS homepage often to see if there are any updates in your investigation approval.***

INVESTIGATION APPROVAL

Turnaround Time for the Review of IRB Applications at the University Level

Exempt Research is usually reviewed within one week upon receipt of the application. Expedited reviews are conducted within about two weeks upon receipt of the application. Please note that the amount of time for an expedited review may be longer if the reviewers request changes or clarification. Full Board reviews are conducted monthly. However, the turnaround time for applications reviewed by the Full Board may be longer than one month if the application is not submitted by the application deadline, the meeting agenda is full when the application is submitted, or the application is not approved as submitted when first reviewed by the Full Board.

Notification of IRB Approval Not via PAS

Approval letters are mailed to the Principal Investigator at the location cited on the IRB application cover page. For applications reviewed by the Full Board, Principal Investigators are notified of the IRB's decision within approximately one week of the meeting. If you would like to know the status of an application, you should send an e-mail to Roxanne Freedman at rfreedman@umresearch.umd.edu or irb@deans.umd.edu

Notification of Approval via PAS

Notification of approval, renewal notifications, or requests for information are automatic via e-mail. Again, check back on your PAS homepage frequently for notifications on the progress of the review of your investigation.

SUBMITTING AN ADDENDUM (PROTOCOL MODIFICATION) REQUEST

Requests to modify an active protocol (also called “addenda” or “amendments”) may be submitted at any time to PAS (<http://pas.umd.edu/PAS/default.aspx>). If your research was not previously approved in the PAS system, then submit the addendum request by sending a signed letter to the IRB. The PAS submission or letter should state the specifics of the changes being sought and should include: the rationale for the changes, a detailed description of the procedures, how the changes will affect the risk to the subjects, and any appropriate supporting documents -- such as new versions of consent forms, those currently in use, data collection instruments, and recruitment materials. Be sure to also include the project title and the protocol identification number (IRB number).

The IRB asks that modification requests not be submitted on application forms. Please note that addenda do not change the duration of IRB approval. The expiration of IRB approval is based on the date when the most recently submitted application was approved, not on when an addendum was approved.

Adding Investigators to a Research Project not via PAS

Whenever there is a change in the project personnel who are collecting data from human subjects, the IRB should be notified. The Principal Investigator should send a signed letter, explaining any such changes which have occurred, including the project title and the IRB protocol identification number.

Requesting an Addendum to an Active Protocol via PAS

1. Once your investigation receives approval it will be listed under Active Protocols on the PAS homepage for your account. Click on the protocol to open the Protocol Information Page.
2. Click the "Create a Request for Addendum" button.
3. The original protocol is then copied and pasted into a new "Request for Addendum" form.
4. At this point, you have the option of making changes to the information on the "Request for Addendum" form.
5. Click "Submit" once appropriate changes have been made.

Upon IRB approval of your modification request, you will receive a modification approval letter from the IRB. Please forward copies of any modification approval letters to The Faculty Liaison to IRB by placing it in her Department mailbox.

RENEWAL OF INVESTIGATION

You should submit an "Application for Renewal" approximately 1-2 months before the IRB approval for your investigation is due to expire.

Renewal of Investigation via hardcopy to the IRB

In order to renew your application by hard copy you must fill out a renewal form and send it directly to the IRB. You can find this form on the IRB website or at <http://www.umresearch.umd.edu/ORAA/forms/umoraa.html#6>. Once you submit your renewal application, and receive a letter of approval to continue your investigation, please forward the original letter and one copy of it to the Faculty IRB Liaison by placing it in her Department mailbox.

Renewing an Active Protocol that is about to Expire via PAS

1. PAS (<http://pas.umd.edu/PAS/default.aspx>) will place a reminder on your To Do list 60 days prior to the expiration of your protocol. You should also receive email reminders at 60, 30, 14, and 7 days prior to the expiration date unless you renew or terminate your protocol.
2. To create a renewal, click on the "Prepare Protocol for Renewal Link" on your To Do list. This will take you to your current Protocol Information Page.
3. Click the "Please Copy this Protocol to Initiate the Renewal Process" button. This will make a copy of all the most recent versions of your documents attached to the protocol, create a new protocol, and attach the copied documents to this new protocol.
4. Complete the Renewal Application. The remainder of the renewal process mirrors the process for creating an initial application.

IRB/PAS Staff Contact Information

Office Location

University of Maryland, College Park
2100 Lee Building
College Park, Maryland 20742

Office Hours

The office is usually open between 8 am and 5 pm.

IRB Manager

Roslyn Edson, M.S., Certified IRB Professional (CIP)
301-405-0678 (telephone) (Mon - Fri 8 am - 4 pm)
301-314-1475 (fax)
redson@umresearch.umd.edu (e-mail)

[Please contact Roslyn Edson if you have questions regarding IRB policy (e.g. additional requirements for research involving children, prisoners, and research to be conducted outside of the United States.)]

IRB Coordinator

Roxanne Freedman
301-405-4212 (telephone) (Mon - Fri 11 am - 7 pm)
301-314-1475 (fax)
rfreedman@umresearch.umd.edu (e-mail)

[Please contact Roxanne Freedman if you have questions regarding the status of an IRB application and questions regarding IRB procedures (e.g. the procedures for submitting an application and a request to change previously approved research.)]

Graduate Assistant

Bhavini Mehta
301-405-4192 (telephone)
301-314-1475 (fax)
bmehta@gradschool.umd.edu (e-mail)

(You may also contact Bhavini Mehta if you have questions regarding the status of an IRB application)

Department of Hearing and Speech IRB/PAS Contact Information

Meggin Petronis is the Graduate Research Assistant currently helping Dr. Gordon-Salant, the Faculty Liaison to the IRB, to manage IRB/PAS information. If you have any questions about the IRB process, the IRB application, or about using PAS, please contact:

Meggin Petronis
Graduate Research Assistant
mpetronis@hesp.umd.edu

-Or-

Sandra Gordon-Salant
Faculty Liaison to the IRB
sgordon@hesp.umd.edu

Meggin Petronis tracks all IRB applications that have been approved previously, or submitted for renewal, modification, or first approval. She will send out reminders if it appears that your approval will be expiring soon.

There is a "Frequently Asked Questions" portion of the IRB website. Also, there is a "Help" section once you sign into PAS (The ? in the lower right hand corner).

IRB Website: <http://www.umresearch.umd.edu/IRB/index.htm>

PAS Website: <http://pas.umd.edu/PAS/default.aspx>

Note: Some of the information and graphics in this manual were copied from the University of Maryland Institutional Review Board website and the University of Maryland Protocol Approval System Website.

Appendix
Important Abbreviations

CFR- Code of Federal Regulations

IRB- Institutional Review Board

ORAA- Office of Research Administration and Advancement

PAS- Protocol Approval System

QA- Questions for the Applicant

RPAF- Request for Approval Form

UNIVERSITY OF MARYLAND, COLLEGE PARK

Institutional Review Board

Initial Application for Research Involving Human Subjects

Please complete this cover page AND provide all information requested in the attached instructions.

Name of Principal Investigator (PI) or Project Faculty Advisor _____ Tel. No _____
(NOT a student or fellow; must be UMD employee)

Name of Co-Investigator (Co-PI) _____ Tel. No _____

Department or Unit Administering the Project _____

E-Mail Address of PI _____ E-Mail Address of Co-PI _____

Where should the IRB send the approval letter? _____

Name of Student Investigator _____ Tel. No. _____

E-Mail Address of Student Investigator _____ @ _____

Check here if this is a student master's thesis or a dissertation research project

Project Duration (mo/yr - mo/yr) _____ -- _____

Project Title

Sponsored Project Data	Funding Agency _____	ORAA Proposal ID _____
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(PLEASE NOTE: Failure to include data above may result in delay of processing sponsored research award at ORAA.)

Vulnerable Populations: The proposed research will involve the following (Check all that apply): pregnant women , human fetuses , neonates , minors/children , prisoners , students , individuals with mental disabilities , individuals with physical disabilities

Exempt or Nonexempt (Optional): You may recommend your research for exemption or nonexemption by completing the appropriate box below. For exempt recommendation, list the numbers for the exempt category(s) that apply. Refer to pages 5-6 of this document.

Exempt----List Exemption Category Numbers _____ *Or* Non-Exempt

If exempt, briefly describe the reason(s) for exemption. Your notation is a suggestion to the IRB Manager and IRB Co-Chairs.

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Date Signature of Principal Investigator or Faculty Advisor (PLEASE NOTE: Person signing above accepts responsibility for the research even when data collection is performed by other investigators)

Date Signature of Co-Principal Investigator

Date Signature of Student Investigator

Date REQUIRED Departmental Signature

Name _____, Title _____
(Please also print name of person signing above)

(PLEASE NOTE: The Departmental signature block should not be signed by the investigator or the student investigator's advisor.)

***PLEASE ATTACH THIS COVER PAGE TO EACH SET OF COPIES**

Instructions for Completing the Application

The Departmental Signature block should be signed by the IRB Liaison or Alternate IRB Liaison unless there is a conflict of interest. If the Department or Unit does not have an IRB Liaison, the Department Head, Unit Head or Designee should sign the application.

Please provide the following information in a way that will be intelligible to non-specialists in your specific subject area.

1. **Abstract:** Provide an abstract (no more than 200 words) that describes the purpose of this research and summarizes the strategies used to protect human subjects.
2. **Subject selection:**
 - a. Who will be the subjects? How will you recruit them? If you plan to advertise for subjects, please include a copy of the advertisement.
 - b. Will the subjects be selected for any specific characteristics (e.g., age, sex, race, ethnic origin, religion, or any social or economic qualifications)?
 - c. State why the selection will be made on the basis or bases given in 2(b).
 - d. How many subjects will you recruit?
3. **Procedures:** What precisely will be done to the subjects? Describe in detail your methods and procedures in terms of what will be done to subjects. How many subjects are being recruited? What is the total investment of time of the subjects? If subjects will complete surveys and/or other instruments on more than one occasion, state this in the procedures section. If you are using a questionnaire or handout, please include a copy within each set of application documents. If you are conducting a focus group, include a list of the questions for the focus group. If you plan to collect or study existing data, documents, records, pathological specimens or diagnostic specimens, state whether the sources are publically available and if the information will be recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects. If you are collecting or studying existing data, describe the dataset and the information that you will extract from the dataset.
4. **Risks and Benefits:** Are there any risks to the subjects? If so, what are these risks including physical, psychological, social, legal and financial risks? Please do not describe the risk(s) as minimal. If there are known risks, please list them. What are the benefits? If there are known risks associated with the subject's participation in the research, what potential benefits will accrue to justify taking these risks?
5. **Confidentiality:** Adequate provisions must be made to protect the privacy of subjects and to maintain the confidentiality of identifiable information. Explain how your procedures accomplish this objective, including such information as the means of data storage, data location and duration, description of persons with access to the data, and the method of destroying the data when completed. If the research involves audio taping, videotaping or digital recordings, state who will have access to the tapes or recordings, where the tapes or recordings will be kept, and state the final disposition of the tapes or recordings (i.e. Will the tapes or recordings be destroyed? If so, when will the tapes or recordings be destroyed?).

6. **Information and Consent Forms:** State specifically what information will be provided to the subjects about the investigation. Is any of this information deceptive? State how the subjects' informed consent will be obtained. Will you obtain informed consent in a language other than English? If so, list the language(s) in which you will obtain informed consent. Provide consent forms in all languages that will be used. Refer to the attached consent form template, sample consent form and additional consent form guidance on pages 7 to 13. If a consent form has more than one page, please add a signature and date line and the number of pages (*e.g.*, "1 of 2," "2 of 2") to each page. Please allow a 2-inch bottom margin to accommodate the IRB approval stamp. If you plan to obtain consent over the telephone (*e.g.* consent for a telephone survey), include a copy of the consent script.
7. **Conflict of Interest:** Describe the potential conflict of interest, including how such a conflict would affect the level of risk to the study participants. Please consult the University of Maryland policy on conflict of interest as defined by the University of Maryland Policies and Procedures III-1.11 and II-3.10. These may be viewed at:
<http://www.usmh.usmd.edu/Leadership/BoardOfRegents/Bylaws/SectionIII/III111.html>
8. **HIPAA Compliance:** State whether you are using HIPAA protected health information or "PHI". Currently, researchers employed by the University of Maryland Center or who are working within or under the auspices of the University Health Center are subject to specific HIPAA requirements regarding the creation, use, disclosure, or access of PHI. Please consult the University of Maryland's Summary of HIPAA's Impact on University Research.
9. **Research Outside of the United States:** Provide responses to the following questions. Separate responses are required for each country where the research will be conducted. If you are not conducting research outside the U.S., please state "Not Applicable"
- Did the investigator(s) previously conduct research in the country where the research will take place? Briefly describe the investigator's knowledge and experience working with the study population.
 - Are there any regulations, rules or policies for human subjects research in the country where the research will take place? If so, please describe and explain how you will comply with the local human subject protection requirements. The United States Department of Health and Human Services, Office for Human Research Protections (OHRP) has an International Compilation of Human Subject Research Protections with a listing of the laws, regulations and guidelines of over 50 countries. This compilation can be accessed on the OHRP website:
<http://www.hhs.gov/ohrp/international/>
 - Do you anticipate any risks to the research participants in the country where the research will take place, taking into account the population involved, the geographic location, and the culture? If so, please describe, including any physical, psychological, social, legal and financial risks. Do you anticipate that subjects who participate in this research will be placed at risk of criminal or civil liability? If so, please describe

- 10. Research Involving Prisoners:** Provide responses to the following additional IRB criteria for research involving prisoners. If you are not conducting research involving prisoners, please state “ Not Application”
- a) the research under review represents one of the categories of research permissible described below;
 - i. study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
 - ii. study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
 - iii. research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults); or
 - iv. research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

 - b) any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
 - c) the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
 - d) procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
 - e) the information is presented in language which is understandable to the subject population;
 - f) adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
 - g) if there is a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

EXEMPTION CATEGORIES

(PLEASE NOTE: Exempt research must be approved by the IRB Manager or an IRB Co-Chair before data collection may begin.)

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management methods. **Research involving surveys or interviews with children does not qualify for exemption. Also, this exemption does not apply to research involving the collection of person identifiable data in which any disclosure of the data outside of 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.**

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subject's 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. **Exemption category #2 does not apply to research with children, except for research involving observations of public behavior when the investigator(s) does not participate in the activities being observed. Also, this exemption does not apply to research involving the collection of person identifiable data in which any disclosure of the data outside of 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.**

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. **E.g,the research is conducted for the Department of Justice under Federal statute 42 U.S.C. 3789g and the research conducted for the National Center for Education Statistics under Federal statute 20 U.S.C. 12213-1, which provide certain legal protections and requirements for confidentiality.**

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects **which are conducted by or subject to the approval of Department or Agency heads**, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs. **If the research is funded by the United States Department of Health and Human Services, the following criteria must be met:**

- a) **The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).**
 - b) **The research or demonstration project must be conducted pursuant to specific federal statutory authority.**
 - c) **There must be no statutory requirement that the project be reviewed by an Institutional Review Board (IRB).**
 - d) **The project must not involve significant physical invasions or intrusions upon the privacy of participants.**
6. Taste and food quality evaluation and consumer acceptance studies, if (a) wholesome foods without additives are consumed or (b) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

NOTE: The 6 exemption categories do not apply to research involving prisoners.