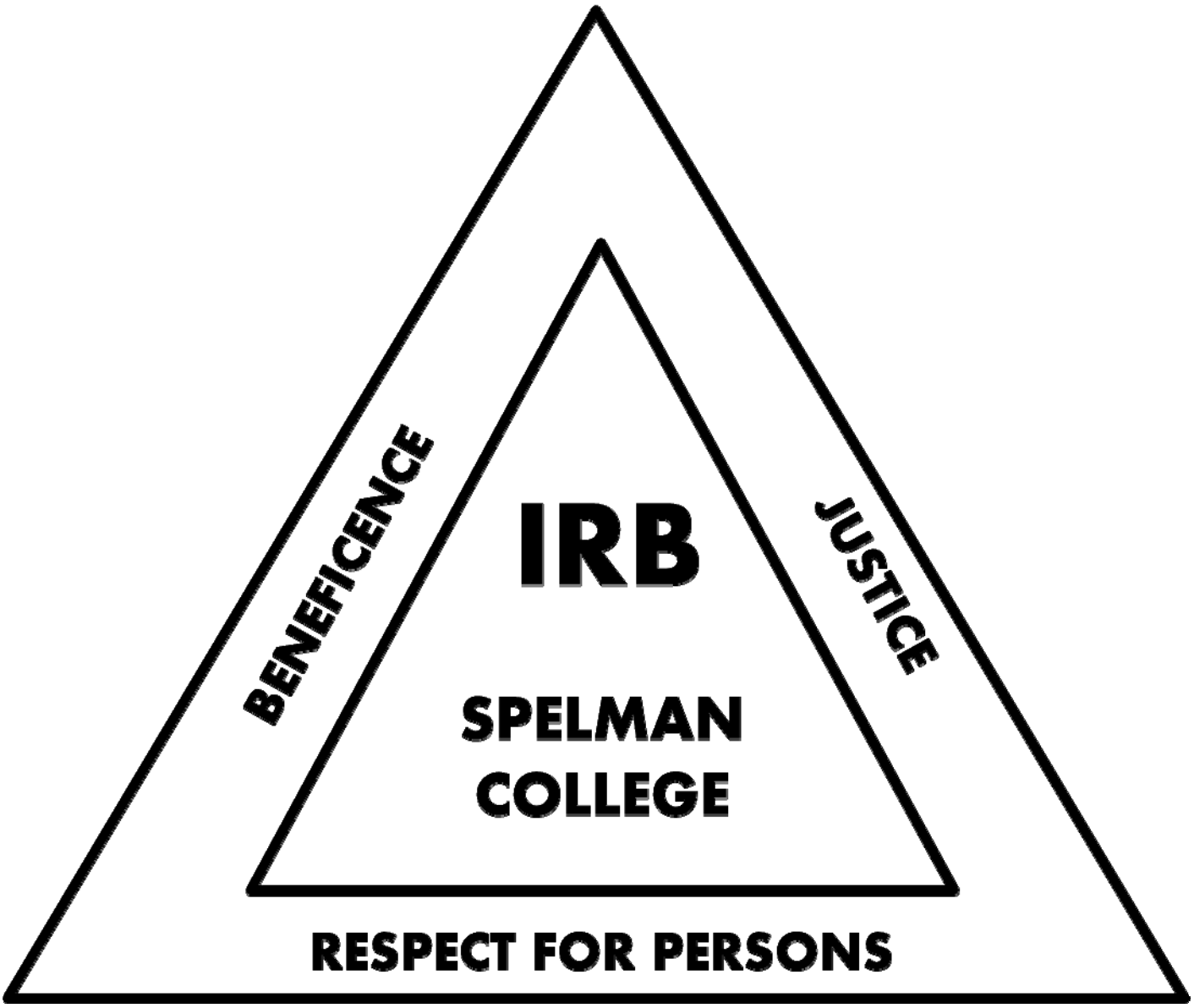
BENEFICENCE
IRB
JUSTICE
SPELMAN
COLLEGE
RESPECT FOR PERSONS

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# THE SPELMAN COLLEGE IRB

Policies and Procedures

## Statement of Ethical Principles

The mission of the Spelman College Institutional Review Board (IRB) is to ensure that all research involving human subjects conducted at the college or by researchers associated with the college be guided by the ethical principles of respect for persons, beneficence, and justice as set forth in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects*.

In particular, the IRB is committed to making sure that research conducted at, by, and for Spelman College:

- Is done with the voluntary consent of participants who are properly informed about the risks and benefits of the study;
- Protects the privacy and dignity of participants;
- Minimizes the risk to study participants, while maximizing a study's benefits;
- Utilizes equitable procedures for participant recruitment and selection so that it does not discriminate on the basis of race, gender, class, sexual orientation or other factor; and
- Is sensitive to the setting in which it takes place.

The Federal Office for Human Research Protections (OHRP) has useful materials related to protection of human subjects available for download.

## Why submit proposals to the IRB?

The IRB at Spelman College exists for reasons both moral and practical. While no reputable researcher would ever intentionally violate the rights of other human beings, it is difficult to anticipate the full range of ethical issues that may arise in the course of a research project. The IRB is a group of colleagues who are committed to helping ensure that proper safeguards are in place. But the IRB is also a government requirement: in order to earn a "Federal Assurance Number" entitling Spelman researchers to apply for certain government grants, the IRB must review all Spelman-affiliated research involving human research *regardless of setting or funding source*. Thus, by submitting a proposal to the Spelman IRB, a researcher not only receives assistance in protecting the rights of research participants including, but not limited to, members of the Spelman community but also helps ensure the eligibility of Spelman College to compete for government grants.

## What research is reviewed by the IRB?

The IRB is responsible for reviewing all research involving human subjects conducted at Spelman College or by Spelman College personnel. **"Research"** as defined by Department of Health and Human Services (DHHS) is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. The regulations regarding research are

outlined in the document known as “The Common Rule” (45 CFR 46). Following is a list defining “Human subjects”, the means by which data may be collected, and types of information covered by IRB review:

- A “**human subject”** is defined by DHHS as a living individual about whom a research investigator (whether a professional or a student) obtains data through intervention or interaction with the individual or from individually identifiable information.
- **"Intervention"** as defined by DHHS regulations means both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. [45 CFR 46.102(f)]
- **"Interaction"** as defined by DHHS regulations means communication or interpersonal contact between investigator and subject. [45 CFR 46.102(f)]
- **"Private information"** as defined by DHHS regulations means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). [45 CFR 46.102(f)]
- **"Identifiable information"** as defined by DHHS means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

Examples of “research with human participants” include:

- The collection of new data on human participants with the goal of presenting the information to the general public (presentation or publication).
- The collection of new data on human participants which involves experimental manipulation, survey research, or ethnographic research.
- The new collection and use of human tissue or cells.
- The collection of data on students in the classroom which examines effective pedagogical techniques, and involves the intention to present the findings to the public (in other words, NOT for the instructor’s own development).

**Evaluation Studies**

Evaluation studies are designed to obtain data that help program directors or institutions determine the degree to which programs of different types are effective in achieving their goals. Such studies have the primary purpose of providing information pertinent to continuing or improving aspects of the program in the future. If used internally in this way only, they do not contribute to 'generalizable knowledge' so are not considered 'research'. However, these projects often have a secondary purpose as well; that of informing others about the progress and outcomes of the program. Data from these projects are often reported to external agencies, presented in public forums such as websites or at conferences, or may even be published in scholarly articles. When evaluation data are disseminated in any of these ways, they have the potential to contribute to generalizable knowledge and are thus considered to be research by the Spelman IRB. With the exception of classroom data used for academic program assessment, all persons planning evaluation studies should contact the IRB co-chairs to get a determination about whether IRB review is necessary. In general, studies that involve solely internal use of and access to data will not need further review beyond the co-chair's statement of determination, while those studies

that plan to disseminate data from human participants to any persons or resources external to the campus community will need to submit a proposal for online review.

**Research Risk Categories**

**No Anticipated Risk to Human Subjects** - No positive or negative physiological/psychological effects. For Examples Initial review will occur within 30 days from submission date.

**Minimal Risk to Human Subjects** – Minimal and temporary discomfort comparable to daily life. For Examples Initial review will occur within 30 days from submission date.

**Moderate to Substantial Risk to Human Subjects** - Unusual discomfort as a direct result of the research which would not typically be experienced in daily life. Discomfort described as severe and long-lasting. For Examples Initial review will occur within 60 days from submission date.

High Risk or Certainty of Permanent Damage to Human Subject - This includes research that has a risk of causing permanent damage including, both physiological and psychological harm; known outcome of permanent damage physiologically or **psychologically. This type of research will not be approved/conducted at Spelman College.**

**Designation of exempt status**

According to the Department of Health and Human services, the following types of projects may be exempt; however the federal guidelines specify that this determination must be made and documented by a representative of the IRB (at Spelman College, the Spelman IRB co-chair). Additionally, an IRB may require stricter review and monitoring for any project. A researcher may not preempt the IRB's role by assuming exempt status.

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

> (i) research on regular and special education instructional strategies, or (ii) 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:

> (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) 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.

(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

(b)(2) of this section, if:

> (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(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:

> (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies,

> (i) if wholesome foods without additives are consumed or (ii) if 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 Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(7) Oral histories and case studies. Although it is not necessary for oral histories to be reviewed by the IRB according to the latest federal guidelines, IRB will review proposals to conduct oral histories to determine that they are indeed oral histories. The determination not to review will be made and communicated in writing by one of the IRB Co-chairs.

**Federalwide Assurance of Protection of Human Subjects (FWA)**

The Federal wide Assurance of Compliance (FWA) is the contract which Spelman College has signed with the federal government which allows research involving human subjects to take place.

> In signing the FWA, Spelman College has agreed to the following terms:

All of the institution's human subject activities, and all human subject activities supervised by the IRB, regardless of funding source, will be guided by the ethical principles in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, a report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The IRB is regarded as the final authority over human subjects research within its jurisdiction. The College commits to provide sufficient funding, meeting space and staff to insure that the IRB is able to perform its supervision and record keeping duties.

In addition, FWA requires Spelman College to insure that federally supported human subjects research complies with the Federal Policy for the Protection of Human Subjects (also known as the Common Rule), with the Code of Federal Regulations in 45 CFR 46 (Policy for Protection of Human Research Subjects), and any additional human subject regulations and policies of the specific supporting Department or Agency.

FWA requires the College to have written procedures (this document) for (a) verifying whether proposed activities qualify for exemption from, or waiver of, IRB review; (b) conducting IRB initial and continuing review, approving research, and reporting IRB findings to the investigator and the institution; (c) determining which projects require review more often than annually, and which projects need verification from sources other than the investigator that no material changes have occurred; (d) ensuring that changes in approved research are reported promptly and are not initiated without IRB approval, except when necessary to eliminate apparent immediate hazards to the subject; (e) documenting any instances in which the College IRB has agreed to allow another institution's IRB to have controlling review authority; and (f) ensuring prompt reporting to the IRB, institutional officials, the relevant Department or Agency Head, any applicable regulatory body, and OHRP of any significant events such as serious and unanticipated problems involving risks to subjects or others in any covered research; serious or continuing noncompliance with Federal, institutional, or IRB requirements; and suspension or termination of IRB approval for Federally-supported research.

FWA requires the College to insure that members of the IRB will complete relevant training in and maintain continuing knowledge of relevant Federal, State and Local regulations and institutional policies before reviewing human subjects research. The IRB is also required to document such training from research investigators as a condition for conduction human subject research.

The FWA agreement requires the College to supply any or all of the above documentation on demand to the Office for Human Research Protection of the Department of Health and Human Services.

**Who must submit proposals to the IRB?**

All researchers intending to work with human subjects must submit an application to and receive authorization from the IRB prior to the start of research activities. Human Subject Research includes, but is not limited to: field observation, focus groups, structured or semi-structured interviews, surveys or questionnaires, research utilization of confidential administrative data (e.g. government data such as individual level welfare data or college data such as student grades), experiments requiring live human participants, and experiments utilizing human tissue. Adding human subjects to an existing research project also requires IRB approval (in accordance with 45 CFR §46.119).

All human subject studies are subject to IRB review regardless of the purpose, extent, context, or source of funding for the study. This includes class projects, experiments conducted within the class setting, and studies that do not receive any external funding.

All research (funded and non-funded) projects that are being conducted **AT** Spelman College or **BY** Spelman College personnel must undergo IRB review. This means, any researcher (students, full-time faculty members, adjunct faculty members, and staff members) conducting research on human participants, and who 1) either is directly affiliated with Spelman College, and/or 2) is conducting

research at Spelman College. Research that is conducted outside of Spelman's campus (e.g. at another campus, or in a public location), must receive Spelman IRB approval due to the researcher's affiliation with the College (and may also need IRB approval from another institution).

Researchers from other institutions wishing to conduct studies with Spelman College students, faculty or staff as primary participants must submit an application to the Spelman College IRB even if an IRB review was completed at their home institution (in accordance with Protection of Human Subjects, 45 CFR §46.114). In fact, the external researcher must obtain IRB approval from their home institution before applying to Spelman's IRB. Such researchers must submit an online Unaffiliated Investigator Agreement Form with the application for IRB review and obtain a Spelman College research sponsor (must be a multi-year or tenure/tenure-track faculty member, or "appropriate supervisory staff member"), who will share responsibility for the conduct of research on campus. In addition, the outside investigator must submit proof of approval (or conditional approval) from the IRB of that researcher's home institution. If the other IRB chooses to waive its review and abide by Spelman's review, a IRB Waiver Agreement must be completed and filed before the study begins.

If the researcher has collected data in the past, and did not submit an IRB proposal at the time of data collection, but would now like to present the data to the general public, he/she should submit a new IRB proposal to obtain permission to present data that has been previously collected. The IRB committee will review the proposal to ensure that the protection of the human participants was and is being maintained. This includes research conducted as part of a course or data used in course evaluation.

When external investigators are soliciting participation from individuals from a number of institutions via email or mail, and have IRB approval from their home institution, then the need for Spelman IRB approval depends on whether access to Spelman participants is available through public or private means. Public access is defined as readily available contact information. Private access is defined as contact made through protected databases or individuals on campus. Only those studies relying on private access need to go through the Spelman IRB review process.

**International Research**

Students and faculty sometimes conduct research at international locations. When conducting research abroad, appropriate approval from a Human Subjects Review Board should be obtained from the host institution or governing body. A copy of that approval should be submitted to the Spelman IRB at IRB@spelman.edu. Such documentation will be necessary to present at Spelman College's Research Day or any other venue for data presentation or publication. If the host institution does not have a human subjects review process, then the investigator must submit a proposal to the Spelman College IRB for approval before data collection begins. Investigators are encouraged to plan their research experiences appropriately.

If a project is started internationally but continued after return to Spelman College, it must be approved by Spelman's IRB regardless of prior approval from the international institution.

Research outside the US creates additional areas of concern for both the PI and the IRB. It is not possible for the IRB to be aware of all the cultural, social and legal ramifications of human subjects research conducted in every country. Consequently, it is the responsibility of the PI to familiarize

him/herself with those issues and explicitly explain to the IRB what they may be and the ways in which they are being addressed by this proposal. Specifically, the following items should be addressed in an attachment to the proposal:

1. Are there aspects of the political, legal, social, economic or religious climate in the foreign country that could reasonably be expected to increase or decrease risk to participants beyond what would be expected in the US? If so, explain in detail what they are and how any increased risks will be mitigated by your proposal.

2. Is there an IRB or ethics committee in the country or at the institution where the project will be conducted? A list of registered committees can be found at http://www.hhs.gov/ohrp/international/index.html. Not all countries have review committees and not all of those that do follow the same regulations or procedures as in the United States. Approval by the Spelman IRB does not override the obligation to follow local laws and regulations. The Spelman IRB requires the PI to provide evidence of having met the conditions of the relevant local law, whatever they may be, and to include an attachment explaining in detail what those regulations are and how they have been met.

3. Federal law requires that all participants be provided with contact information for the PI and/or a responsible party should they have any questions about the research or their rights. In some cases, where accessibility is not an issue, an email address or phone number for the PI and the Spelman IRB may be sufficient. In other cases, where accessibility is limited by either logistical or economic constraints, it may be more advisable to have a contact point in the local ethics committee or institution where the research will be conducted. The Spelman IRB requires that the PI provide evidence that the local entity will be willing to relay any messages to the responsible parties in this country.

4. Consideration should be given to the most appropriate means of obtaining consent, taking into account any language barriers, literacy issues and confidentiality concerns above and beyond those that exist in the US. In some cases, oral consent may be more appropriate than written if a signature on a form would put participants at greater risk. Consent should always be obtained in the native language. A copy of the consent form or script in the native language, with an English translation, along with an explanation for any deviations from written consent, should be provided to the Spelman IRB as part of your application.

**Oral Histories**

Oral histories are interviews that collect information about an individual's past personal experiences or historical events. The federal Office of Human Research Protections has provided guidance (Carome, 2005) that clarifies when IRB review is needed for oral history projects. In general, most oral history activities focus on documenting past events as experienced, and are not meant to be generalizable or predictive. Thus, such oral histories are not considered to be research and do not require IRB review according to OHRP guidance. However, if oral history interview techniques are used to systematically collect data for research purposes, then IRB approval is necessary in those cases. The Spelman IRB will adhere to the OHRP guidance when evaluating the necessity of IRB review for oral history projects conducted by or with Spelman community members. Those conducting oral history projects are strongly encouraged to follow ethical practices of informed consent and minimization of risk even when

IRB review is not necessary. If an investigator has a question about the need for IRB review, he or she should contact one of the IRB co-chairs.

**Mandatory Collaborative Institutional Training Initiative (CITI) Training for all Investigators**

All principal investigators, including faculty, staff, students, and external investigators, must have completed the CITI training prior to application for submission effective September 1, 2011. In addition, the principal investigator is responsible for ensuring that all individuals who contact human subjects or their data in the context of their research project have completed the CITI training prior to their interaction with subjects or data. We anticipate that most researchers at Spelman College will be social and behavioral researchers and should register to complete these modules.

> You are considered a "social or behavioral researcher" if your research involves these or similar processes: life histories, ethnographic research, noninvasive measurement or observation of individual attitudes or behaviors including overt actions and underlying psychological processes, bio-behavioral measurements or interactions, or data provided about personal or social characteristics provided by individuals, or interactions between individuals or groups of people at various levels of social context.

Investigators who have current CITI (or equivalent) training from another institution may receive credit for modules completed from that institution; however they will need to complete any uncompleted modules through the Spelman portal. A Co-chair will determine whether an alternative certification (e.g. NIH) is equivalent to CITI, and whether completion of the Spelman CITI modules can be waived.

CITI training is effective for a period of three years, after which it must be renewed prior to conduct of additional human subjects research.

To complete or confirm completion of CITI Training, access the link below:
https://www.citiprogram.org/

**Who is on the IRB?**

In accordance with Federal regulations (45 CFR §46.107), the Spelman College IRB is composed of members with varying backgrounds to promote complete and adequate review of research activities commonly conducted at Spelman College. There are representatives from the natural sciences, social sciences (both quantitative and qualitative), and the humanities. Also in accordance with Federal regulations, the Spelman College IRB includes at least one member who is not an academic and at least one member who is not affiliated with the college; the regulations permit the same individual to serve in both of these roles.

On occasion, the IRB may invite individuals with competence in special areas to assist with the review of issues requiring expertise beyond or in addition to that available on the IRB. In accordance with Federal regulations (45 CFR §46.107 (f)), such experts participate on a non-voting basis only.

New IRB members may apply or be nominated by other faculty members to serve on the board. IRB members will have the opportunity to discuss nominees before forwarding the names for recommendation to the Associate Provost for Research. Appointment to the Board is made by the

Associate Provost for Research as needed. Membership terms extend for three years, renewable for up to two additional terms. Co-chairs (2) will be elected by the full IRB and will serve a two-year term, renewable for two additional terms. Co-chair terms should be staggered to allow overlap. IRB membership may be terminated by vote of a quorum or determination of co-chairs for reasons of non-participation, non-performance, and/or ethical violations.

The IRB will consist of a minimum of 13 members plus the institutional representative. A quorum will include at least 50 percent of active members.

The current membership of the Spelman College IRB is as follows:

- Mark Lee, Ph.D., Associate Professor and Chair, Biology (co-chair, 8/2014-present)
- Shani Harris, Ph.D., Associate Professor, Psychology (co-chair, 1/2016-present)
- Kimberly Jackson, Ph.D., Associate Professor, Chemistry
- Yassin Jeliani, Ph.D., Assistant Professor, Chemistry and Biochemistry
- Mason Kim, Ph.D. Assistant Professor, International Studies
- Lynn Maxwell, Ph. D., Assistant Professor, English
- Kai McCormack, Ph.D., Associate Professor, Psychology
- Melvina Norwood, PhD. (external member)
- Natarajan Ravi, Ph.D., Professor, Physics
- Shannon Hsianghan-Huang Sung, Ph.D., Assistant Professor, Education Studies
- Nicole Taylor, Ph.D., Assistant Professor, Education Studies
- Yonas Tekle, Ph.D., Associate Professor, Biology
- Jill Triplett, Director, Institutional Research
- Bruce Wade, Ph.D., Professor, Sociology and Anthropology; Director, Census Information Center
- Celeste Walley-Jean, Ph.D., Associate Professor of Psychology, Clayton State University (external member)

## SUBMISSION PROCEDURES

The Spelman College IRB accepts electronic proposals only. The application form may be found on the Spelman IRB website, www.spelman.edu, and submitted through the online form located at http://www.spelman.edu/academics/provost/institutional-review-board/submissions.

### Spelman Faculty and Staff Research

For faculty and staff research, all materials, including the research protocol, instruments to be administered, and proposed Informed Consent Forms must be submitted at least two (2) weeks prior to the monthly IRB meeting. A copy of the Proposal Submission Form (available at the Spelman College IRB website) must accompany the proposal. The IRB will complete initial reviews of faculty research projects within four weeks of their submission.

### Collaboration with External Institutions

Spelman faculty conducting research in collaboration with investigators at other institutions must complete all the requirements in the above paragraphs in addition to submit prior IRB approval from the collaborating institution(s). In addition, external investigators who serve as PI or Co-PI on the collaborative project should complete the Unaffiliated Investigator Agreement Form.

Spelman faculty who enter into collaborative research relationships with other institutions are not typically just recruiters, but are active partners in the research. If a Spelman faculty member is recruiting participants for an external investigator but is not actively involved in the project, please refer to the guidelines for the Spelman Sponsor and Investigators Unaffiliated with Spelman College.
(See also “Waiver of Spelman IRB Review” below)

### Spelman Student Research and Classroom Projects

Student research and classroom projects, all materials must be submitted two (2) weeks prior to the initial decision date desired. This proposal should include a brief description of the research protocol, instruments, the proposed Informed Consent Forms, and a copy of the Proposal Submission Form. The faculty advisor must serve as the PI for student research projects and classroom projects. Whenever permissible, the IRB will handle these projects according to the timeline and procedures for Expedited Review (see below).

### Investigators Unaffiliated with Spelman College

As stated above, human subject researchers who are not affiliated with Spelman College (individuals who are not Spelman College students, faculty or staff) must obtain a Spelman College research sponsor (faculty or staff) who will share responsibility for the conduct of research on campus. These approvals may be indicated in a letter or e-mail to the IRB, or by signature on the Proposal Submission Form. Researchers not affiliated with Spelman College must also submit an Unaffiliated Investigator

Agreement Form and proof of approval (or conditional approval) by the IRB at the researcher's home institution.

### Spelman Sponsor

While Spelman IRB approval is required before the start of research, it is not required for investigators to contact potential research partners at the college. Such consultations with Spelman faculty and staff are informal and are not subject to IRB review or approval until a formal application is made. However, we highly recommend that an outside investigator obtain IRB approval at his or her home institution before contacting Spelman faculty, as some college personnel may understandably hesitate to invest effort in a project that has not been vetted by an IRB. Potential Spelman research sponsors will typically also want to review the research protocol and recruitment plan, know what that person's rights (e.g. access to data or a report of the findings) and responsibilities (e.g. recruitment of participants from the Spelman community, administration of instruments) will be, and know about the intended uses of the data to be gathered. A list of Spelman departments with links to faculty lists may be accessed via this link.

## REVIEW PROCEDURES

### General Procedures

The Spelman IRB relies primarily on electronic expedited review of proposals (procedures detailed below), routed upon submission. If a proposal includes more than minimal risk, or a reviewer otherwise wishes to discuss a proposal with the rest of the Committee, a meeting will be called. The IRB will meet up to once per month during the academic year as needed, with a minimum of one meeting per semester. Precise dates will be scheduled by the Associate Provost of Research with advice and consent of the IRB membership, and are available from that office. Due to 9-month appointments and the difficulty of drawing a quorum during the summertime, the IRB will not meet during June, July, and August. Only proposals eligible for Expedited Review will be entertained during the summer months. As per Federal regulations (45 CFR §46.108), attendance by a majority of the committee including at least one non-scientist is necessary for a quorum; decisions are rendered by a majority vote of those members attending the meeting.

Upon receipt of an application, The IRB Administrator in the Office of Research Resources will examine each complete proposal, determine the type of review necessary (Expedited or Full), and assign a Principal Reviewer (PR), a Secondary Reviewer (SR), and Co-Chair for the proposal. The PR and SR are IRB members selected on a rotating basis who will conduct the review of the proposal. If an application requires full committee review, the IRB Administrator will route the application to all committee members before the next meeting date. Applications that remain incomplete one week before the monthly meeting will not be examined at that meeting. The Office of Research Resources will initiate and monitor electronic routing of the applications to the reviewers and co-chair for examination.

**Expedited Review**

At its discretion, the IRB may conduct an Expedited Review of research that poses no more than minimal risk or involves minor changes in previously approved research during the period for which the original approval had been authorized. The decision to conduct an Expedited Review is **not** based upon the schedule of the investigator. Rather, to be eligible for Expedited review, the research must fall into one of the following categories, as per the Office for Human Research Protections (OHRP):

- Collection of data from voice, video, digital, or image recordings made for research purposes;
- Non-exempt research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies;
- Non-exempt research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis);
- Prospective collection of biological specimens for research purposes by noninvasive means;
- Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

Expedited review will be carried out by one of the two IRB chairpersons and a PR and SR selected by the IRB Administrator from among the IRB membership. Following the Federal Regulations (45 CFR §46.110), the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only by the full IRB.

The IRB Administrator will apprise all members of the IRB of research proposals that have been approved under the procedure in writing at least once per semester.

The Federal authorities may restrict, suspend, terminate, or choose not to authorize the use of the expedited review procedure at any time (45 CFR §46.110).

**Exempt Review**

Some projects such as clinical trials require ongoing IRB oversight (otherwise known as “Full Review”), while others are eligible to be declared exempt from further review. Researchers who plan to conduct human subject research that they believe is exempt from IRB review must nevertheless submit a full application to the IRB prior to conducting research activities or contact one of the IRB co-chairs to render a written decision about whether the project is human subjects research that needs review.

Federal regulations state that only the IRB may determine whether a research activity is exempt from full review (45 CFR §46.101).

Exempt from further review are projects that involve no deception or coercion of the participants, involve risks no greater than those ordinarily encountered in daily life, and fall into one of the following categories:

- The activity is conducted in an established educational setting and involves normal education practices in order to evaluate or compare educational instructional practices, curricula, or methods.

- The research involves the use of standard educational tests (cognitive, diagnostic, aptitude, or achievement) and information taken from those tests will be recorded so that participants cannot be identified directly.

- The research involves surveys, interviews, or observation of public behavior, the responses will be recorded so that either: a) participants cannot be identified directly or indirectly by their answers or b) the responses could not damage or harm a subject's interests, including financial interests, employability, or reputation.

- The research is limited to using existing data to which the investigator has access, and the information will be recorded so that participants cannot be identified directly or indirectly.

**Full Review**

Full reviews will be conducted in accordance with the guidelines provided by the Office for Human Research Protections (OHRP) of the US Department of Health and Human Services (Protection of Human Subjects, 45 CFR §46.109). The PR will lead the discussion of the proposal at meetings of the IRB. The PR will complete a full review form that reports the decision of the IRB and advises the principal investigator of required changes to the protocol or consent forms. The same PR will lead annual and ongoing reviews of revised proposals and consent forms.

In some cases, the IRB may require submission of research reports and analyses as part of the full review. If Spelman College is to be mentioned in any publications or presentations, a preliminary draft of the manuscript must be submitted to the IRB.

**"Blanket" Proposals for Classroom Research Projects**

All researchers, including students, intending to work with human subjects must submit an application to and receive authorization from the Spelman College IRB prior to the initiation of research activities or data collection. **In some cases, a full-time faculty member at Spelman College may request a "blanket" application to cover on-going or one-time research projects for the students enrolled in a given course**. In such cases, the faculty member will have the primary responsibility for submitting the IRB "blanket" application and to supervise the work of students (topics must be "minimal risk" to qualify).

As part of the online application the "Blanket" application the investigator will include:

- Course information (Department or Program, Course Number and meeting location, days and times)
- Sample Consent Form with all required elements
- Assurance Statement by the sponsoring faculty member regarding their commitment to supervise student proposals and research; to supervise student's reporting of their work (and refer problems to the office of the Associate Provost of Research and to summarize (to the IRB) the research projects conducted by students at the end of each semester.

The course instructor will, in essence, serve as a temporary IRB representative for the class. Students will submit IRB proposals to the instructor, who will review them for human subjects concerns, suggest changes, and approve the projects as appropriate. The IRB does not need to review the specific projects if they are minimal risk, unless the instructor requests such a review. Projects that contain greater than minimal risk need to be sent to the IRB for separate full review. The instructor must monitor all projects for human subjects concerns and communicate with IRB as necessary.

Sponsoring faculty should note that students are not permitted to assess self-reported illegal activities, substance use, sexual behaviors, or similarly sensitive behaviors. It is expected that the faculty member will monitor student projects to ensure that the topics of study are appropriate to the level of experience of the student researcher.

Unless the IRB has determined the project to be Exempt from further review, faculty sponsors must submit a summary of the classroom projects completed under the "Blanket" application. The faculty sponsor will maintain all documentation, including all consent forms and research protocols, associated with the sub-projects completed under the "Blanket." **This documentation should be maintained for a period of 3 years, and must be provided to the Spelman College IRB upon request.**

As is the case with any approved research, if any problems arise with the research, research participants must be referred to the office of the Associate Provost of Research (404-270-5706). If approved, at the end of each semester, the professor is required to submit a summary of all research topics conducted by students enrolled in the course.

**Criteria for IRB approval**

In order to approve research, the IRB must determine, within its sole discretion, that the following requirements are satisfied:

1) There are no unnecessary risks to subjects;
2) The risks to subjects are reasonable in relation to anticipated benefits;
3) The selection of subjects will be equitable;
4) Informed consent will be sought and appropriately documented;
5) Adequate provision has been made for monitoring data collection to ensure safety of subjects
6) Adequate provision has been made to protect the privacy and dignity of subjects;
7) Necessary additional safeguards have been included to protect subjects who are likely to be vulnerable to coercion or undue influence; and
8) The research will be conducted in a manner sensitive to the setting in which it takes place.

**Notification of Approval**

Following review by the IRB for initial or continuing approval, notification will be made in two ways. Initially, the PI will receive an electronic message indicating the results of the review from the Co-chair of record. Following this, the IRB Administrator will send a written notification to the principal investigator, copied to the Spelman College Human Subjects Administrator (Associate Provost of Research). Written notification will clearly indicate either approval or non-approval. When a proposal is not approved, the Co-chair of record will provide a statement of the reasons for the IRB decision, provide the principal investigator with an opportunity to respond either in person or in writing, and typically will provide instructions to principal investigators on proposal modifications that would increase the likelihood of approval upon resubmission. However, the IRB is not obliged to approve any research proposals that may present risks to human subjects, regardless of the proposed benefits foreseen by the principal investigator.

**Conditions of IRB Approval**

IRB approval of a proposed study is limited to the specific study described in the proposal reviewed by the IRB. Approval is limited to 12 months. An extension of IRB approval for an additional 12-month period requires that the principal investigator notify the IRB of the following information: 1) number of subjects, 2) location and number of consent forms obtained, 3) adverse reactions encountered and corrective measures taken, and 4) any changes in the research protocol. Proposals for extensions for an additional 12-month period may be submitted no later than two months prior to the expiration of the current 12-month period. Researchers must report to the IRB any changes made to protocols, instruments, or informed consent forms during a study prior to the initiation of such changes. Changes in protocols, instruments, or informed consent forms must be approved by the IRB prior to use with human subjects, except when such change is necessary to eliminate apparent immediate hazard to the subjects. If any such immediate changes are made, the IRB must be immediately notified and approval of the change must be sought. Any incident in which a human subject is injured must be reported immediately to the IRB. In all cases, researchers must report to the IRB on the status to their project at the end of each 12-month approval period or at shorter intervals as specified by the IRB.

Projects that pose a high level of risk to human subjects or that have had problems complying with IRB requirements in the past may be subject to continuing reviews at intervals more frequent than 12 months and/or verification of research activities by individuals other than the principal investigator.

The Spelman College IRB is obligated to report serious or continued noncompliance with Federal Regulations or the Spelman College IRB requirements, unanticipated problems involving risks to research subjects or others, and suspension or termination of IRB approval. Such events will be reported to the Associate Provost of Research, the Director of Sponsored Programs, the Office for Human Protections (OHRP) at the U.S. Department of Health and Human Services, and to the relevant funding and regulatory agencies specific to a given research project.

The IRB has the authority to suspend or terminate approval of any research that is not being conducted in accordance with these guidelines or that is associated with unexpected serious harm to the subjects.

When approval is either suspended or terminated, the IRB will provide the principal investigator with a statement of the reasons for its decision.

**Scope of IRB approval**

The Spelman IRB reviews and approves projects with respect to human subjects concerns only. Although IRB approval is necessary for a research project to be conducted by or with Spelman personnel, other approvals beyond the scope of the IRB's purview may be necessary as well.

**Waiver of Spelman IRB review**

If a member of the Spelman faculty or staff is collaborating on a research project that is being conducted primarily at another institution, the research team may request that the Spelman IRB waive its review of the project, deferring to the IRB review of the other institution. The IRB co-chairs and Associate Provost will jointly determine whether such a waiver will be granted, and will communicate their decision in writing. Such a request will typically only be considered if a) the bulk of the research, including all of the data collection, is conducted at or by the other institution, b) does not recruit members of the Spelman community as participants, and c) the alternative IRB is registered with HHS, has a Federal-wide Assurance Number, and is considered to have good expertise in the type of research under consideration. The waiver of Spelman IRB review must be documented by a signed IRB Review Waiver form kept on file in the Associate Provost for Research's office. The Associate Provost will serve as the signatory official for Spelman College.

**Verbal Consent Exception**

In some circumstances, written consent may compromise confidentiality or may otherwise be untenable. In such cases, the IRB may waive the requirement for written consent and allow researchers to obtain verbal consent. To obtain this waiver, the procedures in the application should indicate something similar to the following:

**Step 1:** Explain the study to the potential subject verbally and provide all pertinent information (purpose, procedure, risks, benefits, alternatives to participation). The potential subject must have reasonable time to ask questions and consider participation.
**Step 2:** Following the verbal explanation, the potential subject may be provided with a study information sheet (written summary as submitted to IRB) and must be afforded sufficient time to consider whether or not to participate in the research. "Sufficient time" can range from minute to hours, dependent on how long it reasonably takes to evaluate the procedures, risks, potential benefits, and potential alternatives.
**Step 3:** After allowing the potential subject time to read, if applicable, the study information sheet, the investigator must answer any additional questions the potential subject may have and may obtain verbal agreement to participate in the research.

A waiver of documentation of informed consent must be approved by the IRB in order to obtain verbal consent from potential subjects. All communication with potential subjects should be in native language.

**Post-Approval Monitoring and Follow-up**

With the exception of exempt protocols which do not typically require further review, all IRB approvals extend for a period of one year. Within one year from the most recent date of approval, each protocol's Principal Investigator must complete and submit an annual status report. This status report will include either a Request for Project Continuation or Statement of Project Completion as appropriate, depending on whether data collection (or analysis?) is continuing.

The annual status report is online and includes the following information:

- Whether data are still being collected
- Initial approval date, last approval date, extended approval date requested
- Participant information: changes in sample size, number enrolled to date, participant withdrawal
- Occurrence and reporting of adverse events or complaints
- Changes in procedures, materials, consent documents, or contact information
- A current consent document must be attached.

As a courtesy, the IRB office will send a reminder to each PI 60 days before approval expires. If no response is received, a second reminder will be sent 30 days before expiration. If no response follows within 2 weeks of this request, then approval will be rescinded (and the PI barred from submitting additional protocols until the appropriate Statement of Project Completion is submitted.

A member (typically a co-chair) of the Spelman IRB will review each Request for Project Continuation in order to make sure that there have been no changes in the protocol, violations of protocol, or adverse consequences. The PI will be informed either of continuing approval (for an additional year), asked to submit a new or modified application, or asked to discuss violations or adverse consequences.

The IRB has the right to rescind protocol approval at any time when violations or adverse outcomes occur, and to impose consequences that include, but are not limited to, the following:

- Written censure
- Additional monitoring or requirements for compliance
- Suspension of research activity
- Termination of the project
- Report to federal agencies and journals
- Rescinding of data usage and reporting rights

**Mandatory Reporting by Researchers**

Although confidentiality is a cornerstone of human research protections, occasionally situations will arise in which, by law, the health and safety of the participants takes priority over research confidentiality. In these rare cases, researchers are mandated to report potential risks to participant health and safety to appropriate agencies. The researcher (PI) has the responsibility to report cases of suspected child, dependent adult, or elder abuse to the appropriate local social services agency (e.g. DFCS). Suspicion of imminent danger to the participant or others must also be reported to the appropriate authorities or agency. The IRB should be notified that a report is being made. The researcher

must disclose these limits to confidentiality in the informed consent document. Disclosure may be confidential; the participant or guardian need not be notified. Sample language for such disclosure follows (to be adapted as needed):

*We will treat all the information that we get from you today confidentially. What this means is that we will not tell anybody who is not part of the research team about the things that you tell us. There is one exception. If your child tells us that s/he is being physically or sexually abused, by law we have to file a confidential report with the Georgia Department of Family and Children Services (DFCS). Also, if you tell us that your child has been abused, or that you or someone else is in danger of being physically hurt, then we are required by law to tell the appropriate authorities. This is for your or your child's protection. Other than this exception, we won't tell anyone about the information that you tell us.*

**Modifications of Approved Protocols**

IRB approves the specific protocols as stated in the application. If changes are made in any of the following areas, then an online protocol modification form must be submitted:

- Recruitment procedures, including means of obtaining informed consent
- Compensation for participation
- Number of participants
- Sample characteristics
- Data collection instruments such as survey or interview questions
- Data collection procedures
- Addition of video or audio taping
- Use or reporting of data

The protocol modification will be reviewed by one of the IRB co-chairs, who will consult as needed with the other co-chair and/or the original primary reviewer before notifying the PI of a decision on the modification.

## UNAUTHORIZED RESEARCH

Spelman College will not tolerate unauthorized human subjects research at, by, or for Spelman College (see the appropriate sections of the faculty, staff, and student handbooks). This applies equally to research that never underwent IRB review, research begun while approval was pending, as well as research for which the IRB has denied, suspended, or revoked authority. In the event that the IRB discovers an unauthorized research project, the committee will at its discretion take one or more of the following actions:

- Warn the investigator in writing;
- Ban said individual or group from conducting further research at the College for a term of its choosing;
- Notify the researcher's department chair or direct supervisor;
- Notify the Director of Sponsored Programs at the researcher's home institution;

- Notify OHRP; and/or
- Notify the funding agency, if such can be determined.

In addition, Spelman College faculty or staff found in violation of these policies will be reported to the Provost for disciplinary action; students found to be in violation of these policies will be reported to the Dean of Undergraduate Studies and the Dean of Student Affairs for violation of the Academic and Conduct codes, respectively.

Procedures for adjudicating non-compliance:

- Gather information from complainants, PI, others
- Write letter informing PI (copied to Associate Provost of Research at Spelman College, IRB Co-chairs) of alleged violations or adverse outcomes
- IRB representatives (at least one co-chair and institutional official, plus others as deemed necessary) will meet with PI to hear response and review relevant documentation within two weeks of written notification
- Discussion at full IRB regular or called meeting to determine sanctions, if any.
- Notification of decisions and sanctions to PI, home institution, federal agencies, and others as appropriate.
- Any response to the final decision should be directed to the Associate Provost of Research at Spelman College.

## RECORD KEEPING

An original copy of each submitted proposal, the IRB review results, and minutes of IRB meetings will be stored in the Office of the Associate Provost of Research, 151 Science Center. All records will be retained for at least 3 years after the completion of each approved research project and available for inspection by regulatory agencies during regular business hours (in accordance with the guidelines in the Protection of Human Subjects, 45 CFR §46.115).

## CONTACTING THE IRB

Additional information on the Spelman College IRB and the procedures for submission of proposals involving human subjects may be obtained by contacting Chandra Byrd Chambliss at the Office of the Associate Provost of Research at (404) 270-5706, or by emailing irb@spelman.edu. Copies of the Protection of Human Subjects guidelines are available at the Office of the Associate Provost for Research, 151 Science Center.

## ADDITIONAL INFORMATION ABOUT HUMAN SUBJECTS RESEARCH PROTECTIONS AND IRB REVIEW GUIDELINES

For information about the Federal Law concerning human subject research, click this link to the Office for Human Research Protections (OHRP) at the U.S. Department of Health and Human Services.

For discipline-specific information concerning protection of human subjects, please click on these links:

Updated: July 26, 2016

American Medical Association
Humanities
Anthropology
Political Science
Psychology
Sociology

APPENDIX A
CITI USER GROUPS AND MODULES

| GROUPS | STAGE |
|---|---|
| **Physical Science Responsible Conduct of Research** | 1 - RCR (ID: 134102) |
| **Clinical Researchers** | 1 - Basic Course (ID: 108187)<br>2 - Refresher Course (ID: 108188) |
| **Biomedical Responsible Conduct of Research** | 1 - RCR (ID: 134098) |
| **CITI Good Clinical Practice Course** | 1 - Basic Course (ID: 108189) |
| **Humanities Responsible Conduct of Research** | 1 - RCR (ID: 134103) |
| **IRB Members** | 1 - Basic Course (ID: 108192)<br>2 - Refresher Course (ID: 108193) |
| **Research with Children** | 1 - Optional Modules (ID: 111760) |
| **Responsible Conduct of Research for Administrators** | 1 - RCR (ID: 134100) |
| **Social & Behavioral Researchers** | 1 - Basic Course (ID: 108190)<br>2 - Refresher Course (ID: 108191) |
| **Social and Behavioral Responsible Conduct of Research** | 1 - RCR (ID: 134101) |
| **Specialized Research** | 1 - Optional Modules (ID: 111759) |
| **Vulnerable Populations** | 1 - Optional Modules (ID: 111758) |