IRB Application (Version 1.5)

1.0 General Information

***Please enter the full title of your study:**

Sexual Health Study for Gay and Bisexual Men

***Please enter a short title for your own personal reference.**

MSM-Prevent Shigella Infections
* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

2.0 Add Department(s)

2.1 Your department is listed below; click "add" to add an additional department, or select the check box next to the department and select "remove" to remove it. PLEASE DO NOT LEAVE "GSU - Georgia State University" AS YOUR PRIMARY DEPARTMENT.:

Primary Dept?	Department Name
◯	**GSU** - Georgia State University
◯	**GSU** - Sociology

3.0 Assign Study Personnel

3.1 *Please add a Principal Investigator for the study:

Wright, Eric R., PhD

3.2 If applicable, please select the Research Staff personnel (If you are adding a GSU student or faculty member and their name does not appear in the list of personnel, ask that person to log-in to iRIS with his/her campus ID and password which will populate their name in the list. If you are adding personnel from outside GSU and their name does not appear in the link they can be added with the form available at http://ursa.research.gsu.edu/working-with-individuals-outside-of-gsu/.):

A) Additional Investigators

B) Research Support Staff

Evener, Steve
Student
Townsend, Ebony S
Student

3.3 *Please add a Study Contact:

Wright, Eric R., PhD

The Study Contact(s) will receive all important system notifications along with the Principal

Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

3.4 Please select the Designated Department Approval(s). You must select the appropriate department sign-off for the study. If you do not know who this is, please contact your department head or chair. For the initial submission of the study, the submission must be routed to the designated department sign-off for endorsement.(YOU MUST ADD A DEPARTMENT SIGN-OFF HERE.)

Reitzes, Donald

Associate Dean

Add the name of the individual authorized to approve and sign off on this protocol from your Department (e.g. the Department Chair or Dean).

3.5 If applicable, please select the Administrative Assistant(s):

Administrative Assistant Note

4.0 Please answer the questions below regarding research personnel:

4.1 * Human Subjects Training is a requirement for approval. Have you and your research team members completed Human Subjects Training?

For step-by-step directions on checking research team members' training, please click here.

(•) Yes ( ) No

4.2 * Below is the PI you selected. Please confirm that the PI listed on the study is a current Georgia State University faculty member. Students or people outside of the University cannot serve as the PI on the study.

Eric R. Wright, PhD

Is the PI listed a faculty member at Georgia State University?

(•) Yes ( ) No

5.0 General Research Information

5.1 * Describe in lay terms the purpose of the research including the research question and what you hope to gain.

Specific aims: Understand perceptions of shigellosis among men who have sex with men (MSM) and preferences for shigellosis prevention messaging and materials. Because MSM are emerging as a population at increased risk for such infections in the United States, we will study how to most effectively reach MSM with shigellosis prevention materials. Findings from this research will be used to develop shigellosis prevention materials for MSM and may be useful in the prevention of sexual transmission of other enteric infections.

Aim 1: To understand the current knowledge of MDR shigellosis and its prevention, perceptions of MDR shigellosis, and motivation to prevent these infections among MSM.
Aim 2: To assess preferences for the tone, format, and medium for messages about prevention of MDR shigellosis and related imagery among MSM.
Aim 3: To develop and improve prevention materials based off feedback from MSM, and finalize MSM shigellosis prevention materials using the knowledge gained from Aims 1 and 2.

5.2 * Describe how human subjects will be involved. If there is interaction with participants, describe the proposed procedures for research. If you are using secondary data, describe the content of the data, the source, and clarify if all data are currently existing at this time. Do not describe recruitment information, informed consent procedures, or confidentiality information in this section. That information is requested elsewhere in the application.

We will use a qualitative approach to address our aims. Focus group discussions, following standardized

guides, will be conducted to understand the degree, content and source of knowledge about MDR shigellosis and appropriate prevention messaging content, tone, and delivery route.
A convenience sample of MSM will be recruited to participate. Focus groups will follow a stratified approach based on known risk factors and groups of shigellosis transmission among MSM. Prior research indicates MSM living with HIV experience disproportionate levels of shigellosis in comparison to HIV-negative MSM [48- Daskalakis et al. 2007]. In addition, we know that sexual risk, in general, manifests differently according to racial and ethnic distinctions [49]. As such, our sampling frame will select focus group respondents according to the following distinctions: African American/black, Caucasian/white, and an undefined group. "We will hold two phases of focus groups, one in Year 1 and one in Year 2. For Phase 1, we will conduct six focus group discussions, each lasting up to one hour or until we reach the point of saturation. Focus groups will allow us to determine the knowledge and perceptions of MDR shigellosis infections and shigellosis prevention among MSM, and to assess preferences for the tone and format of shigellosis prevention materials. These discussions will be led using a phase-specific focus group moderators' guide. (See Phase 1 and Phase 2 Moderator's Focus Group Guides).

5.3 * State who will be conducting each of the procedures detailed above. If there are multiple procedures or populations, be sure to state who will be conducting each procedure or working with each population.

Recruitment- Research Team (Dr. Wright, Ebony Townsend, and Steve Evensen).
Screening- Dr. Wright, Emily Townsend
Focus Groups will be facilitated by Dr. Wright, Ebony Townsend, and Steve Evensen.
Data Analysis and transcription will be conducted by a yet-to-be-determined CDC approved contractor. The research team will submit an amendment to the IRB once the identity of this agency is defined. No analysis or transcription will take place until the amendment is reviewed and approved by the IRB.

5.4 * Will the study involve interaction with participants?

Interaction includes any contact with people including, but not limited to, online interaction, survey distribution, or hiring a company or third person that will interact with people.

(•) Yes ( ) No

6.0 Funding, Dissertation, or Protocol

6.1 * Will the research be funded?

(•) Yes ( ) No

6.2 * Is this study or any part of this study contributing to a dissertation or thesis?

( ) Yes (•) No

6.5 Please be sure to upload your Grant Application in the study document section at the END of the submission packet.

6.6 Will your research be funded externally or internally?

☑ External
☑ Internal

6.7 * What is the CON number (e.g. CON001234) associated with the funded project for this protocol?

N/A

6.8 * What is the Project ID (e.g. SP00012345) for the funded project this protocol is associated with?

N/A

6.9 Please select the type of external funding:

- [x] Federal Government
- [ ] State Government
- [ ] Local Government
- [ ] Foundation or Private
- [ ] Industry

6.10 * Please list your funding agency below.

Centers for Disease Control and Prevention

6.12 Please select your type of internal funding:

- ( ) -GSU
- (•) -Department

6.14 * What is the total award amount?

100,000

7.0 Study Information

7.1 * Will this study be submitted to another IRB for review and approval?

( ) Yes (•) No

7.2 * Does your study involve the use of Protected Health Information (PHI), as such term is defined by HIPAA, obtained from a Covered Entity? For more information on the definitions of PHI and Covered Entity or other terms related to HIPAA, please click here.

( ) Yes (•) No

7.3 * Will the study involve the use or possible exposure to infectious or potentially infectious material? (e.g. blood, bodily fluids, mucosal swabs, tissue samples, etc.)

( ) Yes (•) No

7.4 * Does the study involve the use of non-human animals? (e.g. dogs, mice, non-human primates, etc.)

( ) Yes (•) No

7.7 * Will your study involve data from student education records (e.g. class work, grades, attendance records, communications, projects, classroom tests, standardized tests, journals, SAT/ACT scores, etc.)? This list is not exhaustive. Please see section 1.6 of the IRB manual for more information on FERPA records.

( ) Yes (•) No

8.0 Location

8.1 * Will the study be conducted outside of the United States?

○ Yes ◉ No

8.2 * Is there a research location located outside of Georgia State University?

○ Yes ◉ No

9.0 Investigational Information

9.1 * Will the study involve the use of FDA approved drugs?
Please note: GSU's IRB can only review studies that use FDA approved drugs for approved uses. Please contact the IRB office if you are using a drug not approved by the FDA.

○ Yes ◉ No

9.2 * Will the study involve Investigational New Devices?
Please note: GSU's IRB can only review studies that use FDA approved devices for approved uses. Please contact the IRB office if you are using a device not approved by the FDA.

○ Yes ◉ No

9.3 * Will the study involve Radiation or Lasers?

○ Yes ◉ No

10.0 Additional Information

10.1 * Will the study involve deception or concealment of any information?

○ Yes ◉ No

10.2 * If you are using a survey that will be administered at Georgia State University, does it need to go through the Survey Coordinating Committee? This committee is independent of the IRB. Information on the committee can be found on their website.

○ Yes
○ No
◉ N/A

10.3 Do any research personnel need special certifications, training, or special qualifications to conduct the research procedures? If so the individual's name and qualifications should be listed along with any certification or licensure number and dates of qualification. This includes studies that utilize venipuncture, EKGs, direct patient care, CPR, EEGs, and studies involving clinical psychologists, physicians, nurses, physical therapists, and others.

○ Yes
○ No
◉ N/A

11.0 Vulnerable Populations

11.1 * If you are including women, are you recruiting pregnant women because they are pregnant or are you including any procedures that could be more than minimal risk for a pregnant woman or fetus?

○ Yes
○ No, I am including women of childbearing age, but the study includes no procedures that are more

than minimal risk for the participant or fetus.

- (•) No, I am excluding women of childbearing age (a study specific justification must be provided elsewhere in the application).
- ( ) No, I am excluding pregnant women (a study specific justification and procedures for the exclusion must be included in the application)

11.2 * Are you including any students or trainees in your research?

- ( ) Yes, participants are the students or trainees of a researcher.
- (•) Participants may be students or trainees, but they are not the students or trainees of anyone on the research team.

11.3 * Are you including any employees or subordinates?

- ( ) Yes, participants are the employees or subordinates of someone on the research team.
- (•) Participants may be employees or subordinates, but they are not the employees or subordinates of anyone on the research team.

11.4 * Are you using any patients in your research?

- ( ) Yes
- (•) No

11.5 * Are you using prisoners in your study?

- ( ) Yes
- (•) No

11.6 * Are you using children (ages 0-17 in Georgia) in your research?

- ( ) Yes
- (•) No

11.7 * Are you including any individuals that may be cognitively or decisionally impaired?

- ( ) Yes
- (•) No

12.0 Population Data

12.1 * Will enrollment be limited to a specific ethnic, social, or gender group? If so, describe and justify.

(•) Yes ( ) No

Shigellosis is a nationally notifiable disease with an annual estimated incidence of 500,000 cases in the United States. Shigellosis is most commonly transmitted from person-to-person among young children and their caretakers; however, multidrug-resistant (MDR) shigellosis, particularly among men who have sex with men (MSM), is emerging in the United States. As such, this project will focus on individuals of male gender. Through this project, we will gather qualitative data to develop evidence-based and sociocultural-appropriate materials to prevent MDR shigellosis among MSM. These data may also inform future efforts to develop messaging for prevention of sexual transmission of other enteric infections.

12.2 * Total number of participants

(You cannot enroll more than the total number of participants without an amendment.)

96

12.3 * Total number of participants per a year

48.00

12.4 * Justification for the number of participants

We will hold two phases of focus groups, one in Year 1 and one in Year 2. For Phase 1, we will conduct six focus group discussions, with 6-8 men. The health promotion materials will be tested during the Phase 2 focus groups. Groups of 6–8 men, ≥18 years old of different races (e.g. African American, Hispanic, and Caucasian) and HIV statuses will be recruited for hour-long focus group discussions.

The number of participants was selected because the number of participants recommended for standard focus groups include 8-12 individuals per session. However, given the sensitive nature of the topic, research suggests we should limit the number to less than 8 individuals. Additionally, we feel keeping the number of participants in each group small, will help improve confidentiality for participants. We believe that hosting 6 groups,in each phase of the project, resulting in approximately 96 total participants will ensure that we receive enough information, because this population is historically difficult to recruit. However, once we reach the point of information saturation, we will no longer recruit additional participants.

12.5 * What will be the age range(s) of the participants?

- ☐ 0-17
- ☑ 18-89
- ☐ 90 and above

12.6 * What is the time commitment for each participant? If you are using multiple populations, provide the time commitment required for a participant in each population. (e.g., "Participation will take 2 hours of time, one day a week, for 9 weeks for a total of 18 hours over 9 weeks.")

Each focus group session will be no longer than one hour.

12.7 * Describe where the procedures will take place and how privacy will be maintained while conducting procedures. If you are conducting multiple procedures or using multiple populations, be sure to describe where each interaction will take place. Please Note: If research is to be conducted off site and not at a public location, you MUST submit the approval letter from the site stating that the research may be conducted there.

Focus groups will be conducted in a private conference room on the Georgia State University campus.

12.8 * Federal regulations require that you include minors (e.g. participants aged 0 - 17) in your research unless you can justify their exclusion. Are you including minors? If not, check the appropriate box and provide a justification specific to this study in the text box.

- ○ No, inappropriate due to lack of safety data in studies conducted in adults
- ◉ No, inappropriate with respect to the purpose of the research
- ○ Other
- ○ Yes, minors are included

* Please provide justification for not including minors in your study if applicable.

The existing literature and documented cases suggest that the population with heightened risk for Shigella infection are young adult men who have sex with men (18-45), we are focusing this pilot study on this specific population.

12.9 * Federal regulations require that you include minorities (i.e. minority ethnic, racial, gender groups, etc.) in your research unless you can justify their exclusion. Are you including minorities? If not, describe and provide a justification specific to this study

○ No, minorities are not included
◉ Yes, minorities are included

13.0 Recruitment

13.1 * Describe in detail the recruitment plan. Who will be recruited and how (i.e. will the study use a subject pool, announcements, recruitment ads, email, etc.?) If materials such as flyers, emails, advertisements, screen shots from websites, or any other recruitment material is used, it must be uploaded with this application.

Do not use the terms 'word of mouth' or 'snowball sampling'. Instead, describe what you will be doing to let people know about the study and how you will invite them to participate.

We will recruit potential respondents by advertising the study through various community and social media outlets as well as health care and social service providers serving the LGBT community in Georgia. Passive recruitment will occur through these partners via printed materials that describe the study and direct interested participants to call the study telephone number. We will also incorporate the snowball method of recruitment, in which callers are asked to share the study's contact information with their network. All data collected as part of screening is subject to confidentiality and human subject protections (see additional information below; see also Recruitment Script).
Eligible callers who agree to participate will be offered participation in all applicable focus groups as part of the screening process. Respondents will be placed into the group corresponding to their respective racial category. Once the African American/Black and Caucasian/White categories have reached capacity, all other respondents will be assigned to the undefined group.

13.2 * Describe the inclusion and exclusion criteria.

Respondents will be screened according to the following inclusion criteria: 1)Must be 18 years of age or older, 2) Cisgender Male, 3) Gay or Bisexual Man and reports having sex with another man in the past 3 months, and 4) Be able to speak and understand English. No exclusion criteria are proposed. Screening will take place upon the potential respondents' voluntary initiation, and will occur over the telephone or in person. The screening will introduce the potential respondent to the study, inform them of their rights and our responsibilities if they chose to participate, and assess eligibility.

13.3 * Will participants be compensated or incur any costs for their participation? If so, provide details of the compensation (i.e. what the compensation is, the total amount, etc.). Compensation might include money, gifts, food, class credit, or extra credit provided for participation. Any costs to the subjects that may result from participation in the research should also be described. Detail what compensation participants will be given if they do not complete the study. If extra credit is given, describe the assignment of equal difficulty and length that will be provided for the same amount of credit if students wish to not participate in the research. If a lottery or drawing will be used, specific information must be provided to ensure it meets requirements in GSU policy and state law.

◉ Yes ○ No

For their time, participating respondents will be given $40 in a VISA gift card for participating in the focus group. All participants who are present for the focus group will be compensated for their time, upon completion of the focus group session to which they are assigned. Individuals will be compensated even if they choose to withdraw from the study before the end of the focus group period.

14.0 Benefits & Risks

14.1 * Describe the benefits, if any, to the participants and to society from the proposed research. Compensation is not a benefit of participating in research.

Please note: The benefits and risks described in the application must match the benefits and risks described in the informed consent form.

Participation in this focus group may not benefit the respondent personally. Overall, we hope to gain information about how to inform MSM about shigellosis, appropriate messages to help MSM prevent infection during sexual encounters, and understand the behaviors that may result in disease.

14.2 * Describe the risks or discomforts, if any, to the participants, whether physical, psychological, or social, and the means proposed to minimize them. If participants may become upset or require medical or psychological attention as a result of the research procedures, a means of addressing attention to these concerns should be described in this section. A participant is at risk in research if he or she may be exposed to a possibility of harm that is greater than that ordinarily encountered in daily life or during routine examinations or tests. Each investigator should make a conscientious assessment of possible harms and disclose them to the IRB.

In this study, respondents will not have any more risks than they would in a normal day of life. They may find some questions uncomfortable to answer. If so, they are free to skip any and all questions they do not wish to answer.

Additionally, there are disclosure risks associated with being in a focus group. We will keep respondent records private, to the extent allowed by law. Eric Wright, Ebony Respress Townsend, graduate research assistant, and the transcription service will have access to the information respondents provide. All parties involved in a focus group will be asked to maintain each other's confidentiality; however, confidentiality cannot be guaranteed given the other parties involved in the focus group will be present during the interview.

15.0 Participant Data

15.1 * Will information that personally links the participants to the research be collected?

(•) Yes ( ) No

If **Yes**, state what identifying information will be collected. Identifying information includes (but is not limited to) name, social security or student ID number, date of birth, contact information including email address or phone number, photographs, and audio or video recordings.

Protecting the privacy and confidentiality of participating respondents is a foremost concern. Focus group participants sign the Informed Consent Form with their legal name, at the beginning of the focus group. This is the only record of a participating respondent's identity, and this record will be secured by lock at GSU. All other study-related processes and documents ask for a nickname, of their choosing, to link their focus group responses. These privacy mechanisms are communicated to respondents at every defined point of interaction: Screening, Phase 1 and Phase 2 Focus Group. (See Appendix: Focus Group Guide – Phase 1, and Focus Group Guide – Phase 2) Respondents are encouraged not to use a unique identifier, including their given or legal name, as their nickname, just a name they feel comfortable being referred to and responding to during the focus group discussion.

15.2 * Will photographs, audio recordings, or video recordings be used?

(•) Yes ( ) No

If **Yes**, describe and provide information how any special precautions used to protect photographs, audio or video recordings.

Audio-recordings of focus groups will be secured in a locked environment, separate from Informed Consent Forms. Only the GSU PI and the GSU graduate research assistant will have access. Given the semi-public nature of a focus group (up to ten other people can be in the room) we cannot guarantee confidentiality. We ask focus group respondents to voluntarily agree to maintain one another's privacy.

15.3 * State where and how any data will be collected, stored, and transported; who will have access to the data and what will be done with it after the study is over; protections for storing or sharing hard-copy and electronic data (flash drive, cloud storage, Drop Box, etc.)
If a code sheet will be used to separate identifying information from the participant data describe the means of protecting this document.
If identifiable data are inadvertently collected, please state how it will be managed.

We will keep all records private to the extent allowed by law. Eric Wright and Ebony Townsend, graduate research assistant, and the transcription service, will have access to the information respondents provide. All parties involved in a focus group will be asked to maintain each other's confidentiality; however, confidentiality cannot be guaranteed given the other parties involved in the focus group will be present during the interview.

We will use a pseudonym (nickname) rather than the respondent's legal name during audio recording; however, the "Informed Consent" requires their signed, legal name. The information provided will be audio recorded. The audio recording files will be stored on a password and firewall protected computer, and all paperwork with identifying information will be kept in a locked box at Georgia State University. All study materials, including original audio recordings and Informed Consent forms will be maintained until successful completion of the study, at which time these materials will be destroyed.

16.0 Review Categories

16.1 Review Categories

Select Category	Description
☐ Full Board Review	More than minimal risk/does not meet other categories' requirements
☐ Exempt - Category 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.
☐ Exempt - Category 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.
☐ Exempt - Category 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.
☐ Exempt - Category 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.

☐ Exempt - Category 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.
☐ Exempt - Category 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.
☐ Expedited - Category 1	Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared /approved labeling.
☐ Expedited - Category 2	Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

	(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
☐ Expedited - Category 3	Collection of biological specimens by noninvasive means. Examples are: (a) hair and nail clipplings; (b) teeth routinely shed or extracted; (c) excreta and external secretions; (d) uncannulated saliva; (e) placenta removed after delivery; (f) amniotic fluid collected in accordance with accepted prophylactic techniques; (h) mucosal or skin cells collected by scraping, skin swab, or mouth washing; (i) sputum collected after saline mist nebulization;
☐ Expedited - Category 4	Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐ Expedited - Category 5	Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
☑ Expedited - Category 6	Collection of data from voice, video, digital, or image recordings made for research purposes.
☑ Expedited - Category 7	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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.)

17.0 Informed Consent

17.1 * Directions: Check all applicable consent procedures. These procedures must be approved by the IRB.

Name	Description
☑ Signed Consent Required	Signed consent will be sought from the subject or the subject's legally authorized representative.
☐ Waiver of Consent or Waiver/Alteration of the required elements of consent	Per 45CFR46.116 (d) an IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that: (1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration;

	(4) whenever appropriate, the subjects will be provided with additional pertinent information; and (5) the research is not FDA-regulated OR Waiver of Consent Process-Demonstration Project (1)The research is conducted by or subject to the approval of state or local government officials (2)The research or demonstration protocol is designed to study, evaluate, or otherwise examine: - Public benefit or service programs. - Procedures for obtaining benefits or services under those programs. - Possible changes in or alternatives to those programs or procedures. - Possible changes in methods or levels of payment for benefits or services under those programs. (3)The research cannot practicably be carried out without the waiver or alteration. (4)The research is not FDA-regulated
☐ Waiver of Documentation of Consent	Per 45CFR46.117(c) an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either: (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

17.2 * **If participants are unable to give consent (i.e., children or decisionally impaired adults) describe how and by whom permission or consent will be granted. For children, permission must be obtained from the child's parent or legal guardain unless a waiver of consent is approved to waive the parental permission.**

N/A

17.3 * **Provide a description of the informed consent procedures. Include who will obtain consent, where, when, and how. Include steps taken to minimize the possibility of coercion or undue influence, the language that will be used by those obtaining consent, how you will ensure the language is understood by the prospective participant or the legally authorized representative, and any information that will be communicated to the prospective participant or the legally authorized representative. Also state if there will be any waiting period between informing the prospective participant and obtaining consent.**

Participants will be asked for their informed consent during screening by either Dr. Eric Wright or Ebony Townsend. The informed consent will be read to them and they will be asked whether they consent to participating. During registration, the participants will be asked to provide informed consent again by Steve Evensen.

17.4 * **What is the estimated lowest reading level of each population?**

10th Grade reading level.

17.5 * **What is the reading level of your informed consent document? The reading level of the consent form must be at the lowest estimated reading level for the population. Keep in mind that half of all adult Americans read at or below the 8th grade reading level. To check the readability of your consent form please see Obtaining Grade Level Information.**

8th Grade reading level.

17.6 * **If your population includes participants that are non-English speaking, a translated consent form must be provided. The translation must be completed by a certified translator (provide documentation) or a translation and a back translation must be provided. A researcher cannot complete their own translation. In addition to the translated documents, the consent form must be uploaded to the application in English. The IRB may request changes to the consent; therefore, we recommend you indicate that a translated consent form will be uploaded through an amendment after the study is approved.**

N/A

18.0 COI

18.1 * **Does the PI, Co-Investigators, or other research staff including their spouse and dependents have a significant financial conflict of interest defined as:**

- An equity interest that, when aggregated for the Investigator or research staff and their spouse or dependents meets all of the following tests: Exceed $5,000 in value as determined through reference to public prices or other reasonable measures of fair market value, represents more than a 5% ownership interest in any single entity, and value is affected by the outcome of the research; or

- Salary, royalties or other payments that, when aggregated for the Investigator or research staff and their spouse and dependents over the next 12 months, are expected to exceed $5,000 and value is affected by the outcome of the research.

○ Yes ◉ No

18.2 * **Does the PI, Co-Investigators, or other research staff including their spouse and dependents have:**
- A board or executive relationship related to the research regardless of compensation.
- Proprietary interest related to the research including by not limited to a patent, trademark, copyright, or licensing agreement.

○ Yes ◉ No

19.0 Endorsement

19.1 * **Please affirm the following endorsement statements:**

- **I will not begin this research study before receiving a formal letter of IRB approval;**
- **I will document informed consent according to my approved procedure;**
- **I will report to the IRB in a timely manner any unanticipated events to participants;**
- **I will renew my IRB application before expiration or submit a study closure form;**
- **I will gain IRB approval before altering the research study and/or consent forms;**
- **I will notify the IRB if there are any changes in my contact information.**

◉ I agree

Georgia State University - Department of Sociology
Informed Consent

Title: Sexual Health Study for Gay and Bisexual Men

Principal Investigator: Eric R. Wright, Ph.D.

I. Purpose:

We are asking you to join a focus group. We are trying to understand the sexual health needs of men who have sex with men (MSM), including gay and bisexual men. We want to develop messages to inform MSM about shigella and how to protect themselves from the infection. We would like you to join because you are an adult man who has sex with men. The target number of overall participants for this focus group is approximately 50. The focus group will take about one hour of your time.

II. Procedures:

If you join, you will be asked about your life. We will ask about your background, your knowledge of, and preferences for sexual health prevention messages. We would like your approval to audio record the interview. Audio recording will let the interviewer focus on what you (all) have to say instead of taking notes. The recording will be transcribed by a data service. The only other people who will have access to the recordings are Dr. Eric Wright and Ebony Respress. The interview will be conducted in a comfortable and safe space. The focus group is planned for one hour. If for any reason you wish to stop your participation in the focus group, you are free to do so at any time. You will still receive a gift card.

III. Risks:

In this study, you will not have any more risks than you would in a normal day of life. You may find some questions uncomfortable to answer. If so, you are free to skip any questions you do not wish to answer.

There may be disclosure risks related to being in a focus group. Everyone involved in the focus group is asked to maintain each other's privacy. But, confidentiality cannot be guaranteed because other people, in the focus group, will be present.

We will use a "nickname" rather than your name during the session. Everyone is asked to only use "nicknames" when speaking to other people. Everyone is also asked not to discuss anyone (names, health information, etc.) who is not in the focus group. Participants are encouraged to speak about their own experiences or only to speak in general terms about others' experiences.

IV. Benefits:

You may not benefit personally. We hope to gain information to help MSM prevent infections during sex. We also want to understand the behaviors that may result in disease.

V. Compensation:

You will receive a $40 gift card for participating in this focus group. You will receive the gift card at the end of the interview.

VI. Voluntary Participation and Withdrawal:

Participation in the focus group is voluntary. You do not have to be in this study. If you decide to be in the study and change your mind, you have the right to drop out at any time. You may skip questions or stop the interview at any time. Whatever you decide, you will not lose any benefits to which you are otherwise entitled.

VII. Confidentiality:

We will keep your records private to the extent allowed by law. Eric Wright and Ebony Respress will have access to the information you provide. Everyone involved in the focus group will be asked to maintain each other's privacy. But, confidentiality cannot be guaranteed given other people will be in the focus group.

This Informed Consent requires your signed, legal name. But, we will use a "nickname" instead of your name during audio recording. The information you provide will be audio recorded. The audio files will be stored on a password and firewall, protected computer. All paperwork with your information will be kept in a locked box, at Georgia State University. We will keep all study materials, including original audio recordings and Informed Consent forms, until the study is complete. After the study is completed, all materials will be destroyed. Your name and other facts that might point to you will not appear when we present this study or publish results. You will not be identified personally, but by your nickname.

Information may also be shared with those who make sure the study is done correctly (GSU Institutional Review Board, the Office for Human Research Protection [OHRP]).

VIII. Contact Persons:

Contact Eric Wright at 404-413-6527 if you have questions, concerns, or complaints about this study. You can also call if you think you have been harmed by the study. Call Susan Vogtner at Georgia State University Office of Research Integrity at 404-413-3513 or svogtner@gsu.edu if you want to talk to someone who is not part of the study team. You can talk about questions, concerns, offer input, obtain information, or suggestions about the study. You can also call Susan Vogtner if you have questions or concerns about your rights in this study.

IX. Copy of Consent Form to Subject:

We will give you a copy of this consent form to keep for your records.

If you are willing to volunteer for this research and to be audio recorded, please sign your name below.

_____	_____
Participant	Date
_____	_____
Student Principal Investigator	Date

INSTITUTIONAL REVIEW BOARD

Mail: P.O. Box 3999
Atlanta, Georgia 30302-3999
Phone: 404/413-3500
Fax: 404/413-3504

In Person: Dahlberg Hall
30 Courtland St, Suite 217

November 06, 2017

Principal Investigator: Eric R. Wright, PhD

Key Personnel: Evener, Steve; Horwitz, Samantha N; Jacobson, Kathleen M; Martin, Caitlin; Reitzes, Donald; Taylor-Diggs, Kamil D; Townsend, Ebony S; Wesley, Jonathan; Wright, Eric R., PhD

Study Department: Georgia State University, Sociology

Study Title: Sexual Health Study for Gay and Bisexual Men

Funding Agency: Centers for Disease Control and Prevention/ Georgia State University, Georgia State University (Internal Funding)

Review Type: Expedited Amendment

IRB Number: H17541

Reference Number: 347064

Approval Date: 08/24/2017

Expiration Date: 08/23/2018

Amendment Effective Date: 11/06/2017

The Georgia State University Institutional Review Board reviewed and **approved** the amendment to your above referenced Study.
This amendment is approved for the following modifications:

- The study would like to submit a personnel amendment to include the following GSU students: Kathleen Jacobson (kjacobson3@student.gsu.edu), Caitlin Martin (cmartin88@student.gsu.edu), Jonathan Wesley (jwesley4@student.gsu.edu), Samantha Horowitz (shorwitz2@student.gsu.edu), and Kamil Taylor-Diggs (ktaylordiggs1@student.gsu.edu). These students will serve as research assistants for the study.

The amendment does not alter the approval period which is listed above and the study must be renewed at least 30 days before the expiration date if research is to continue beyond that time frame. Any unanticipated/adverse events or problems resulting from this investigation must be reported immediately to the University Institutional Review Board.

For more information visit our website at www.gsu.edu/irb.

Sincerely,

Tracy Cermak, IRB Member

Federal Wide Assurance Number: 00000129

INSTITUTIONAL REVIEW BOARD

Mail: P.O. Box 3999
Atlanta, Georgia 30302-3999
In Person: 58 Edgewood
3rd Floor
Phone: 404/413-3500
Fax: 404/413-3504

August 24, 2017

Principal Investigator: Eric R. Wright, PhD

Key Personnel: Evener, Steve; Reitzes, Donald; Townsend, Ebony S; Wright, Eric R., PhD

Study Department: Georgia State University, Sociology

Study Title: Sexual Health Study for Gay and Bisexual Men

Funding Agency: Centers for Disease Control and Prevention/ Georgia State University, Georgia State University (Internal Funding)

Review Type: Expedited, 6,7

IRB Number: H17541

Reference Number: 344125

Approval Date:
08/24/2017
Expiration Date:
08/23/2018

The Georgia State University Institutional Review Board (IRB) reviewed and approved the above referenced study in accordance with 45 CFR 46.111. The IRB has reviewed and approved the study and any informed consent forms, recruitment materials, and other research materials that are marked as approved in the application. The approval period is listed above. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the Institution.

Federal regulations require researchers to follow specific procedures in a timely manner. For the protection of all concerned, the IRB calls your attention to the following obligations that you have as Principal Investigator of this study.

1. For any changes to the study (except to protect the safety of participants), an Amendment Application must be submitted to the IRB. The Amendment Application must be reviewed and approved before any changes can take place

2. Any unanticipated/adverse events or problems occurring as a result of participation in this study must be reported immediately to the IRB using the Unanticipated/Adverse Event Form.

3. Principal investigators are responsible for ensuring that informed consent is properly documented in accordance with 45 CFR 46.116.

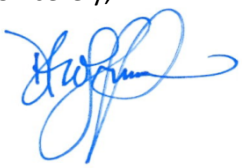
    - The Informed Consent Form (ICF) used must be the one reviewed and approved by the IRB with the approval dates stamped on each page.

4. For any research that is conducted beyond the approval period, a Renewal Application must be submitted at least 30 days prior to the expiration date. The Renewal Application must be approved by the IRB before the expiration date else automatic termination of this study will occur. If the study expires, all research activities associated with the study must cease and a new application must be approved before any work can continue.

5. When the study is completed, a Study Closure Report must be submitted to the IRB.

All of the above referenced forms are available online at http://protocol.gsu.edu. Please do not hesitate to contact the Office of Research Integrity (404-413-3500) if you have any questions or concerns.

Sincerely,



David Alan Washburn, IRB Member