



OFFICE OF RESEARCH INTEGRITY

Institutional Review Board (IRB)

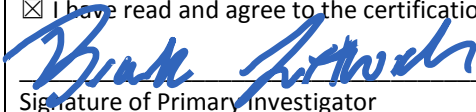
Application for Research Approval – Expedited/Full Board

For Office Use Only: Protocol ID _____

Please submit this protocol to IRB@georgiasouthern.edu in a single email; scanned signatures and official Adobe electronic signatures are accepted. Applications may also be submitted via mail to the Georgia Southern University Office of Research Integrity, PO Box 8005.

Principal Investigator	
PI's Name: Brandon Leftwich	Phone: 423-400-3863
Email: bl03096@georgiasouthern.edu <small>(Note: Georgia Southern email addresses will be used for all correspondence.)</small>	Department: Jiann-Ping Hsu College of Public Health
Primary Campus: <input type="checkbox"/> Armstrong Campus <input checked="" type="checkbox"/> Statesboro Campus <input type="checkbox"/> Hinesville Campus	
<input type="checkbox"/> Faculty <input checked="" type="checkbox"/> Doctoral <input type="checkbox"/> Specialist <input type="checkbox"/> Masters <input type="checkbox"/> Undergraduate <input type="checkbox"/> Other: _____	
Georgia Southern Co-Investigator(s)	
Co-I's Name(s): Dr. Adhikari <small>(By each name indicate: F(Faculty), D(Doctoral), S(Specialist), M(Masters), U(Undergraduate), O(Other))</small>	Email: aadhikari@georgiasouthern.edu <small>(Note: Georgia Southern email addresses will be used for all correspondence.)</small>
Personnel and/or Institutions Outside of Georgia Southern University involved in this research:	
_____	<input type="checkbox"/> Training Attached <input type="checkbox"/> IRB Approval Attached <input type="checkbox"/> intent to rely on GSU
_____	<input type="checkbox"/> Training Attached <input type="checkbox"/> IRB Approval Attached <input type="checkbox"/> intent to rely on GSU

Project Information	
Title: ASSESSING RISK FACTORS AND RISK MANAGEMENT PROCEDURES FOR POTENTIAL MICROBIAL CONTAMINATION OF GEORGIA HOTEL WATER DISTRIBUTION SYSTEMS	
Number of Subjects (Maximum) 200	
Funding Source: <input type="checkbox"/> Federal <input type="checkbox"/> State <input type="checkbox"/> Private <input type="checkbox"/> Internal GSU <input checked="" type="checkbox"/> Self-funded/non-funded	
Funding Agency/Department: _____ Grant Number: _____	
Compliance Information	
Do you or any investigator on this project have a financial interest in the subjects, study outcome, or project sponsor? (A disclosed conflict of interest will not preclude approval. An undisclosed conflict of interest will result in disciplinary action.) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Certifications	
I certify that the statements made in this request are accurate and complete, and if I receive IRB approval for this project, I agree to inform the IRB in writing of any emergent problems or proposed procedural changes. I agree not to proceed with the project until the problems have been resolved or the IRB has reviewed and approved the changes. It is the explicit responsibility of the researchers and supervising faculty/staff to ensure the well-being of human participants. At the conclusion of the project I will submit a termination report. I will comply with annual project update requests to maintain approval.	
<input checked="" type="checkbox"/> I have read and agree to the certifications of investigator responsibilities located on the last page of this form.	
	12/4/18
Signature of Primary Investigator	Date
_____	_____
Signature of Co-Investigator(s)	Date
By signing this cover page I acknowledge that I have reviewed and approved this protocol for scientific merit, rational and significance. I further acknowledge that I approve the ethical basis for the study. I have read and agree to the certifications of investigator responsibilities located on the last page of this form.	
If <u>faculty</u> project, enter department chair's name; if <u>student</u> project, enter research advisor's name: _____	
_____	_____
Signature of Department Chair or Research Advisor	Date

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Compliance Information	
Please indicate which of the following will be used in your research: (applications may be submitted simultaneously)	
<input checked="" type="checkbox"/> Human Subjects <input type="checkbox"/> Care and Use of Vertebrate Animals (Submit IACUC Application) <input type="checkbox"/> Biohazards (Submit IBC Application)	
Please indicate if the following are included in the study (Check all that apply):	
<input type="checkbox"/> Survey delivered by email to .georgiasouthern.edu addresses <input type="checkbox"/> Deception <input type="checkbox"/> Prisoners <input type="checkbox"/> Children <input type="checkbox"/> Individuals with impaired decision making capacity, or economically or educationally disadvantaged persons	<input type="checkbox"/> Video or Audio Tapes <input type="checkbox"/> Human Subjects Incentives <input type="checkbox"/> Medical Procedures, including exercise, administering drugs/dietary supplements, and other procedures, or ingestion of any substance

Instructions: Please respond to the following as clearly as possible. The application should include a step by step plan of how you will obtain your subjects, conduct the research, and analyze the data. Make sure the application clearly explains aspects of the methodology that provide protections for your human subjects. Your application should be written to be read and understood by a general audience who does not have prior knowledge of your research and by committee members who may not be expert in your specific field of research. Your reviewers will only have the information you provide in your application. Explain any technical terms, jargon or acronyms.

Personnel
<i>Please list any individuals who will be conducting research on this study. Also, please detail the experience, level of involvement in the process, and the access to information that each may have.</i>
<p>I, Brandon Leftwich, will be conducting research on this study. I am a third year Doctorate of Public Health Student, with an interest in Environmental Health. I will be the person who interacts with the subjects by handing them the survey and answering any questions they might have about the research. I will preserve the survey responses of study participants and maintain confidentiality. Dr. Adhikari (Assistant Professor in the College of Public Health), will be the overseer over this research because he is my Dissertation chair. He will assure that systems are in place to guarantee institutional compliance with US laws including human research, data, and facilities. Dr. Yin and Dr. Opoku are part of the College of Public Health faculty as well. They also reside on my dissertation committee, so they will also have access to the results and assist in the data analysis.</p>

Purpose
<i>Briefly describe in one or two sentences the purpose of your research.</i>
<p>The purpose of this study is to identify potential barriers on the adaption of water safety plans in hotels and assessing risk factors for potential microbial contamination in GA water distribution systems. This will be assessed through the integration of the Health Belief Model.</p>
<i>What questions are you trying to answer in this experiment? Please include your hypothesis in this section. The jurisdiction of the IRB requires that we ensure the appropriateness of research. It is unethical to put participants at risk without the possibility of sound scientific result. For this reason, you should be very clear about how participants and others will benefit from knowledge gained in this project.</i>
<ol style="list-style-type: none"> 1) Is it necessary for hotels to have a water safety plan to prevent risk of microbial contamination in hotel water systems? 2) Are hotel managers knowledgeable of the risk factors that are associated with waterborne illnesses in the premise plumbing? 3) What are the perceived barriers that are preventing managers from having a water management plan? 4) Are hotel managers aware of the ASHRAE Standard 188 or the CDC Water Management Plan Toolkit?
<i>Provide a brief description of how this study fits into the current literature. Have the research procedures been used before? How were similar risks controlled for and documented in the literature? Have your instruments been validated with this audience? Include citations in the description. Do not include dissertation or thesis chapters.</i>
<p>The purpose of this study is to assess the risk management procedures for potential microbial contamination of Georgia hotel water distribution systems and to assess risk factors associated with waterborne illnesses.</p>

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The aims of this study are to develop resourceful guidelines to provide hotel facilities to help reduce the risk of a waterborne illness outbreak, increase awareness for the need of water safety plans for tourist accommodation hotels, and to increase knowledge of risk factors associated with hotel waterborne disease outbreaks. Currently, the State of Georgia Department of Public Health does not have any mandatory guidelines on what procedures to take during an event where hotel facilities water system may be comprised. There is little to no literature on water safety plans in buildings water supply systems particularly for hotels. This project is intended to identify the gap between lack of knowledge of water safety plans and the increased need for water safety plans for hotel facilities to ensure a safe environment for the public. By completing this study, the findings will be used to explain what barriers hotel owners and or management are facing that are preventing them from developing a water safety plan. In return these findings can be used for potential policy change within the plumbing code and for the tourist accommodations rules and regulations in the state of Georgia. If these barriers are identified and addressed, the potential for hotels to have a smooth transition for adopting a water safety plan will be favorable.

Outcome

Please state what results you expect to achieve? Who will benefit from this study? How will the participants benefit (if at all). Remember that the participants do not necessarily have to benefit directly. The results of your study may have broadly stated outcomes for a large number of people or society in general.

I expect to gain better knowledge on what barriers are preventing hotel facilities from implementing water safety plans. I also expect for this study to encourage further research on risk factors that are associated with microbial contamination for water systems in hotel facilities. All parties are expected to benefit from this study. Having a better understanding of the increased risk of waterborne illnesses may help industry and public health to combat the chances of an outbreak.

Describe Your Subjects

Maximum number of participants

200

Briefly describe the study population.

The study population are employees currently employed at different hotel facilities in Fulton County. The job titles of these people include: owner, maintenance engineer, and the lead hotel manager.

Applicable inclusion or exclusion requirements (ages, gender requirements, allergies, etc.)

Only people who work directly in the hotel facility that are involved in implementing water safety plans are eligible (Owner, maintenance engineer, lead house keeper, etc.)

How long will each subject be involved in the project? (Number of occasions and duration)

There will only be one visit where the subject will complete the survey that should take approximately 15-20 minutes

Recruitment

Describe how subjects will be recruited. (Attach a copy of recruitment emails, flyers, social media posts, etc.)

Subjects will be recruited through random selection. I plan to visit random hotels to speak with the owner. I will explain the purpose of the study. If owner agrees to have his facility participate in the study, I will collect their email address to communicate on setting a time to conduct the survey.

Incentives

Are you compensating your subjects with money, course credit, extra credit, or other incentives?

Yes No

If yes, indicate how much, how they will be distributed, and describe how you will compensate subjects who withdraw from the project before it ends.

Research Procedures and Timeline

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Outline step-by-step what will happen to participants in this study (including what kind of experimental manipulations you will use, what kinds of questions or recording of behavior you will use, the location of these interactions). Focus on the interactions you will have with the human subjects. Specify tasks given as attachments to this document.

Procedure at the Hotel Facilities:

- 1) I will give a brief introduction of myself then explain the purpose for the research and give an opportunity for any questions before the survey is administered.
- 2) The participants will complete the survey in a room designated by the manager of the hotel facility.
- 3) I will hand out the informed consent acknowledgment with the survey. I will advise everyone to read each question carefully and answer each question honestly. I will reiterate that the survey participation is completely voluntary and I also will reiterate that the surveys are completely confidential (See attached "Informed Consent" and "Survey instrument")
- 4) Surveys can be completed via handout or on computer via survey money. After completion of paper handouts, the forms will be placed in a drop box for submittal.
- 5) Once surveys are completed a thank you email will be sent to email provided.

Describe how legally effective informed consent will be obtained. Attach a copy of the consent form(s). If minors are to be used describe procedures used to gain consent of their parent (s), guardian (s), or legal representative (s), and gain assent of the minor.

A cover letter/informed consent form will accompany the questionnaire to clarify to the respondents the purpose of the research and to develop an understanding that they are giving their consent to be involved in this research and that their participation is completely anonymous. See attached "Informed Consent form".

Describe all study measures and whether they are validated. Attach copies of questionnaires, surveys, and/or interview questions used, labeled accordingly.

The survey will be sectioned into 2 parts. The 1st section will consist of general questions about hotel knowledge and practices. The 2nd section will consist of questions about water safety plans. These questions will be formulated using the Health Belief Model. See Attached "Survey Instrument"

Describe how you will protect the privacy of study participants.

The type of survey used will be an anonymous, self-administered questionnaire. The respondents will be instructed to not put their name on the survey. The only information that would be needed besides the survey is the facilities address city and state. This will be needed to help prevent back tracking and duplication of facilities surveyed. Participant's response will not be shown in correlation with the company.

Data Analysis

Briefly describe how you will analyze and report the collected data.

Statistical analysis of the categorical data and numeric variables will be analyzed through the use of the **Chi-Square Test and the Mann-Whitney U test or Pearson Correlation or Spearman Correlation**. The statistical significance will be shown as $P < 0.05$. This research will also use Cronbach's alpha statistical analysis to determine internal consistency and reliability. Frequency distributions of the responses on each construct will also be produced

What will you do with the results of your study (e.g. contributing to generalizable knowledge, publishing sharing at a conference, etc.)?

The results will be presented as part of my dissertation thesis. The results will contribute to generalizable knowledge, but I have hopes of getting published into the Journal of Safety Health and Environmental Engineers or any other journals involving environmental and occupational health and safety.

Include an explanation of how will the data be maintained after the study is complete. Specify where and how it will be stored (room number, password protected file, etc.)

All data will be collected specifically for research purposes and identifiable by study ID number only. All study data will be stored and analyzed on a desktop PC or network server with built-in security. All paper files will be stored in locked cabinets in close proximity to the faculty. All information from this study will be kept completely confidential. Only the subject ID numbers will be entered into the database. Databases will be maintained in a password protected secure system. All hard copy files will be kept in locked filing cabinets.

Student researchers must specify which faculty or staff member will be responsible for records after you have left the university.

Dr. Adhikari, who is my committee chair and a faculty member of the Jiann-Ping Hsu College of Public Health will be responsible for the records after I graduate from the university.

Anticipated destruction date or method used to render it anonymous for future use.

- Destroyed 3 Years after conclusion of research (minimum required for all PIs)
- Other timeframe: _____
- Method used to render it anonymous for future use: _____

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Special Conditions

Risk
Even minor discomfort in answering questions on a survey may pose some risk to subjects. Carefully consider how the subjects will react and address ANY potential risks.
<i>Is there greater than minimal risk from physical, mental, or social discomfort?</i> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<i>If yes, describe the risks and the steps taken to minimize them. Justify the risk undertaken by outlining any benefits that might result from the study, both on a participant and societal level</i>
<i>If no, Do not simply state that no risk exists. If risk is no greater than risk associated with daily life experiences, state risk in these terms.</i>
There is no significant potential risks for the participants of this survey questionnaire. This survey is to gather general knowledge on water safety programs for hotel facilities.
Will you be carrying out procedures or asking questions that might disturb your subjects emotionally or produce stress or anxiety? If yes, describe your plans for providing appropriate resources for subjects.
No

Research Involving Minors
<i>Will minors be involved in your research?</i> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<i>If yes, describe how the details of your study will be communicated to parents/guardians. Please provide both <u>parental consent</u> letters and <u>child assent</u> letters (or processes for children too young to read).</i>
<i>Will the research take part in a school (elementary, middle, or high school)?</i> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<i>If yes, describe how permission will be obtained from school officials/teachers, and indicate whether the study will be a part of the normal curriculum/school process.</i>
<input type="checkbox"/> Part of the normal curriculum/school process <input type="checkbox"/> Not part of the normal curriculum/school process

Deception
<i>Will you use deception in your research?</i> <input checked="" type="checkbox"/> No Deception <input type="checkbox"/> Passive Deception <input type="checkbox"/> Active Deception
<i>If yes, describe the deception and how the subject will be debriefed. Include a copy of any debriefing materials. Make sure the debriefing process is listed in your timeline in the Procedures section.</i>
<i>Address the rationale for using deception.</i>
Be sure to review the deception disclaimer language required in the informed consent. Note: All research in which active deception will be used is required to be reviewed by the full Institutional Review Board. Passive deception may receive expedited review.

Medical Procedures
Does your research procedures involve any of the following procedures: <input type="checkbox"/> Low expenditures of physical effort unlikely to lead to physical injury <input type="checkbox"/> High expenditures of physical effort that could lead to physical injury <input type="checkbox"/> Ingesting, injecting, or absorbing any substances into the body or through the skin <input type="checkbox"/> Inserting any objects into bodies through orifices or otherwise <input type="checkbox"/> Handling of blood or other bodily fluids

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- Other Medical Procedures
 No Medical Procedures Involved

Describe your procedures, including safeguards. If appropriate, briefly describe the necessity for employing a medical procedure in this study. Be sure to review the medical disclaimer language required in the informed consent.

Describe a medical emergency plan if the research involves any physical risk beyond the most minimal kind. The medical research plan should include, but not necessarily be limited to: emergency equipment appropriate for the risks involved, first rescuer actions to address the most likely physical risk of the protocol, further actions necessary for the likely risks.

Reminder: No research can be undertaken until your proposal has been approved by the IRB.

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CERTIFICATION OF INVESTIGATOR RESPONSIBILITIES

By signing the cover page, I agree/certify that:

1. I have reviewed this protocol submission in its entirety and I state that I am fully cognizant of, and in agreement with, all submitted statements and that all statements are truthful.
2. This application, if funded by an extramural source, accurately reflects all procedures involving human participants described in the proposal to the funding agency previously noted.
3. I will conduct this research study in strict accordance with all submitted statements except where a change may be necessary to eliminate an apparent immediate hazard to a given research subject.
 - a. I will notify the IRB promptly of any change in the research procedures necessitated in the interest of the safety of a given research subject.
 - b. I will request and obtain IRB approval of any proposed modification to the research protocol or informed consent document(s) prior to implementing such modifications.
4. I will ensure that all co-investigators, and other personnel assisting in the conduct of this research study have been provided a copy of the entire current version of the research protocol and are fully informed of the current (a) study procedures (including procedure modifications); (b) informed consent requirements and process; (c) anonymity and/or confidentiality assurances promised when securing informed consent (d) potential risks associated with the study participation and the steps to be taken to prevent or minimize these potential risks; (e) adverse event reporting requirements; (f) data and record-keeping requirements; and (g) the current IRB approval status of the research study.
5. I will not enroll any individual into this research study: (a) until such time that the conduct of the study has been approved in writing by the IRB; (b) during any period wherein IRB renewal approval of this research study has lapsed; (c) during any period wherein IRB approval of the research study or research study enrollment has been suspended, or wherein the sponsor has suspended research study enrollment; or (d) following termination of IRB approval of the research study or following sponsor/principal investigator termination of research study enrollment.
6. I will respond promptly to all requests for information or materials solicited by the IRB or IRB Office.
7. I will submit the research study in a timely manner for IRB renewal approval.
8. I will not enroll any individual into this research study until such time that I obtain his/her written informed consent, or, if applicable, the written informed consent of his/her authorized representative (i.e., unless the IRB has granted a waiver of the requirement to obtain written informed consent).
9. I will employ and oversee an informed consent process that ensures that potential research subjects understand fully the purpose of the research study, the nature of the research procedures they are being asked to undergo, the potential risks of these research procedures, and their rights as a research study volunteer.
10. I will ensure that research subjects are kept fully informed of any new information that may affect their willingness to continue to participate in the research study.
11. I will maintain adequate, current, and accurate records of research data, outcomes, and adverse events to permit an ongoing assessment of the risks/benefit ratio of research study participation.
12. I am cognizant of, and will comply with, current federal regulations and IRB requirements governing human subject research including adverse event reporting requirements.
13. I will notify the IRB within 24 hours regarding any unexpected study results or adverse events that injure or cause harm to human participants.
14. I will make a reasonable effort to ensure that subjects who have suffered an adverse event associated with research participation receive adequate care to correct or alleviate the consequences of the adverse event to the extent possible.
15. I will notify the IRB prior to any change made to this protocol or consent form (if applicable).
16. I will notify the IRB office within 30 days of a change in the PI or the closure of the study.

***Faculty signature indicates that he/she has reviewed the application and attests to its completeness and accuracy**

The Informed Consent Form must be on GSU letterhead or maintain the letterhead elements and include the required elements on the following checklist: (Note: The informed consent sample is on GSU letterhead in Word format. You are not required to use the same format as the sample.)

- Title of the study, exactly as it appears on the IRB application
- Affiliation with Georgia Southern University (clearly identify who you are and your role in project)
- Must begin with** a concise and focused presentation of the key information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research presented in a manner to facilitate comprehension. (.116(a)(5)(i))
- Consent document must be organized and presented in sufficient detail and in a fashion to facilitate comprehension. May not be a list of facts. (.116(a)(5)(ii))
- May not include any exculpatory language through which the subject waives or appears to waive legal rights or releases the investigator, institution, sponsor or agents from liability for negligence. (.116(a)(6))
- Basic Elements:
 - Statement that the study involves research. (.116 (b)(1))
 - Explanation of the purpose of the research (.116 (b)(1))
 - Expected duration of the subjects participation (.116 (b)(1))
 - Description of the procedures to be followed including identification of procedures that are experimental (.116 (b)(1))
 - Description of any reasonably foreseeable risks or discomforts to the subject (.116 (b)(2))
 - Description of any benefits to the subject or others that may reasonably be expected to result from the research. (.116 (b)(3))
 - Disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the subject. (.116 (b)(4))
 - N/A (applies where standard of care or standard curricula are available)
 - Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. Please remember that Georgia is an "Open Records" state and you cannot guarantee confidentiality. (.116 (b)(5))
 - (Greater than minimal risk only) Statement will compensation or incentive be provided – if so, describe. (.116 (b)(6))
 - (Greater than minimal risk only) Explanation as to whether medical treatments are available if injury occurs – if so, describe what they consist of and where to obtain further information. (.116 (b)(6))
 - Contact for answers to questions about the research (.116 (b)(7))
 - Investigator contact information (and advisor contact information, if investigator is a student) May be the same as researcher if appropriate. (GSU policy)
 - Contact for answers to questions about subjects rights (GSU IRB– irb@georgiasouthern.edu. Phone 912-478-5465.) (.116 (b)(7))
 - This project has been reviewed and approved by the GSU IRB under tracking number H___. (GSU policy)
 - Statement that participants must be 18 years of age or older to participate or If subjects are/may be minors, parental consent and minor's assent documents are required.
 - (Greater than minimal risk only) Contact in the event of research-related injury to the subject. (.116 (b)(7))
 - Statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled(.116 (b)(8))
 - Statement that the subject may discontinue participation at any time with no penalty or loss of benefits to which the subject is otherwise entitled(.116 (b)(8))
 - Statement telling the subject if data already provided can be removed from the research data set upon withdraw or if data already provided will be retained. (e.g., anonymous data sets) (.116 (b)(8) added)
 - (Identifiable data or biospecimens) Include one of the following 2 statements as applicable (.116 (b)(9))
 - (1) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
 - (2) a statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies. (Justification required in narrative and statement of compliance upon study close) *(If this option is selected – the researcher must pledge to destroy the data at the end of the 3 year retention period and notify the IRB when destruction is complete.)*
 - Signature and date lines (for participants and investigators), unless requesting a waiver of documentation of consent
 - Connecting page numbers if more than one page (e.g. Page 1 of 2, Page 2 of2)

Additional Elements of Consent: (These elements may or may not be applicable to the study)

<input checked="" type="checkbox"/> N/A	<input type="checkbox"/> If student educational data is used – a statement that specifically identifies which course or educational data will be collected, how it will be collected and how it will be used/reported. (FERPA permission to use educational data for research purposes.) (34 CFR Part 99)
<input checked="" type="checkbox"/> N/A	<input type="checkbox"/> If participants are students where the survey is administered in a group or class setting, a statement allowing students to place a blank survey in the collection envelope with the other surveys if they choose not to participate and do not want to self-identify. (.116 (b)(5))
<input checked="" type="checkbox"/> N/A	<input type="checkbox"/> Statement that the particular treatment or procedure may involve risks to the subject (or embryo or fetus if the subject becomes pregnant) that are currently unforeseeable. (.116 (c)(1))
<input checked="" type="checkbox"/> N/A	<input type="checkbox"/> Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s or the legally authorized representative’s consent; (.116 (c)(2))
<input checked="" type="checkbox"/> N/A	<input type="checkbox"/> Any additional costs to the subject that may result from participation in the research; (.116 (c)(3))
<input type="checkbox"/> N/A	<input checked="" type="checkbox"/> The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject; (.116 (c)(4))
<input type="checkbox"/> N/A	<input checked="" type="checkbox"/> A statement that significant new findings developed during the course of the research that may relate to the subject’s willingness to continue participation will be provided to the subject; (.116 (c)(5))
<input type="checkbox"/> N/A	<input type="checkbox"/> The approximate number of subjects involved in the study; (.116 (c)(6))
<input checked="" type="checkbox"/> N/A	<input type="checkbox"/> A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit; (.116 (c)(7))
<input checked="" type="checkbox"/> N/A	<input type="checkbox"/> A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; (.116 (c)(8))
<input checked="" type="checkbox"/> N/A	<input type="checkbox"/> For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). (.116 (c)(9))
<input type="checkbox"/> N/A	<input type="checkbox"/> For surveys that are anonymous where the only documented connection between the subject and the data is the consent document, a waiver of documentation of consent may be requested. The waiver means that the Informed Consent Form does not need to be signed, but the following statement must be included. <i>“Completion and return of the survey, questionnaire, etc. implies that you agree to participate and your data may be used in this research.”</i> (If there is any other means of identifying a participant in the study, a signed consent form is required.)
<input type="checkbox"/> N/A	<input checked="" type="checkbox"/> If surveys are to be administered electronically, but not anonymously, <input type="checkbox"/> State that there is only limited assurance of confidentiality due to the technology of the Internet; <input type="checkbox"/> Alternate means of electronic signature may be used
<input checked="" type="checkbox"/> N/A	<input type="checkbox"/> If audio- or videotaping will be used, state: <input type="checkbox"/> where tapes will be stored; <input type="checkbox"/> when tapes will be destroyed (within a definitive time frame such as “by the year 2020” or tapes will be destroyed immediately following transcription or tapes will be maintained indefinitely with understanding that the identifiable data may be reused in future research.); <input type="checkbox"/> who will have access to the tapes now and in future.
<input checked="" type="checkbox"/> N/A	<input type="checkbox"/> If deception is involved and the full purpose of the study will not be disclosed to participants until their participation has ended, a statement such as the following needs to be included: <i>Because the validity of the results of the study could be affected if the purpose of the study is fully divulged to me prior to my participation, I understand that the purpose of the study cannot be explained to me at this time. I understand that I will have an opportunity to receive a complete explanation of the study’s purpose following the completion of the study.</i> If the consent statement will affect the outcome of the research, a through description of the debriefing as well as justification statement should be inserted in the methodology section of the proposal.
<input type="checkbox"/> N/A	<input checked="" type="checkbox"/> Participants must receive a copy of the consent document for their records. Therefore, it cannot be attached to or be part of the instrument unless provisions are made for supply of a copy.
<input checked="" type="checkbox"/> N/A	<input type="checkbox"/> If extra credit or course credit is offered as compensation for participation, the consent form must state what the alternatives to participating are to earn equivalent extra credit or course credit.
<input checked="" type="checkbox"/> N/A	<input type="checkbox"/> If compensation or incentive is offered, the following statement may need to be included in the consent form, <i>“If you are an employee of Georgia Southern University, the compensation you receive for participation will be treated as taxable income and therefore taxes will be taken from the total amount. If you are not employed by Georgia Southern University, total payments within one calendar year that exceed \$600 will require the University to annually report these payments to the IRS. This may require you to claim the compensation that you receive for participation in this study as taxable income.”</i>
<input type="checkbox"/> N/A	<input checked="" type="checkbox"/> All wording must be at a 6th grade reading level or below. A layperson or someone unfamiliar with your research should easily understand it. Avoid highly technical terms, jargon, etc.

Turn in a copy of the checklist with each IRB application. This checklist is a tool for helping you create your informed consent and not a consent document. Create your consent in the format that best conveys your study to your potential participants



Dear Survey Participant,

You are invited to participate in a research study titled: Assessing risk factors and risk management procedures for potential microbial contamination of Georgia hotel water distribution systems. This study will assess the risk factors for waterborne illnesses in hotels and also assess the knowledge and barriers for the implementation of Water Management Plans (WMP). Conducting this research is required in partial fulfillment of the requirements for the degree of Doctorate of Public Health at Georgia Southern University. Your participation in this research is entirely voluntary and you may choose, without negative consequences, not to participate. Your responses to this survey will be kept strictly confidential. This study has been reviewed and approved by Georgia Southern University Review Board under tracking number H19202.

We would appreciate your completion of the attached survey. Do not put your name on the questionnaire. We realize that your time is valuable. However, we hope that the 15-20 minutes that it takes to complete this survey will help lead to new innovations to develop ways to better protect employees and visiting guest by implementing WMP and reduce risks of a waterborne disease outbreak. By returning this completed survey, you are giving your consent to participate.

If you have any questions or concerns about the study, please feel free to contact Brandon Leftwich, at 423-400-3863. You may also contact Georgia Southern University Institutional Review Board for answers to questions about subject's rights at 912-478-5465 or via email at irb@georgiasouthern.edu. Thank you for your participation. Your willingness to assist with this project is truly appreciated.

Sincerely,

Brandon Leftwich,



Invitation to Participate in Research

Dear Manager/Supervisor,

My name is Brandon Leftwich, and I am a Doctoral student at the Jiann-Ping Hsu College of Public Health at Georgia Southern University. I would like to invite you and your employees to participate in an interesting thesis research topic titled: Assessing risk factors and risk management procedures for potential microbial contamination of Georgia hotel water distribution systems. This study looks to address the knowledge of Water Management Plans and barriers that are preventing the implementation of Water Management Plans for hotel facilities. The information gained from this study will allow leaders in the industry to gain a better understanding of the use of Water Management Plans in hopes to reduce the risk of a waterborne illness outbreaks.

Your participation is entirely voluntary, and you may choose, without negative consequences, not to participate. Your responses to this survey will be kept strictly confidential. This study has been reviewed and approved by the Georgia Southern University Institutional Review Board under tracking number H19202.

We realize that your time is valuable. However, we hope that the 15-20 minutes that it takes to complete this survey will help aid new ways to better protect employees and visiting guest by implementing WMP and reduce risks of a waterborne disease outbreak. By returning this completed survey, you are giving your consent to participate.

If you have any questions or concerns about the study, please feel free to contact Brandon Leftwich at 423-400-3863. You may also contact Georgia Southern University Institutional Review Board for answers to questions about subject's rights at 912-478-5465 or via email at irb@georgiasouthern.edu. Thank you for your participation. Your willingness to assist with this project is greatly appreciated.

Sincerely,

Brandon Leftwich

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2 COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** brandon leftwich (ID: 3101675)
- **Email:** bl03096@georgiasouthern.edu
- **Institution Affiliation:** Georgia Southern University (ID: 1063)
- **Institution Unit:** Public Health
- **Phone:** 423-400-3863

- **Curriculum Group:** Human Subjects-Social & Behavioral Research - Basic/Refresher
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course
- **Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social/Behavioral Research with human subjects.

- **Report ID:** 21099092
- **Completion Date:** 09-Oct-2016
- **Expiration Date:** 09-Oct-2019
- **Minimum Passing:** 80
- **Reported Score*:** 83

REQUIRED AND ELECTIVE MODULES ONLY

	DATE COMPLETED	SCORE
Belmont Report and CITI Course Introduction (ID: 1127)	09-Oct-2016	3/3 (100%)
Students in Research (ID: 1321)	21-Sep-2012	10/10 (100%)
History and Ethical Principles - SBE (ID: 490)	09-Oct-2016	4/5 (80%)
Defining Research with Human Subjects - SBE (ID: 491)	09-Oct-2016	5/5 (100%)
The Federal Regulations - SBE (ID: 502)	09-Oct-2016	4/5 (80%)
Assessing Risk - SBE (ID: 503)	09-Oct-2016	4/5 (80%)
Informed Consent - SBE (ID: 504)	09-Oct-2016	5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505)	09-Oct-2016	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	21-Sep-2012	3/5 (60%)
Consent in the 21st Century (ID: 17060)	09-Oct-2016	1/5 (20%)
Records-Based Research (ID: 5)	21-Sep-2012	2/2 (100%)
Internet-Based Research - SBE (ID: 510)	21-Sep-2012	5/5 (100%)
Research and HIPAA Privacy Protections (ID: 14)	21-Sep-2012	3/5 (60%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: <https://www.citiprogram.org/verify/?6a976750-65c2-4332-a24e-cb8eed2434fe>

CITI Program

Email: support@citiprogram.org

Phone: 888-529-5929

Web: <https://www.citiprogram.org>

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2

COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** brandon leftwich (ID: 3101675)
- **Email:** bl03096@georgiasouthern.edu
- **Institution Affiliation:** Georgia Southern University (ID: 1063)
- **Institution Unit:** Public Health
- **Phone:** 423-400-3863

- **Curriculum Group:** Human Subjects-Social & Behavioral Research - Basic/Refresher
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course
- **Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social/Behavioral Research with human subjects.

- **Report ID:** 21099092
- **Report Date:** 09-Oct-2016
- **Current Score**:** 89

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Students in Research (ID: 1321)	21-Sep-2012	10/10 (100%)
History and Ethical Principles - SBE (ID: 490)	09-Oct-2016	4/5 (80%)
Defining Research with Human Subjects - SBE (ID: 491)	09-Oct-2016	5/5 (100%)
Belmont Report and CITI Course Introduction (ID: 1127)	09-Oct-2016	3/3 (100%)
Records-Based Research (ID: 5)	21-Sep-2012	2/2 (100%)
The Federal Regulations - SBE (ID: 502)	09-Oct-2016	4/5 (80%)
Genetic Research in Human Populations (ID: 6)	21-Sep-2012	2/2 (100%)
Assessing Risk - SBE (ID: 503)	09-Oct-2016	4/5 (80%)
Informed Consent - SBE (ID: 504)	09-Oct-2016	5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505)	09-Oct-2016	5/5 (100%)
FDA-Regulated Research (ID: 12)	27-Sep-2012	5/5 (100%)
Internet-Based Research - SBE (ID: 510)	21-Sep-2012	5/5 (100%)
Research and HIPAA Privacy Protections (ID: 14)	21-Sep-2012	3/5 (60%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	21-Sep-2012	3/5 (60%)
Consent in the 21st Century (ID: 17060)	09-Oct-2016	4/5 (80%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: <https://www.citiprogram.org/verify/?6a976750-65c2-4332-a24e-cb8eed2434fe>

Collaborative Institutional Training Initiative (CITI Program)

Email: support@citiprogram.org

Phone: 888-529-5929

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ASSESSING WATER MANAGEMENT PLANS FOR HOTEL FACILITIES

The purpose of this survey is to identify potential barriers on the adaption of water safety plans in hotels of Georgia and assessing risk factors for potential microbial contamination in hotel water distribution systems. This will be assessed through the integration of the Health Belief Model. The completing the survey is voluntary, the results are anonymous. Completing or not completing the survey has no effect on the respondent's employment, and completing the survey means the subject agrees to have their responses included in the study.

Subject Identification Number:

Location (City and State): _____

Date: ____/____/____

Month Day Year

GENERAL TIPS BEFORE YOU START

- This questionnaire will ask you mainly about your hotel water management systems.
- Read the whole question before making an answer.
- Try to answer all questions unless you are told to skip them.
- If you cannot decide whether to answer YES or NO, leave the question blank.
- If there are several responses, select the one which best describes your situation or symptoms, unless you are told to choose multiple answers.

Questionnaire (Please Circle One)

Section I

1) What type of establishment is your facility?

Hotel-Motel Bed & Breakfast RV Park Cabins Camp Ground

2) What is the approximate age of your facility?

0-10 10-15 16-20 21-30 31- older

3) How many rooms does your facility provide?

0-25 26-50 51-75 76-100 100- up

4) What is the current ownership of facility?

Individual Corporation/Chain Partnership LLC Association

5) What is your designated work title?

Owner Manager Employee Seasonal

6) How many years of experience do you have at your current position?

0-5 6-10 11-15 16-20 21-up

7) What type of water supply services your facility?

Public (City/County) Private (well) Community well

8) Have you heard of a water management plan?

Y N

9) Does your facility have a water management plan?

Y N Don't Know

10) Does your facility have emergency guidelines and or procedures in the event of a water outage?

Y N Don't Know

11) Have you heard of a boil water advisory?

Y N

12) Does your facility have emergency guidelines and or procedures during an event of a boil water advisory?

Y N Don't Know

13) What are some barriers that are preventing you from developing a water management plan?

14) Does your facility have a cooling tower?

Y N Don't Know

If so, how often does the cooling tower gets serviced?

Once a year, Every 2-5yrs, Every 6-10 years, Never, Don't Know

15) Does your facility have designated personnel/staff for routine maintenance of your buildings water system?

Y N Don't Know

16) Does your facility have any decorative water fountains?

Y N

17) Does your facility have a hot tub (also known as a spa) that is not drained between each use?

Y N

18) Does your facility have a swimming pool?

Y N

If yes, how often are the chemicals checked?

Once a day Twice a Day Once a week Never

19) Are there any sections of rooms in your facility that are not used year-round?

Y N

Section II

- 5 — agree strongly
- 4 — agree
- 3 — neither agree nor disagree
- 2 — disagree
- 1 — disagree strongly

Perceived Susceptibility

- I believe the chances of an waterborne outbreak occurring at my facility is great
1 2 3 4 5
- I worry about my guest and staff getting a waterborne illness
1 2 3 4 5
- I feel that there is a good chance of getting a waterborne illness during my career.
1 2 3 4 5
- I know other hotel facilities that had a waterborne outbreak at their facility
1 2 3 4 5
- I can prevent a waterborne illness by developing proper maintenance procedures for my facilities water/plumbing system
1 2 3 4 5

Perceived Severity

- The thought of my hotel causing a waterborne outbreak concerns me
1 2 3 4 5
- If a waterborne illness occurs at my facility, my facility reputation would be ruined
1 2 3 4 5

- Financial security would be endangered if a waterborne outbreak occurs at my facility
1 2 3 4 5
- I believe my staff and guess could die prematurely if they contract a waterborne illness at my facility
1 2 3 4 5

Perceived benefits

- Having a water management plan will help reduce the risk of a waterborne outbreak from occurring
1 2 3 4 5
- Having a water management plan ensures that my staff and guess are not exposed to waterborne contaminates
1 2 3 4 5
- The implementation of a water safety plan will be beneficial to my facility.
1 2 3 4 5

Perceived barriers

- I don't have enough staff to implement and maintain a water safety plan
1 2 3 4 5
- Implementing water safety plan is time consuming
1 2 3 4 5
- We lack understanding of ASHRAE Standard 188 and the CDC Water Management Plan Toolkit?
1 2 3 4 5

- I don't have a water safety plan because it is not mandatory
1 2 3 4 5
- We lack the financial support to maintain a water management plan
1 2 3 4 5
- We lack training for staff to effectively maintain water safety plan
1 2 3 4 5
- We lack explanation of concepts and more guidance needed on the public health aspect of water safety plan.
1 2 3 4 5
- There are no benefits to implement a water safety plan
1 2 3 4 5

Cues to Action

- Receiving more encouragement from the local health authority to implement a water safety plan is important
1 2 3 4 5
- Regular and frequent education on the importance of water safety plans will help with implementation.
1 2 3 4 5
- Having a simple method to implement a water safety plan will increase my chances of maintaining one.
1 2 3 4 5
- Provided training will encourage our facility to implement water safety plans
1 2 3 4 5

- I am interested in water safety plans because I do not want my staff and guests exposed to any waterborne diseases

1 2 3 4 5

Self-Efficacy

- Once I receive more education on water safety plans I will be more comfortable in implementing the program

1 2 3 4 5

- I am confident that maintaining a water safety plan will help prevent a waterborne illness outbreak at my facility

1 2 3 4 5

- I can train my staff to maintain records for water safety plans

1 2 3 4 5

- I am confident that I can manage the additional duty of implementing a Water Safety Plan.

1 2 3 4 5

- It is our responsibility as hotel staff to provide safe potable water to our guests.

1 2 3 4 5