

Study Protocol Social/Behavioral/Humanist IRB

Pathways of Exposure to Heavy Metals in Children Along the Pilcomayo River, Bolivia

Background:

Bolivia is one of the world's largest producers of silver. One of the country's largest mines is located in Potosí, a city high in the Andean mountain range and at the mouth of the Pilcomayo River. In order for this mine to produce marketable silver, miners use water to wash away impurities like arsenic, lead, and cadmium. This soluble waste is then released back into the river where it flows to populations living downstream (Allan, 1997). Water contamination through panning of silver, however, is not the only source of these heavy metals in this area. A large-scale disaster occurred in 1996 when a section of a mine-tailing wall collapsed, dumping an estimated 235,000 m³ of mine wastes into the Pilcomayo River (Hudson-Edwards et al., 2001).

True to both of these release mechanisms, heightened levels of lead, arsenic, tin, cadmium, copper, mercury, thallium and zinc from the Potosí mine have been found downstream of the Pilcomayo River based on WHO standards (Hudson-Edwards et al., 2001). The contaminant levels were the highest closest to the mines and progressively decreased as the distance from the mines increased (Hudson-Edwards et al., 2001). In one community located 180 kilometers downstream from Potosí, Marapampa, lead levels in the Pilcomayo River were found to be 451 micrograms per liter and arsenic levels measured 716 micrograms per liter (Safi, 2004). These levels were elevated when compared with World Health Organization acceptable levels of 20 micrograms per liter and 10 micrograms per liter for drinking water, respectively. This high metal contamination causes concern due to the fact that 44% of inhabitants of Marapampa drink water straight from the river and do not use filters or any other water purification system (Safi, 2004). Elevated lead, cadmium and arsenic levels have also been found in the soil on the riverbank, and in agricultural plots along the river edge that contain vegetable crops such as carrots, lettuce, and beetroots (Miller et al., 2004). All these findings are of concern due to the potential exposure of the populations to lead, arsenic, and cadmium through the ingestion of contaminated vegetables, drinking water, and accidental ingestion of contaminated soil.

These contaminants, namely arsenic, cadmium, and lead, are hazardous to children's health and can lead to cancers, lesions, and other serious medical conditions (Jarup, 2003). Lead has been linked to mild retardation, seizures, stroke, and comas (Meyer et al., 2003). In children, lead is associated with lethargy, abdominal cramps, anorexia, and irritability. Low chronic exposure is linked to lower neurobehavioral functioning due to the child's developing brain (Lidsky et al., 2003). In China, low lead exposure is associated with IQ deficiencies, lower neurobehavioral development and slower physical growth when children had blood lead levels of at least 10 micrograms/deciliter (Shen et al., 2001). Furthermore, another study indicates that children with lower blood lead levels also have intellectual impairment (Koller et al., 2004). It is therefore very important to consider the effects of lead exposure in these communities living along the Pilcomayo River. Lead concentration in the blood is also correlated with anemia; children who are anemic are more likely to have high lead levels in their blood (Kwong et al., 2004).

As well, arsenic and cadmium are harmful to health. In Bangladesh, chronic exposure to arsenic-containing well water (average intake of 500 micrograms of arsenic per day) has been associated with skin lesions and skin cancer (Smith et al., 1992). Other studies have indicated that children playing in arsenic-containing media such as water and soil may also be significantly exposed to arsenic (Kwon et al., 2004).

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Cadmium has been found to cause weakening of bone and kidney damage in exposed individuals (Jarup, 2003).

The Environmental Protection Agency (EPA) suggests studying children in the age range of 3-11 years for exposure assessment studies due to the behavioral and psychological similarities in children in this age range (EPA-NCEA, 2002). These characteristics make children more susceptible to the effects of heavy metal exposure.

The proposed project will be completed in collaboration with the Fundación Boliviana Para la Salud (FunSalud) (Bolivian Foundation for Health). FunSalud's president is the former Minister of Health of Bolivia, Dr. Enrique Paz, and has the support of the Bolivian government and the Centers for Disease Control and Prevention (USA). The CDC laboratory has been contacted in regards to its role in the chemical analysis of biological samples that will be collected. The laboratory will provide the LeadCare instrument to measure lead in blood. Information about exposures will also be obtained through a questionnaire.

This study is a follow-up to a thesis completed during the summer of 2004 by Global Environmental Health student Basil Safi (MPH '04). Mr. Safi investigated arsenic and lead levels in the water in the Pilcomayo River. He found heightened lead and arsenic levels in the river water in the community of Marapampa (mentioned above). This study will continue his research and tie his data with human exposure through connecting the previously collected environmental data with blood lead measurements in children.

Project Objective:

The overall objective of this study is to evaluate the internal dose of lead and link this dose to environmental exposures. There are four specific parts of the project: 1) A questionnaire about exposures; 2) Blood samples to use in the LeadCare instrument; 3) Blood samples to determine concentrations of other metals. In case of problems incurred during blood sample collection, we will revert to collecting urine samples from the male children.

Aim (s):

- Conduct a survey in order to assess the time and dosage of each child's exposure to media coming from the riverbed (e.g.: quantity of soil played on and for how long, what type of water was consumed and how much, where the vegetables consumed came from and how much was consumed, etc.);
- Collect finger prick blood samples from children and urine samples, if necessary, from male children in order to obtain an internal dose measurement;
- Input both the survey and laboratory results into a regression model in order to obtain an estimate of the importance of each exposure pathway to the overall internal dose.

Hypotheses:

Hypothesis 1: The blood (and urine) samples obtained from children along the Pilcomayo River will show heavy metal levels that are significantly elevated from zero.

Hypothesis 2: The digital readings of lead from the LeadCare will be statistically equivalent to the ICPMS readout of lead from the second drop of blood from the finger prick.

Hypothesis 3: Children with anemia are more likely to have high lead levels than children who are not anemic.

Hypothesis 4: Drinking water is the most significant exposure pathway of heavy metals in children living along the Pilcomayo River as compared with ingestion of vegetables or soil.

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Significance:

No previous study has quantified the internal dose of children exposed to heavy metals along the Pilcomayo River. In the 1970s, an estimated 1.3 million people lived along the Pilcomayo River (Organization of American States, 1984). Thus, the heavy metal contamination of the river affects many individuals. As stated above, the present study proposes to determine the blood concentrations of primarily lead, and secondarily of arsenic and cadmium in children through urine samples and will attempt to identify the major routes of exposure to these metals through a questionnaire.

This knowledge will be the basis for future interventions that will aim at reducing exposures to the most potentially hazardous metals.

Even though the individual communities living along the Pilcomayo River are small in size, the results can be extrapolated to other communities. Therefore, studying one or two communities has a public health significance for all surrounding communities.

Methods of Data Collection and Subject Population

Interviewer training: Interviewers will be needed in order to conduct the childhood exposure questionnaire. They will receive instruction sheets containing all pertinent information (such as study background, questionnaires, IRB procedures, etc.). They will practice interviewing each other and the principal investigator will observe to minimize bias. The interviewers will be fluent in both Spanish and Quechua in order to be able to conduct the interview in both languages based on maternal preference.

Study Population Selection: The study population is children between the ages of 3 and 11. The village of Sotomayor was chosen as a target population due to its closeness to the river, its accessibility and its "large" population (over 250 individuals). The village has also been involved with certain studies in the past dealing with vegetable, soil, and irrigation water, yet no information has been gathered about the exposures of their children. This study would therefore increase the knowledge on the heavy metal problem of the river and will eventually help produce an intervention to reduce exposures. Other communities, with similar exposures and demographics, will be selected along the Pilcomayo River in order to increase the sample size from 50 (power calculations with the proportion method indicated that a sample size of 50 would allow detection of a proportion of 50% with high levels and with +/-10% sampling error (calculated with Epi Info version 3.3)) to around 100 individuals. The principal investigator will approach the mayors of Sotomayor and of the other villages with a letter of recommendation for the project from the Minister of Public Health. Once the mayor agrees to support the study, the principal investigator will request that the mayor calls a town meeting. At this meeting, the mayor, the representative of the Ministry of Health and other officials will speak of the importance of the project, its impact, and its legitimacy. Then we will ask for volunteers and test the child and conduct the interview with the mothers. This will therefore be a volunteer convenient sample.

Once the mothers have shown interest, the mothers of the households will be approached about the project. The mothers will be read the informed consent form (see procedure below).

Questionnaire: The mother will then be asked to respond to several questions about her child's exposures. If she has more than one child in her care in the desired age range (between 3-11 years of age), the interviewer will pick one of the children using the random number table (Weiss, 2005) corresponding to the code in the questionnaire. The mothers will have the choice of completing the questionnaire in Spanish or in Quechua.

Blood samples: The physician will then use the methods discussed by Kaiser et al. (2001) and Shen et al. (2003) to collect blood from a finger prick. Physicians will be provided with latex gloves in order to protect themselves. Once the child has assented to the process (see below), a physician will wash the child's hands with uncontaminated water, soap, and EDTA recommended by the Centers for Disease Control and Prevention in order to remove cross contamination with lead on the child's hands. A wipe of

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absolute alcohol will be used to avoid infection of the area. The physician will then prick the child's finger with a lancet and fill a 50-uL capillary tube with blood. This sample will be placed on test strips that will then be inserted into the LeadCare instrument for a reading (ESA Biosciences Inc). The physician will also place a well-beaded drop of blood on a piece of filter paper, which will be left to dry for ten minutes. A third drop of blood will be analyzed using a HemoCue machine in order to analyze for anemia (HemoCue Ltd). The drop of blood will be placed on a microcuvette that will then be inserted into the reader. A piece of gauze will then be given to the child to hold on his/her finger until bleeding stops. The total amount of blood collected will not exceed 50mL or 3mL per kilogram.

Urine collection: If the above protocol produces some problems (or if the LeadCare instrument does not work), urine will be collected from male children. Based on NHANES data, male and female children within the age range do not have significantly different levels of metals in their urine (Riederer, personal communication). Males will be the sample population because of the ease with which their urethral opening can be washed. They will be washed with filtered water and soap (as above) and the physician will catch a midstream sample from the child in a pre-washed container.

Consent Process

The principal investigator will approach the mothers of the selected household. The study purpose and objective will be explained to them and the informed consent will be read to them and they will be asked to repeat what they understood. They will be asked to sign the consent form in front of a witness. See attached consent form (Appendix 1) for more details.

Once the parents have given consent, the physician and the principal investigator will approach the children. Assent will be obtained from the children using the attached form (Appendix 2). If the child has levels of lead higher than 10ug/dL, the parents will be consulted in giving their name to the Ministry of Health representative to determine course of treatment.

Data Collection Instrumentation

Questionnaire: A questionnaire will be completed with the mothers in the selected houses. See attached document for the complete interview (appendix 3). The Spanish translation is attached. A back translation will be obtained within the week. The Quechua version and back translation will be completed once in Bolivia because of the lack of fluent translators here in the United States. Both translations will be sent as an amendment once they are completed.

Each family (mother-child pair) will be assigned an identification number. The number and the name of the mother and child will only appear on the cover sheet of the questionnaire. All other pages of the questionnaire will contain the identification number of the pair. Once all the pertinent information is obtained, the cover sheet will be destroyed in order to ensure privacy of the information.

Blood sampling: Blood from a finger prick of each child enrolled in the study will be collected. The blood will be immediately used in a LeadCare instrument in order to determine the concentration of lead in the child's blood. This instrument has been successfully used in developing countries in the past (Kaiser et al., 2001; Counter et al., 1998; Taylor et al., 2001). Its validity has already been proven compared to longitudinal electrothermal atomic absorption spectrometry (Pineau et al., 2002).

The second blood drop will be used in order to analyze in an ICPMS machine. The drop will be collected on filter paper, a method that was validated by Shen et al. (2001). The filter paper will be placed in a Ziploc bag and shipped to Emory University (Shen et al., 2001).

The third drop of blood will be used in a HemoCue machine, if possible, in order to determine anemia levels. This machine was validated for "initial diagnosis" of anemia by Munoz et al. (2005).

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Urine sampling: as mentioned, if the blood sampling poses a problem, urine will be collected from the children. The urine will be conserved and shipped at room temperature to Emory in order to be analyzed using the ICPMS machine (as with the blood on filter paper).

Statistical Analysis: Parametric and nonparametric statistical methods will be used to test the research hypotheses. For example, the nonparametric Wilcoxon rank sum test will be used to determine if the mean urine metal measurement is statistically significant compared with the null value. SAS 9.1 will be used for all statistical analyses.

Ethical Considerations

Since the children being tested are exposed to elevated levels of lead, it is possible that they have blood lead levels higher than the recommended dose of 10ug/dL. Since the LeadCare and HemoCue instruments give digital readouts, the mothers of the children will be told the lead and iron level of their child. The children with elevated lead levels will be contacted once the results of the study are summarized. As mentioned, the mothers of the children will be consulted about giving their name to the representative of the Ministry of Health. This will be done in order to determine future actions. All children will receive a pamphlet developed by the EPA on lead and how to reduce exposure to lead at home. After the results are analyzed, the physicians from the Ministry of Health will teach community members how to reduce their lead exposures based on the results of the study. The physicians will also hold a town meeting to discuss the results and an intervention will be commenced to reduce childhood exposures to lead.

Timeline in the Field

	Set-up support team of Bolivians	Test questionnaires	Train Interviewers and physicians	Visit/select communities and obtain permission	Start data collection
Week 1	X				
Week 2	X				
Week 3	X	X			
Week 4				X	
Week 5				X	
Week 6			X		
Week 7			X		
Week 8					X
Week 9					X
Week 10					X

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http://www.epa.gov/opptsfrs/OPPTS_Harmonized/875_Occupational_and_Residential_Exposure_Test_Guidelines/Series/875-1500.pdf
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Social, Humanist, and Behavioral IRB Initial Submission Form

Emory University IRB
Briarcliff Campus
1256 Briarcliff Rd., Rm 426-S
Atlanta, GA 30306
phone: (404) 727-5646
fax: (404) 727-1358
<http://www.emory.edu/IRB>

OFFICE USE ONLY

IRB #:	
Review Type:	
Committee:	
Specialist:	

PLEASE PRINT OR TYPE

A. BASIC INFORMATION

Title of Proposal	Pathways of Exposure to Heavy Metals in Children Along the Pilcomayo River, Bolivia		
Proposed Start Date	June 15 th , 2005	Anticipated Duration of Research	7 weeks

B. Personnel (list the principal investigator first; add rows by hitting the TAB key from the bottom right cell):

ALL personnel involved in the design or conduct of the study must be listed and must have successfully completed the Human Subjects Education Program (for more information go to <http://www.emory.edu/IRB/educationFAQ.htm>). To verify, we need the username assigned by the test program, the WebCT ID.

Name (type or print)	Dept/Div	Address	Phone Number	E-mail Address	WebCT ID
Stephanie Maurissen	GEH	2445 Dooley Dr. Apt. EP20	404-251-9009	smauris@sph.emory.edu	smauris

Faculty Advisor/Sponsor (if applicable)

Name:	Dr. Anne Riederer	
Phone number:	404-712-8459	Fax number: 404-727-8744
e-mail address:	arieder@sph.emory.edu	Mailing address:

Contact (if different than Principal Investigator)

Name:	
Phone number:	Fax number:
e-mail address:	Mailing address:
Send correspondence to:	

C. Sponsorship and Funding

Has or will this proposal be submitted for funding?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
If yes:	Agency/sponsor	Global Field Experience (Rollins School of Public Health)
	Submission date:	3-23-2005

Does this research fall under the auspices of a local sponsor or affiliate?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
If yes:	Agency/sponsor	Fundacion Boliviana Para la Salud
	Contact person	Enrique Paz, MD, MPH
	Address	Calle 24 A#91 La Paz, Bolivia
	Phone number	591-22791108 or 404 498 0912

Is this protocol subject to review by another Institutional Review Board or Human Subjects Review Committee at another institution?		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If yes:	What IRB/HSRC? Attach a copy of the approval.	
	→	

D. Project description

1a. Have the data described here already been collected?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
1b. If this protocol is for secondary analysis of data, are identifiers included?	<input type="checkbox"/> Yes <input type="checkbox"/> No
1c. What is the source of the data set?	
1d. Is it publicly available?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. If you will be collecting data, will subjects participate on fully voluntary basis?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
3. Number of research participants to be used:	~100
4. Age range of participants:	<input checked="" type="checkbox"/> 0-13 <input type="checkbox"/> 14-17 <input type="checkbox"/> 18-64 <input type="checkbox"/> 65+
5a. Will the participants include prisoners?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
5b. Is the research focused on pregnancy or pregnant women?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
6. Briefly indicate the type(s) research methodology (e.g., structured or unstructured interviews, participant observation, participatory or action research, case studies, life histories, discourse analysis, questionnaire, census, archival, focus groups, community intervention, evaluation research, experimental, etc.). If relevant, specify the methods for each phase of the research.	
→ questionnaire, finger pin pricks, urine samples from male subjects	
6a. Method by which participants will be selected or recruited	
→ Voluntary sampling of families (and random selection of children within the families) until 50 children are enrolled, if possible, in each village (maximum anticipated number of subjects approximately equal to 100)	

Attach research protocol, summary of the research background, details of the methodology, data collection instruments, and consent documents.

E. Participant Risks

7. Will participants be exposed to any stresses (e.g. anxiety, exhaustion, pain, confusion, etc.) or physical harms (e.g. infection, injury, disability, death, etc.) in connection with this research		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If yes:	7a. Briefly describe these stresses or harm.	
	→	
	7b. What specific steps will be taken to <u>minimize</u> and <u>monitor</u> this risk?	
	→	
If yes:	7c. If participants are physically harmed, what will be done to compensate and/or treat participants who are harmed by the research?	
	→	
8. Does the research design require that the participants be deceived? If so, please explain in your research protocol.		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
9. Please note any special or unusual circumstances related to this research that might give rise to special concern for the welfare of research participants and describe how these special concerns will be addressed.		
→		

F. Confidentiality

10. Will participants provide information that they might want to remain confidential? (e.g. information regarded as personal, private, or embarrassing; exposing the participant to risk of criminal or civil liability; or damaging to financial standing, employability, or reputation).		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
10a. Will all information about the participants be kept confidential?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
If no:	10b. If some information will not be kept confidential (which must be indicated in the consent procedure), why is this required by the research?	
	→	
	10c. How will you ascertain whether a participant wants some information kept confidential?	
	→	
11. Will it be possible to identify the participants directly (e.g. by name) or indirectly (e.g. by reconstruction from circumstantial information) in the published research?		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
12. Will audio, video, or photographs be part of the publication or presentation of the results?		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If yes:	12a. How will the participants' consent for the publication of these specific recordings or images be obtained?	
	→	

G. Data Handling

13. What steps will be taken to prevent irresponsible or unauthorized use of the data and findings?

→ Subjects will be given coded identifications and, once all the data have been collected, personal identifiers will be destroyed.

14. How will data assembled be used (e.g., as mass or aggregated data, case studies with or without anonymity, personal narratives with or without pseudonyms, direct quotation, narrative, etc.)?

→ aggregated data

H. Informed Consent

15. How will participants be informed of the nature of this research and their participation in it? If multiple components to the study please check all applicable boxes.

- Written document (please attach the document to your application)
 Orally from script (please attach the script to you application)
 Orally without script (please attach an explanation and a description of the consent process)
 No Consent

Indicate the type of consent that corresponds to each part of the study: →

16. Will the participants be fully informed about the following aspects of the research?

16a. Voluntariness of participation, including freedom to skip questions or withdraw	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
16b. The purposes and procedures of the research	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
16c. Any reasonably foreseeable risks or discomforts	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
16d. Any benefits to the participant or to others from the research	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
16e. The extent to which confidentiality will be maintained	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
16f. For research involving risks of injury, a description of compensation or medical treatments available if injury occurs	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
16g. Whom to contact for answers to questions about the research, participants' rights, and research-related injury	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

If the answer to any of the above questions is "No," attach an explanation of why the research requires such an alteration of the standard elements of informed consent.

17. If children (or individuals with diminished capacity) are to participate, how is the consent of parents or guardians to be obtained? How is the assent of the participant to be obtained or ascertained?

→ The consent of the mother will be obtained through a written document and the assent of the child will be obtained through a verbal "yes" after being read a short script.

18. How will the participants' informed consent be documented? Check all relevant boxes. Please explain in your research protocol.

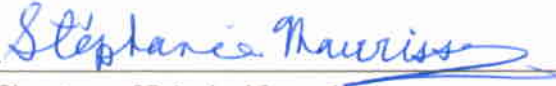
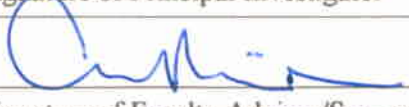
- Signature on written consent document
- Signature on document to be read to the participants and witnessed by another party
- Written documentation of the participants' informed consent will NOT be obtained because one of the following criteria is satisfied. Check all that apply and attach an explanation of why the research requires a waiver of written consent documentation.
 - The only link between the subject and the research would be the informed consent documentation, and the primary risk is loss of confidentiality.
 - The risks to the participants (including risks related to loss of privacy) are no greater than those ordinarily encountered in daily life and the research involves no procedures for which written consent is normally required outside of the research context

19. Who, other than the principle investigator(s), will obtain informed consent from the participants?

→ None

CERTIFICATION OF PRINCIPAL INVESTIGATOR:

I certify that I have read and agree to comply with the Arts and Sciences' "Assurance of Compliance with the DHHS Regulations for Protection of Human Research Subjects" and that the above is a true representation of the research to be undertaken.

	4/26/2005
Signature of Principal Investigator	Date
	4/26/05
Signature of Faculty Advisor/Sponsor	Date

Investigator's Checklist for IRB Submission

For new projects, make sure your application is complete prior to submitting it to the Departmental Human Subjects Review Committee. In addition, be certain that your consent form (or consent procedure) includes all of the information listed below.

Application:

- Form completed (signed by advisor, if necessary) and blank recommendation form
- Protocol summary (**5 page limit** – do not include complete; identifies research question; describes methods)
- Data collection instruments (must coincide with parts of study described in protocol)
- Recruitment materials (if necessary)
- Consent document (If you are not obtaining written documentation of informed consent or are altering some of consent elements [application questions 16 and 18], provide rationale for deviation from written consent if research is not exempt.)

Consent Form: (written at 8th grade level)

- Identification of researcher's position, institution
- Consent form version and date
- Description of study (for lay audience)
- Description of procedures (activities, duration; audio or videotaping)
- Statement of benefits and risks (even if there are no direct benefits or known risks; explain precautions if there are risks; monetary payment does not constitute a benefit)
- Statement of voluntariness (including skipping questions)
- Statement of confidentiality (rationale if deviate from complete anonymity; may include waiver to use names of respondents; specify how data will be used)

Contact persons (PI; advisor; IRB – include line, “If you have questions about your rights as a participant in this study, you may contact Dr. Karen Hegtvedt, Chair, Social, Humanist, and Behavioral Institutional Review Board, which oversees the protection of human research participants. She can be reached at 404-727-7517 or khegtv@emory.edu.”)

Copy of consent form given to respondent

Signatures and date (must include respondent; may include investigator, witness)

RECOMMENDATION OF DEPARTMENTAL HUMAN SUBJECTS REVIEW COMMITTEE

To be completed by Departmental HSRC

The Departmental Human Subjects Review Committee recommends that this study be:

Exempt from further review because there is no deception of the participants, the risks are not greater than those ordinarily encountered in daily life, and it falls into one of the following categories:

- the activity is conducted in an established educational setting and involves normal education practices in order to evaluate or compare regular or special educational instructional strategies, curricula or methods.
- the research involves the use of educational tests (cognitive, diagnostic, aptitude or achievement) and information taken from those tests will be recorded so that participants cannot be identified directly or indirectly.
- the research involves surveys, interviews, or observation of public behavior **AND**
 - a. the responses will be recorded so that participants cannot be identified directly or indirectly by their answers, **AND**
 - b. the responses could not damage or harm a subject's interests, including financial interests, employability or reputation.
- the research is limited to using existing data to which the investigator has access, and the information will be recorded so that participants cannot be identified directly or indirectly.

Subject to **expedited** review because there is no deception of the participants, the risks are not greater than those ordinarily encountered in daily life, all participants will provide written informed consent, and the research consists entirely of one or more of the following specific activities:

- The research is on individual or group characteristics or behavior **AND**,
- while a breach of confidentiality could expose the participants to a risk of criminal or civil liability, or damage to financial standing, *employability*, *insurability*, or reputation, the research is designed to make the risk of a breach of confidentiality no greater than that ordinarily encountered in daily life.

Examples include research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior that employs survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- Collection of data from voice, video, digital, or image recordings made for research purposes.
- The study of existing data, documents, records, pathological specimens, or diagnostic specimens collected solely for non-research purposes, such as medical treatment or diagnosis (if not exempt, as specified above).

Categories of expedited research continued on next page...

- Collection of biological specimens by noninvasive means.
Examples include the collection of hair and nail clippings in a non-disfiguring manner, deciduous teeth; and permanent teeth if patient care indicates a need for extraction, excreta and external secretions, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor, and mucosal and skin cells collected by buccal scraping, swab, or mouth washing
- Collection of data through noninvasive procedures routinely employed in clinical practice, not including procedures involving x-rays, microwaves, sedation, or general anesthesia. Participants must be non-pregnant adults.
Examples include the use of physical sensors applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or invasion of the subject's privacy. Examples also include weighing, testing sensory acuity, magnetic resonance imaging, electrocardiography, electroencephalography, thermography, electroretinography, ultrasound, infrared imagery, and detection of naturally occurring radioactivity
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture not exceeding 550ml in an 8-week period for healthy non-pregnant adults, or not exceeding the lesser of 50ml or 3ml per kg in an 8-week period. Collection may not occur more than twice per week.

Subject to **full board** review because the research falls into at least one of the following categories (check all that apply).

- The study population includes persons not able to give legal consent, prisoners, and pregnant women (application questions 3 and 4).
- The research involves deception (application question 8).
- The research requires waiver or alteration of one of the elements of informed consent (application question 16), and the research does not fall into one of the categories of exempt research, above.
- There will be no written documentation of informed consent (application question 18), and the research does not fall into one of the categories of exempt research, above.
- The research presents risks greater than those encountered in everyday life, including risks from breach of confidentiality (application questions 7, 9, and 10).
- It is possible to directly or indirectly identify participants, and the risk of a breach of confidentiality is greater than that encountered in everyday life (application questions 7, 9, 10, and 11)
- Other.

Signature of Chair, Departmental HSRC

Date