

Institutional Review Board for Human Investigation

The Institutional Review Board has reviewed the proposal and informed consent

Submitted by: \_\_\_\_\_\_Jonathan D. Amith\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Entitled: *Corpus and Lexicon Development: Endangered Genres of Discourse and Domains of Cultural Knowledge in Tu'un ísaví (Mixtec) of Yoloxóchitl, Guerrero*C:\Program Files\Microsoft Office\MEDIA\OFFICE12\Lines\BD14845_.gif

Please be advised that with respect to: (1) The rights and welfare of individuals

(2) The appropriateness of the methods to be used to  
 secure informed consent

(3) The risks and potential benefits of the investigation

The Board considers this project, IRB protocol # \_\_\_\_\_\_\_\_\_\_:

\_\_\_\_\_\_**Fully Acceptable**, without reservations; approved through \_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_**Approved contingent on revisions**

\_\_\_\_\_\_**Not Acceptable** for reasons noted

\_\_\_\_\_\_**Exempt** (see reasons below)

Protocols involving children approved under

\_\_\_\_\_45 CFR 46.404 \_\_\_\_\_45CFR 46.405 \_\_\_\_\_45CFR 46.406

REMARKS:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Date of Approval Signature of Reviewer

Type of Project: \_X\_New \_\_\_Renewal \_\_\_Addendum

Human Risk: \_\_\_Yes (minimal) \_\_\_Yes (significant) \_X\_No

Source of Support: \_\_\_None \_\_\_Departmental \_X\_Outside Funding

Agency (Potential) \_National Science Foundation\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Agency Number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Are any of the following involved? \_\_X\_No \_\_\_Yes, those checked below:

\_\_\_Minors \_\_\_Prisoners \_\_\_Pregnant Women \_\_\_Mentally Disabled \_\_\_Mentally Retarded

**The Gettysburf College IRB opeates under the   
HHS Multiple Project Assurance of Compliance Number FWA 0000 2006**

**CC: Investigator**

** Request for Review of Faculty Research Project Involving Human Subjects**

**(FOR OFFICE USE ONLY)**

**Project #**

**Date Rec’d:**

**Date Appr’d:**

**Type:**

All faculty research projects involving human subjects must undergo a review process for  
 human subjects protection. In order to facilitate the initial review, please complete this  
 application and send it with a copy of your proposal to the Office of the Provost, Box. 410.   
Questions may be direct to ext. 6835. This application meets the requirements of both our  
 Federal Wide Assurance for human subjects research and College institutional policy.

According to Gettysburg policy, all research must be certified to conduct research with  
 human subjects. Certification indicates that appropriate training in human subjects  
 protection has been received. Certification can be obtained through a tutorial offered

online on the Gettysburg IRB website ([www.gettysburg.edu/academics](http://www.gettysburg.edu/academics)......).

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**Section A. Applicant Information and Assurances**

|  |  |
| --- | --- |
| Researcher’s  Name | Jonathan D Amith |
| Title of Proposed  Research | *Corpus and Lexicon Development: Endangered Genres of Discourse and Domains of Cultural Knowledge in Tu'un ísaví (Mixtec) of Yoloxóchitl, Guerrero* |
| Anticipated Start  Date of Project | June 2010 Anticipated May 2013  Ending Date |
| Department | Anthropology Box Number 412 |
| E-mail | jamith@gettysburg.edu Phone 337-6795 |
| Co-Researcher(s),  if applicable | n.a. |
| Source of funding,  if applicable | National Science Foundation, Documenting Endangered Languages Program |

**Faculty Assurance**

I certify to the following:

1. The research will not be initiated until written approval is obtained from the IRB.
2. I have completed the appropriate training for human subjects protection.
3. I will obtain prior written approval for modifications to this project, including but not limited to changes in procedures.
4. I will report to the IRB any unanticipated problems and adverse effects, as well as my findings during the course of the study that may affect the risks or benefits to the subjects.
5. I agree to keep records of IRB approved documents and to retain research data with appropriate confidentiality.
6. I understand that this research is subject to continuing review and approval by the IRB.
7. The information in this application is correct.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Researcher #1 Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Researcher #2 Date

**Section B. Exemption Criteria Checklist**

Your project may qualify for an exemption from further IRB review. You are encouraged to review the exemption criteria checklist below to determine if your research qualifies as exempt. In each case, the **risk to the subject must be no more than** **minima**l i.e., no greater than the risk encountered in normal day-to-day activities or during routine physical or psychological examinations. **Research classified as involving more than minimal risk may not be exempt from review. Also, if the project includes any research activity with human subjects not listed below, the research is not exempt from further IRB review is required.**

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, observation of public behavior, **unless** the information is obtained and recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; **and** any disclosure of the human subjects’ responses outside the research could reasonable place the subject at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

**N.B.** The exemption for survey and interview research (#2 above) does not apply to research in which the subjects are children, except for research involving observation of public behavior where the researcher does not participate in the activities being observed.

1. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, or observation of public behavior that is not exempt under item #2 above; **if** the human subjects are elected or appointed public officials or candidates for public office; **or** federal statute(s) require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
2. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if there sources are publicly available, or if the information is recorded by the Researcher in such a manner that subjects cannot be identified directly, or through identifiers linked to the subjects.
3. 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 methods and procedures of public benefit or service programs.
4. Taste and food quality evaluation and consumer acceptance studies, **if** wholesome foods without additives are consumed, or a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or an agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDP or approved by the EPA or the USDA.

**Section C. Review Criteria Checklist**

Please answer the following questions, even if you think your research qualifies as exempt.

1. Does you research involve minors (under the age of 18)? Yes\_\_\_\_\_ No\_X\_\_
2. Does your research involve pregnant women, infants, prisoners, or cognitively

Impaired human subjects? Yes\_\_\_\_\_ No\_X\_\_

1. Does your research involve any people who are psychiatric inpatients or

institutionalized (e.g., mental health facility, nursing home, halfway house)?

**If yes, please identify the subject group\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** Yes\_\_\_\_\_ No\_\_X\_\_

1. Does your research use deception of the subjects by the researcher? Yes\_\_\_\_\_ No\_X\_\_\_
2. Could any disclosure of a research subject’s identity or responses outside the

research environment reasonably place the subject at risk of criminal or

civil liability or be damaging to the subject’s financial standing, employability,

or reputation (e.g., illegal drug use, alcoholism, gambling, perpetrator of abuse)? Yes\_\_\_\_\_ No\_X\_\_

If you answered “yes” to any of the above five questions, your research must be subject to review by the full IRB.

1. Does your research involve collection of blood samples by finger stick, heel stick,

ear stick or venipuncture from healthy, non-pregnant adults who weigh at least

110 pounds? Yes\_\_\_\_\_ No\_X\_\_

1. Does your research involve collection of biological specimens by noninvasive

means (e.g., hari and nail clippings, saliva, skin cells collected by swab or

mouth washings, sweat)? Yes\_\_\_\_\_ No\_X\_\_

1. Does your research involve collection of data through noninvasive procedures

routinely employed in clinical practice, excluding procedures involving x-rays

or microwaves? Examples include physical sensors placed on the body;

weighing or testing sensory acuity; moderate exercise, muscular strength  
testing, body composition assessment, and flexibility testing where appropriate  
given the age, weight, and health of the individual. Yes\_\_\_\_ No\_X\_

1. Does your research involve materials (data, documents, records, or

specimens) that have been collected, or will be collected solely for

nonresearch purposes? Yes\_\_\_ No\_\_X\_\_

1. Does your research involve collection of data from voice, video, digital, or

Image recordings made for research purposes? Yes\_\_\_\_ No\_X\_\_

1. Does your research involve surveys, questionnaires, interviews, focus groups,

program evaluations, human factors evaluation, or quality assurance

methodologies? **If yes, please attach a copy of these materials to this form.**  Yes\_\_\_\_\_ No\_X\_\_

1. Will your research be done 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)? Yes\_\_\_\_ No\_\_X\_

If you answered “yes” to questions 6-12, your research may be eligible for expedited review, if not already deemed exempt. For further clarification on expedited categories, please refer to Section F.

1. Will the study target or exclude a particular gender or ethnic or racial group?  
    **If yes, please identify. All participants will be fluent speakers of Yoloxóchitl Mixtec** Yes\_\_\_ No\_\_X\_
2. Will your data be collected and recorded in such a manner that the human

subjects can be identified, either directly or through identifiers linked to the

subjects? Yes\_X\_\_\_ No\_\_\_\_

1. Will this study use advertising, brochures, or recruitment posters or letters to

Recruit subjects? **If yes, please attach a copy of these materials.**  Yes\_\_\_\_ No\_X\_\_

1. Will you conduct any part of this research outside of the United States?  
   **If yes, please indicate where.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Mexico\_\_\_\_\_\_\_\_** Yes\_X\_\_ No\_\_\_\_

**Section D. Project Description**

Briefly answer the following questions: *(Attach additional pages as needed)*

1. What is the purpose of the study?

**The purpose of this project is to document an endangered language through recordings and transcriptions and, with proper permissions, to use these materials for academic and educational purposes, both within the communities of origin (Mixtec-speaking villages in southern Guerrero, Mexico) and beyond (in Mexico and other countries, though also in other Mixtec-speaking communities outside of the region of recording).**

**The recordings are generally of fictional stories, archaic texts, information on the natural environment, and life history testimonials. Digital recordings are carried out in the field with a clearly visible recording device and a headset or lavalier microphone. The materials are then placed on computers for transcription by Rey Castillo, a native speaker of Yoloxóchitl Mixtec who has an advanced degree in linguistics and collaborates on this project. Copies (on CD) of all recordings are given to the respective narrators.**

**At the time of recording permission is sought (in Mixtec, a language in which my principal collaborator, Rey Castillo, is fluent) to use these materials for community and extra-community education and linguistic or anthropological research. There are three levels of consent, each explained and documented in conversations with the consultant/narrator:**

* **LEVEL 1: consent to record and transcribe and to use the material outside of the community for educational and research purposes, allowing the material to be made available to students and scholars. Consultants/narrators are told that any sensitive material on the recording will be removed (e.g., personal comments or information). An informed consent (see attached form) is signed. Consultants/narrators are always given the material to review before it is distributed beyond the community (e.g., in the US). In the event that they change their mind about the original agreement to scholarly and limited distribution, they will be allowed to restrict the distribution even further (in accord with access restrictions now in place in many digital libraries, e.g, the Archive of Indigenous Languages of Latin America at the University of Texas). The nature of Internet distribution is explained in Mixtec and Spanish in terms familiar to all participants (e.g., access to a recording as through a telephone, one can dial up and hear the text, etc.);**
* **LEVEL 2: consent to distribute the recordings and transcriptions to communities and bilingual schools in the area for non-profit educational and revitalization efforts that are now underway. Consultants/narrators will again hear the text they recorded; they will be allowed to remove any part of the recording/transcription (through sound/text editing) and determine the level of acknowledgement (named or anonymous). The written consent form, in Spanish, will be read to them and explained in Mixtec. There is a special section for allowing local community and school use. No commercial or for-profit use will be allowed. The consultants/narrators may decide not to release this material for local community and educational use.**
* **LEVEL 3: consent for commercial use of the recording. In the event that wider, commercial distribution of the recordings and transcriptions is sought, this will need to be arranged through a further contractual arrangement (note that Level 2 does not allow for-profit or commercial use). This separate arrangement with the authors/narrators will be undertaken with the organization or individual seeking commercial use.**

**NOTE: To date approximately 110 separate recordings have been made of Yoloxóchitl Mixtec, involving a dozen individuals and totaling over 40 hours. In all cases the narrators have agreed, signing the form with the relevant data listed (narrator's name and a list of the recordings made). This form (a blank copy of which is submitted with this request) allows the archiving and use of the material outside of the community for academic and educational purposes. A separate paragraph gives explicit permission to allow the recordings to be deposited locally and be made available to the community. It is important to note that to date all narrators have agreed to both permanent archiving (Archive of the Indigenous Languages of Latin America, U. Texas, and the Endangered Language Documentation Project Archive, School of Oriental and African Studies). In fact, many *insisted* that such distribution to their and other Mixtec-speaking communities be assured.**

1. How will you conduct the research? Describe all procedures that will involve subjects and estimate how long each procedure will take. Please attach surveys, interview questions, focus group questions, or other instruments that will be used in your research.

**Research has begun following the guidelines outlined here and supported by a Pilot Project Grant from the Endangered Language Documentation Programme. Grant support pending, the project will continue for another 4 years.**

**Two methodologies for recording are employed. In the first, narrators offer a small amount of material (perhaps 1 or 2 hours maximum) which is digitally recorded. In the second a pair of narrators work together, alternating recording, for a full day.**

**There are no surveys or any set interview questions although narrators may be asked, depending on their knowledge, to describe processes such as farming, production of material culture, and information on the natural environment.**

1. Describe the participation of human subjects in the research. Who will they be? How many will be involved? How will you select participants? Will this study target or exclude a particular ethnic or racial group?

**Subjects are recruited on a volunteer basis from the general population of Yoloxóchitl and surrounding Mixtec-speaking communities. The consultants/authors are approached personally. The project (documentation and education) is clearly explained and Level 1 consent is obtained before recording begins. Usually an audio CD of the recording is given to the narrator at this time along with a statement of rights and informed consent, which is signed in multiple copies (for the narrator, the project, and the archive). In the event that a CD cannot be made, it is later made and given to the narrator.**

**Almost all narrators are elderly (over 40 years of age) fluent speakers of Mixtec. Initial contacts were made through Rey Castillo, a native Mixtec speaker born in Yoloxóchitl, but presently many members of the community are aware of the project and volunteer to record.**

1. What are the risks to human subjects associated with this project (e.g., breach of confidentiality) and how will these risks be minimized? What are the benefits of this study?

**There are no risks to any narrators who participate in the study. Confidentiality is strictly respected. Most of the recordings are of fictional stories, elaboration and use of material culture, descriptions of the natural environment, and ritual texts. As stated, narrators are directly asked if they wish to allow the recorded material to be deposited locally and be made available to community members and local schools. As the narrators are given copies of the material, they can listen to their recordings and ask that any section be edited out (a simple process).**

**The major goal of this research is to document endangered language and culture and, with the required consent, to make this material available to the local educational institutions (as well as to students and researchers outside the community, again with the proper consent forms documented above). In regard to benefits, this research is oriented to language and cultural documentation, academic research and education in Mixtec. It enjoys the support of the director of the Instituto Nacional de Lenguas Indígenas, the Mexican federal institution charged with working with indigenous communities to preserve their languages and culture and develop government policies on language rights and education (see attached letter). The project also enjoys the strong support of the Yoloxóchitl community, as evidenced in the letter of support from the authorities.**

**In sum, the documentation project will create a permanent recorded and transcribed record of the endangered language, Yoloxóchitl Mixtec. It will be elaborated according to best practice procedure and archived in secure permanent sites. Without fail, the narrators and their families, and the villages, welcome the audio CDs of the recordings that they are given. The results will have important and significant benefits to the community in their efforts to preserve and revitalize their indigenous language.**

1. How will you record the data collected in this study? Will it be anonymous (no identifiers between subject and data) or confidential (you will be able to link data to a specific individual, but you will not reveal this information to anyone outside the project)? How will you store the data to ensure privacy is maintained? Who will have access to the data?

**Recordings are digital with a headworn cardiod microphone. ubjects are recruited on a volunteer basis from the general population of Yoloxóchitl and surrounding Mixtec-speaking communities. The consultants/authors are approached personally. The project (documentation and education) is clearly explained and Level 1 consent is obtained before recording begins. Usually an audio CD of the recording is given to the narrator at this time along with a statement of rights and informed consent, which is signed in multiple copies (for the narrator, the project, and the archive). In the event that a CD cannot be made, it is later made and given to the narrator.**

**As best fieldwork practice, I maintain a confidential database of information pertinent to all recordings (date, consultant data, genre, length, recording equipment, etc.). Consultants/authors may request anonymity even at Level 1 consent, although in general they request recognition of their expertise and authorship. This is usually desired by the consultant. If the consultant/author so requests, all distribution/publication of the material clearly recognizes their expertise authorship.**

**Permanent archiving will be servers at institutions such as the Archive of Indigenous Languages of Latin America (U Texas) that have their own protocol for access, respecting the wishes of the narrators and the instructions of the depositor. If the narrator requests anonymity (which has never occurred in 10 years of language documentation as the narrators are often proud of their expertise), this is respected, as are any instructions on limiting access (again, this has never occurred except in one case, and this was a desire to not archive the material locally, in the community).**

1. How will you get consent from the participants? If you want a waiver of written informed consent, please indicate that here.

N.B.—A waiver of written consent is appropriate when the only record linking the subject and the research is the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. The waiver does not eliminate the need to obtain verbal consent from the research participant.

**This research is oriented to language documentation, literacy training, and education in Yoloxóchitl Mixtec. The major goal of this research is to document endangered language and culture and, with the required consent, to make this material available to the local educational institutions (as well as to students and researchers outside the community, again with the proper consent forms documented above).**

**LEVEL 1: informed consent.**

**At this point consultants/authors will have the project explained to them and their consent requested for distribution outside of the local community for research and educational purposes. All explanations requests for consent will be given in Mixtec and Spanish in translation of the following below.**

**1) Project description (here I mention my goals and how this recording fits in with the goals)**

**My goals are to document local knowledge by recording what you have to say to me and then writing down exactly what you have said. I would like to allow people to hear this material for free and they can do so (here an explanation of Internet distribution) by using a machine similar to a telephone. They dial up and request to hear this text. They can hear it and follow the written version in Mixtec and, occasionally, their own language (English or Spanish). You will have an opportunity to hear this recording later so that you can ask me to remove any parts that you wish to be maintained confidential (so that no one hears them).**

**What is your name?**

**What village are you from?**

**How old are you?**

**Do you agree that I can let people here the material you have just recorded and do you understand that they will be allowed to do this for free, with no one making money from selling this recording?**

**Do you understand that if I want to make this material available locally (to the communities and schools) I will ask your permission separately.**

**LEVEL 2: informed consent**

**The attached form in Spanish will be explained orally and consultants/narrators will be asked to sign two copies, one for themselves and one for my archive. The basics of the form are the following:**

* **That the material was recorded with the narrator’s consent**
* **That they recognize the cultural and linguistic importance of the material**
* **That they will allow it to be used in non-profit ventures such as education, documentation, and analysis.**
* **That they will allow it to be transcribed.**
* **That they will allow it to be archived permanently**
* **That they will allow this material to be distributed freely (i.e., no profit) locally within the the regional Mixtec-speaking communities and schools as well as in other communities to be used in the public school system.**
* **That they understand that no commercial use will be nor can be made of this material unless additional consent is obtained**

1. How will your research findings be disseminated? Please check all that apply.

\_\_\_ Presentation at a workshop or conference

\_\_\_Poster presentation

\_\_\_Publication (please describe)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_X\_Other (please describe)

**Recorded material will be deposited in the major archives dedicated to maintaining digital recordings and text involving endangered langauges: the Archive of Indigenous Languages of Latin America, University of Texas, and the Endangered Language Documentation Programme archive at the School of Oriental and African Studies, London. Some use in academic publications (as per the agreement with narrators) may occur.**

**Section E. Elements of Informed Consent**

Every research study needs an informed consent document, even those that are exempt. Be sure to include the elements listed below in the document. If your data will be anonymous (i.e., not linking individual names with data nor recording any names of research subjects and/or information that can be identified to a particular research subject), you may request a waiver of written informed consent. Please attach a separate sheet indicating this request.

♦ Introduction (with a statement that this is research).  
♦ Purpose of study.  
♦ Description of study procedures.

♦ Duration of subject involvement.

♦ Identification of potential risks or discomforts to the subjects for participation in the study.

♦ Identification of potential benefits to subjects for participating in the study.

♦ Confidentiality of records statement—how this will be accomplished.

♦ Contact persons for questions related to the research.

♦ Statement of voluntary participation, including the option for subjects to withdraw from the study at  
 any time without penalty.

Also, follow the guidelines for the informed consent document:

♦ Use simple language targeted at a 6th grade reading level.

♦ Use font size 12 point or larger and no more than 6 lines per inch.

♦ Use reasonable margins and include a blank line at the bottom of the header and the top of the

footer to keep them separated from the text.

♦ Avoid scientific and technical terms.

♦ Consent forms written in the second person are preferred, but first person is allowed. Pronoun use

must be consistent throughout the document.

♦ Use more than one consent form, if appropriate, and add a qualification to the consent document   
 title to identify the target population (e.g., children, adults, etc.)

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**Office Use Only**

\_\_\_\_\_\_ This research project is **exempt** from IRB review based on 45 CFR 46.101(b)\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_This project is **approved** as submitted.

\_\_\_\_\_\_This project is **approved contingent** on the changes listed below.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_A **waiver** of informed consent is granted.

**F. Information on Expedited Review**

An expedited review procedure consists of a review of research involving human subjects by the IRB Chairperson and his/her designate without review of the protocol by the entire IRB. To qualify for expedited review, the study must

1. present no more than minimal risk i.e., the probability and magnitude of harm or discomfort to the subject from participation in the research are no greater than that encountered in normal day-to-day activities or during routine physical or psychological examinations or tests **AND**
2. qualify under one of the following categories:

1.a. Clinical studies of drugs for which an investigational new drug application is not required.

1.b. Clinical studies of medical devices for which an investigational device exemption application is not required or the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collect may not occur more frequently than two 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 less of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than two times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. *Examples:* a) hair and nail clippings in a non-disfiguring manner; b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; c) permanent teeth if routine patient care indicates a need for extraction; d0 excreta and external secretions (including sweat); e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or way or by applying a dilute citric solution to the tongue; f) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; g) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; h) sputum collected after saline mist nebulization.

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 generally not 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) 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.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes.

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

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.

Name of Reviewer \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Box #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_E-mail \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_