PROTOCOL NARRATIVE
University of California, Irvine
Institutional Review Board
Version: March 2006

HS#:_____
For IRB Office Use Only

Lead Researcher Name: Allison Fish
Title: Digitizing Traditional Knowledge: Reactions to Intellectual Property Claims on Yoga

Important: Please read the **instructions** before completing this protocol narrative.

NON-TECHNICAL SUMMARY

Provide a non-technical summary of the proposed research project that can be understood by IRB members with varied research backgrounds, non-scientists and community members. The summary should include a brief statement of the purpose of the research and related theory/data supporting the intent of the study and a brief description of the procedure(s) involving human subjects. *This summary should not exceed more than ½ a page.*

Issues surrounding the management, generation, and circulation of traditional and cultural knowledge are the subject of increasing debate at local and global levels and the new tools and techniques that are developing in response will have wide ranging impacts. Using the case study of transnational yoga (which I define as the practice of yoga in commercial exchange) this project examines how traditional knowledge is contested and reconfigured in the contemporary era. Specifically, the PI will be following the debates and reactions in the transnational yoga community that were sparked by one US yoga school's attempt to enforce copyright claims to a sequence of asanas (postures). This project explores how, given modern market logics, traditional practices such as yoga become the subject of globally franchised businesses and how local, national, and international events influence these flows. Furthermore, this project analyzes how the globalization and commercialization of tradition prompts new understandings of not only yoga, but information management techniques, to emerge.
Significance: This study is invested in the following domains: (1) Tracking new understandings of yoga and its practice, (2) Tracking the emergence of new concepts of information and its management, (3) Studying how the market incorporates tradition, and (4) The rearticulation of the boundaries between the public and private domains.
Methods: Ethnographic research will take place in the United States (4 months), Hong Kong (2 months), and India (10 months). Data will be collected through archival research, participant-observation, and interviews.

SECTION 1: PURPOSE AND BACKGROUND OF THE RESEARCH

1. Describe the **purpose of the research** project and state the overall objectives, specific aims, hypotheses (or research question) and rationale for performing the study.
2. Provide the **relevant background information** on the aims/hypotheses (or research

question) to be tested and the procedures/products/techniques under investigation.
3. Include a description of the predictor and outcome variables, as appropriate.
4. Include a critical evaluation of existing knowledge, and specifically identify the information gaps that the project intends to address.
5. Describe previous research with animals and/or humans that provides a basis for the proposed research. Include references/citations, as applicable.

Traditionally, yoga is a five thousand year-old Indian philosophy that trains the embodied mind to accept Truth through a combination of physical and mental practices. These practices were compiled into an eight-fold path by the ancient sage, Pantanjali in his work *The Yoga Sutras.* In the past five decades cosmopolitan consumers, mostly in the United States, Europe, Japan, and Australia, who are attracted to indigenous and orientalized alternative health and exercise practices, have created a market demand for transnational yoga (Alter 2005, De Michelis 2004, Strauss 2005). This practice of yoga for commercial exchange is a multi-billion dollar industry that has recently become a site of increasing regulation and the subject of management practices. The primary questions these techniques are meant to resolve include: (1) What is yoga and its practice?, (2) What is its public or private nature?, and (3) Who has the right to manage an expression or represent a practice? Different parties are using different information management techniques to answer these questions and to preserve control over different aspects of the international yoga market. In the most notorious example of this phenomenon a California-based international yoga franchise, the Bikram Yoga College of India (BYCI), attempted to enforce its copyright claim for a popular 26 posture yoga series. This attempt resulted in two US federal district court cases --- both of which received significant amounts of attention in the international yoga community. This project seeks to examine the reactions provoked by this event in the transnational yoga community at locations in India (the origin of the traditional practice), the United States (the location of the BYCI controversy), and Hong Kong (a globalized city where yoga is emerging as a widespread practice).

Despite the settlements, the BYCI lawsuits have brought public attention to the question of the nature and appropriate management of yogic knowledge should be managed. In the wake of this event several interested groups have weighed in on this matter, including;

1. The claim by Bikram Choudhury that a series of yoga postures can be the invention of a singular author and subject to IP protections.
2. The claim by traditionalists, such as the Bihar and Iyengar schools, that yoga is a spiritual practice that exists in the public domain.
3. The Open Source Yoga Unity (OSYU) argument that advocates the application of Open Source philosophies to yoga. OSYU formed specifically to challenge the BYCI claims and was the plaintiff in one lawsuit. And
4. A group of Indian scholars' attempt to define, catalogue, and preserve the traditional nature of yogic knowledge through the creation of a digital library containing ancient yoga-related texts translated into five languages and illustrating over 1500 postures.

Through the case study of transnational yoga this project explores how tradition goes global and how local, national, and international systems influence these flows. The hypothesis of this project is that the real significance is not which party emerges as the victor in a particular legal dispute over the proprietary nature of a cultural practice. Instead, the significance is how the subjects, yoga and information, get redefined through debates sparked by such high-profile events and how this process is rationalized by affected parties. Further, the dissertation hypothesizes that differently positioned parties reformulate their understandings of nature of yoga and information based on the positions that each actor assumes in the public debate.

SECTION 2: ROLES AND EXPERTISE OF THE STUDY TEAM

List all study team members below.

1. Describe their **specific role and responsibility** on the study in the text box provided.
2. **Faculty Sponsors** - list as Co-Researchers and describe their role on the project; include oversight responsibilities for the research study.
3. Explain who will have access to subject identifiable data.
4. Indicate who will be involved in recruitment, informed consent, research procedures/interventions, and analysis of data.
5. Provide a description of their **qualifications, level of training and expertise**. Include information about relevant licenses/medical privileges, as applicable.

Lead Researcher:

Allison Fish

1. Lead Researcher
2. Complete access to subject identifiable data.
3. Involved in recruitment and informed consent, research procedures, and analysis of data.
4. Level of training: Graduate student in Anthropology, Several courses in anthropological research methods completed with a GPA of 4.0. Four years of ethnographic research experience at the Bureau of Applied Research in Anthropology at the University of Arizona under the supervision of Dr. Diane Austin.

Co-Researcher(s):

Dr. William Maurer

1. Faculty Sponsor of lead researcher – complete oversight of PIs dissertation research
2. Access to subject identifiable data if need should arise or PI requires advising on a matter.
3. Qualifications: Dr. Maurer is an associate professor and chair of the department of Anthropology at UCI. He specializes in the anthropology of law and property with a special interest in the creation of the public/private dichotomy. He has provided guidance for several other graduate students in anthropology conducting international ethnographic research to their successful completion of the Ph.D.

Research Personnel:

None

SECTION 3: RESEARCH METHODOLOGY/STUDY PROCEDURES

1. Provide a detailed description of **each** phase of the study (e.g., pilot, screening, intervention, and follow-up).
2. Include the sequence and timing of **all study procedures** to be performed.
3. When applicable, provide information about the **measures and outcome variables** and the **statistical methods of analysis**.

Additional information about completing this section is included in the Protocol Narrative instructions.

The research consists of a two-pronged, multi-sited ethnography (Marcus 1995) to take place in the US, Hong Kong, and India. The first prong focuses on four international yoga schools with different styles of practice and understandings of the nature of yogic knowledge:

(1) The Bikram Yoga College of India,
(2) The B.K.S. Iyengar School of Yoga,
(3) The Art of Living, and
(4) The Bihar School of Yoga.

The second prong will focus on the reactions provoked by the Bikram Yoga College of India lawsuits in the transnational yoga community.

Research in each of the locations will consist of (1) archival materials, (2) participant observation, and (3) semi-structured interviews (Bernard 2002).

Archival materials: Archival materials related to the functioning of the yoga schools will be collected and analyzed to develop an understanding of the organizations. Additionally, materials such as advertising and promotional literature, press releases, and annual reports related to yoga schools' management will be analyzed.

Participant-Observation: Data for research done via participant-observation will be conducted in yoga classes of the four schools. Data will be collected in the PI's field notes. The notes generated from participant-observation in yoga classes will focus on delivery of instruction, who may instruct others, what is emphasized (e.g., knee alignment, breath work, or awareness), and class composition. Data from these notes will be coded and analyzed against each other in an effort to understand how (1) teacher and student relationships compare across the different schools, (2) studios differ, (3) information collected during the interviews and archival analysis compares to actual teaching styles, and (4) how transmission of information is related to beliefs of the appropriate management practices for yogic knowledge. Through participant-observation the PI expects to capture the behind-the-scenes discussions and assumptions that do not always surface during formal interviews. Participant-observation will help the PI to understand the individual's consciousness as well as their situated understandings of concepts like yoga, culture, tradition, and the market. Building a compendium of people's everyday categories, taxonomies and understandings will be crucial to analyzing the relationship between yogic doctrine and practice.

Interviews: Interviews will be conducted with different groups of people including yoga school operators, teachers, studio owners, not-for-profit yoga organizations (e.g., Open Source Yoga Unity), yoga practitioners, and scholars working on the digital yoga library. During interviews the researcher will be particularly attentive to discourses of ethics and morality with regard to how traditional cultural knowledge (i.e., yoga) is or should be treated and what methods of management are most appropriate. The PI expects to interview not more than 60 people in total (12 in US, 8 in Hong Kong, and 40 in India). The PI expects to conduct interviews primarily in English. English is an official state language in all locations and a common language of daily use for most individuals practicing transnational yoga. However, if a subject desires to use another language in which he or she feels more comfortable, then a translator will be hired. Should the interviewee consent, then the interviews will be audio-taped. The audio-tapes will be transcribed within one year of the taping and the tapes will be destroyed within two years of the close of the project. Please find attached to this document a set of semi-structured interview questions to be used for the interviews (see document titled "Interview Questions").

Data Analysis: A major portion of the data analysis will focus on a comparison of archival materials to participant observation to interviews. To do this the PI will use computer programs

designed for textual data analysis such as NUDist, InVivo, and TAMS. The PI has used these and similar computer programs previously in the course of anthropological research.

SECTION 4: SUBJECTS (PERSONS/CHARTS/RECORDS/SPECIMENS)

A. Number of Subjects (Charts/Records/Specimens)

1. Indicate the **maximum number of subjects to be consented** on this UCI protocol. • Include projected screen failures and early withdrawals. • For Mail/Internet surveys include the number of people directly solicited. • If the study involves use of existing charts, records, specimens, specify the maximum number that will be reviewed to compile the data or the sample population necessary to address the research question.
Maximum number of subjects: 100 for interview component of study. 150 for observation component of study.
2. Of the maximum number of subjects listed above, indicate the **target sample size** for the study. • The target sample size is the number of subjects expected to complete the study or the number necessary to address the research question. • If the study only involves use of existing records, charts, specimens, specify the target number needed to address the research question.
Target sample size: 60 for interview component of study. 80 for observation component of study.
3. Explain **how the study sample size was determined** (e.g., power analysis; review of related literature).
Literature on ethnographic methods recommends a minimum of thirty research subjects and, given a one to one-and-a-half year research period, a maximum of 100 (Bernard 2002).
4. For **multi-center research**, indicate the overall sample size for the entire project (across all sites).
[XX] Not applicable - This study is not a multi-center study.

B. Inclusion and Exclusion Criteria

1. Describe the **characteristics** of the proposed subject population (age, gender, health status, language, etc.)

The subject population includes those people who are involved in yogic practice and the generation and exchange of yogic knowledge. This includes yoga teachers and the creators of the digital yoga library. It takes several years of education, training, and practice to become a yoga guru or teacher. Therefore, all the study participants will be much older than 18 years.

I expect that most subject participants will be able to speak English fluently as English is a state language of each country and the subject groups that I expect to interview (transnational yoga practitioners and instructors and academics creating the digital yoga library) are an elite and highly educated group. However, should any subject prefer to speak in a language other than English for the sake of his/her comfort or clarity, the PI will hire a translator.

2. Provide the **inclusion and/or exclusion criteria** for the proposed subject population, as applicable.

[ ] Not applicable – This is not a clinical investigation and/or characteristics of the population sufficiently describe the proposed subject population.

The inclusion criteria for the subject population includes members, specifically advanced yoga students and teachers (often teachers consider themselves to be advanced students of yoga), of the four yoga schools studied and the scholars creating the digital yoga library.

3. If inclusion/exclusion is based on age, gender, pregnancy/childbearing potential, or race/ethnicity, **provide a scientific rationale**.

<Type here>

SECTION 5: RECRUITMENT METHODS AND PROCESS

A. Recruitment Methods

Please check **all** applicable recruitment methods that apply to the study. Place an "**X**" in the bracket **[ ]** next to the recruitment method.

[ ] This study involves no direct contact with subjects (i.e., use of existing records, charts, specimens)

- Skip to Section 6.

[ ] UCI IRB approved advertisements, flyers, notices, and/or media will be used to recruit

subjects.

- Passive Recruitment - Potential subjects initiate contact with the study team.
- Complete Question 5B - Explain where recruitment materials will be posted.

[XX] The study team will recruit potential subjects who are unknown to them (e.g., snowball sampling, use of social networks, direct approach in public situations, random digit dialing, etc.)

- Active Recruitment – Researchers contact potential subjects.
- Complete Question 5B.

[ ] The UCIMC Clinical Trials web page will be used.

- Passive Recruitment - Potential subjects initiate contact with the study team.
- Skip to Section 6.

[ ] The UCI Social Sciences human subject pool will be used.

- Passive Recruitment - Potential subjects initiate contact with the study team.
- Skip to Section 6.

[ ] Study team members will contact potential subjects who have provided permission to be contacted for participation in future research studies.

- Active Recruitment – Researchers contact potential subjects.
- Complete Question 5B – Explain when and how these individuals granted permission for future contact; provide the IRB protocol numbers, if applicable.

[ ] Study team members will approach their own patients, students, employees for participation in the study.

- Active Recruitment – Researchers contact potential subjects.
- Complete Question 5B.

[ ] Study team members will send UCI IRB approved recruitment materials (e.g., recruitment flyer, introductory letter) to colleagues asking for referral of eligible participants.*

- Passive Recruitment - Potential subjects initiate contact with the study team or
- Active Recruitment – Colleagues get permission from interested individuals to release contact information to researchers. Researchers contact potential subjects.
- For Active Recruitment, complete Question 5B.

**Additional requirements for using this recruitment method are included in the Protocol Narrative instructions.*

[ ] Study team members will provide their colleagues with a UCI IRB approved introductory letter. The letter will be signed by the treating physician and sent to his/her patients to inform them about how to contact study team members.

- Passive Recruitment - Potential subjects initiate contact with the study team.
- The IRB approved letter must be sent by the treating physician.
- The study team does not have access to patient names and addresses for mailing.

- Skip to Section 6.

[ ] UCI study team members will screen UCIMC medical records to determine subject eligibility and approach patients directly about study participation.*
  - Active Recruitment – Researchers contact potential subjects.
  - Complete Appendix T to request a partial waiver of HIPAA Authorization.
  - Complete Question 5B.

**Additional requirements for using this recruitment method are included in the Protocol Narrative instructions.*

[ ] Other Methods: <indicate the recruitment method(s) here>
  - Complete Question 5B, as applicable.

B. Recruitment Process

1. Based on the boxes checked above, describe and provide **details of the recruitment process** (i.e. when, where, by whom and how potential subjects will be approached).
2. If active recruitment methods will be used, explain how the individual's privacy will be protected.

The PI will contact potential subjects through personal contact or email, letter, or by publicly listed phone number. This contact information will be collected via public documents, such as telephone books or websites. In each case the PI will explain the project, its purpose, and proposed products to the potential subject before requesting participation. For consideration of participation the PI will offer the subject a printed letter that details the project (Please find attached the document titled "Recruitment Letter"). Additionally, this letter will contain the PI's contact information (both local phone number and email address), her supervisor's contact information (UCI office phone number and email address), and the Human Research Protections Program contact information (email) should the subject have any concerns or in case of emergency.
Subjects already participating in the research will be asked for references to other suitable subjects. When receiving these references the PI will ask if she can use the name of the original subject when contacting the potential subject or if the original subject will personally make the introduction. In all cases the wishes of the original subject will be honored in terms of confidentiality.
In all other cases the identity of informants will be kept confidential.

SECTION 6: INFORMED CONSENT PROCESS

Describe the specific steps for obtaining informed consent.
1. Include information about **when and where** consent will take place and the **length of time** subjects are given to decide whether they wish to participate.
2. If study team members will approach their own patients, students, or employees for participation in the study, explain what precautions will be taken to **minimize potential undue influence** or coercion, and how compromised objectivity will be avoided.

Check all that apply:

[ ] Written (signed) informed consent will be obtained from subjects. Explain below.

[X] Requesting a waiver of written (signed) informed consent. Explain below and complete Appendix P.

[XX] Requesting a waiver of informed consent (no consent). Complete Appendix O. Skip to Section 7.

A waiver of written (signed) informed consent is requested for the interview component of the research.
Justification:
This request is justified because the research poses no more than minimal risk to the participants and because the research involves activities for which consent is normally required outside of the research context. For a detailed explanation of these points please see Appendix P.

A waiver of informed consent (no consent) is requested for the observation component of the research.
Justification:
This request is justified because (1) the research will involve no more than minimal risk to the participants, (2) this waiver will not adversely affect the rights or welfare of the participants, (3) research on yoga classes could not practicably carried out without this waiver, (4) the participants will be provided with information regarding the study through the classes yoga teacher, and (5) the research is not a clinical investigation subject to FDA approval. For a detailed explanation on each of these points see Appendix O.

3. **Non-English Speaking Participants:** In order to consent subjects who are unable to read and speak English, the English version of the consent form must be translated into appropriate languages once IRB approval is granted.

Check all that apply:

[ ] Not applicable - Only individuals who can read and speak English are eligible for this study.

[X] The English version of the consent form will be translated into appropriate languages for non-English speaking subjects once IRB approval is granted. **Note:** The IRB must stamp the translated consent forms before they are used. An interpreter will be involved in the consenting process.

[ ] Requesting a short form consent process. Complete Appendix Q.

SECTION 7: RISK ASSESSMENT AND POSSIBLE BENEFITS

Review of the instructions for this section is strongly recommended.

A. Risk Assessment

Place an "**X**" in the bracket **[ ]** next to the level of review (based upon the investigator's risk assessment).

[ ] This study requires **full committee** review.

[X] This study qualifies for **exempt or expedited review** status. List the applicable exempt or expedited category(ies) and provide justification for the level of review and for the category(ies) chosen in the space below:

This study is eligible for Expedited Review as it proposes to collect interview and participant-observation data on non-sensitive subjects (ie, the study participant's relationship with yogic practice and the generation/exchange of yogic knowledge). There is a risk for that an invasion to the subject's privacy will result from research activities (please see the description of risk below in section 7B). In an attempt to prevent and minimize this risk I will assign all subjects a random identification number. This random identification number will be used to organize data and in field notes. The key linking subject contact information and the random identification number will be kept in a separate and locked location from the data and field notes.

B. Risks and Discomforts

1. Describe the **risks/potential discomforts** (e.g., physical, psychological, social, economic) associated with **each** intervention or research procedure.
2. Estimate the probability (e.g., chance or likelihood of occurrence) that a given harm may occur and its severity (e.g., mild, moderate, severe).

The only conceivable risk from the study is that personal information about informants and their relationship to yoga could be revealed. However, I will take measures to ensure against the risk of improper disclosure. I will change all identifying information of the subject at the locations of data storage to protect confidentiality, following standard anthropological practice.

3. Discuss what measures have been taken and/or will be taken to **prevent and minimize** any risks/ potential discomforts.

The PI has taken several courses and independent study classes related to ethnographic research methods in order to become aware of points that may require sensitive treatment.
If, at any time during the course of the research, the PI becomes aware that project-related activities are causing risk or discomfort to the subjects, then she will immediately cease these activities. The PI will immediately contact her supervising professor for advice on what course of action to take. All efforts will be made to see that risks and potential discomforts will be prevented or minimized.

4. For **Full Committee protocols**, state whether any study procedures may involve risks to the subject (or embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.

[XX] Not applicable - This study qualifies for Exempt or Expedited review.

C. Potential Benefits

1. Discuss the benefits that may accrue **directly to the subjects**. *Note: Compensation is not a benefit. Do not include it in this section.*

[XX] There is no direct benefit anticipated for the subjects.

<Type here>

2. Describe the **potential societal/scientific benefit(s)** that may be expected from this study.

An increased understanding of how yogic and other bodily knowledges are represented, generated, circulated, managed, and subject to change. Additionally, it will help to answer the question, "What is yoga and its practice?" both in a traditional and its transnational context.

D. Risk/Benefit Assessment

For **Expedited and Full Committee protocols**, explain why the study risks are reasonable in relation to the **potential benefits** to subjects and society.

[ ] Not applicable - This study qualifies for Exempt review; there is virtually no risk/potential discomfort to the subjects.

Though risk is possible, it is highly unlikely that lasting damage will occur to the participating subjects who discuss their understandings of and involvement with yoga with the PI. Thus, the potential scholarly benefits, which address the intersection of tradition and modernity, that will result in this study are, in relation, reasonable.

SECTION 8: ALTERNATIVES TO PARTICIPATION

Describe appropriate **alternative procedures or courses of treatment**, if any, which might be advantageous to the subject or indicate that the only alternative is non-participation.

[XX] No alternatives exist. The only alternative to subjects is not to participate in the study.

SECTION 9: ADVERSE EVENT REPORTING/MANAGEMENT AND COMPENSATION FOR INJURY

A. Adverse Events and Unanticipated Problems

1. Indicate that you are familiar with UCI's Adverse Events/Unanticipated Problems reporting policy and procedures. See http://www.rgs.uci.edu/ora/rp/hrpp/adverseexperiences.htm for details.

[ ] Not applicable - This study involves no subject contact (i.e., use of existing records, charts, specimens).

[XX] The researchers will comply with UCI's Adverse Events/Unanticipated Problems reporting policy and procedures.

2. Explain how the research team will respond to **adverse events and unanticipated problems** that may occur during the study or after completion of the study.

[ ] Not applicable - This study involves no subject contact (i.e., use of existing records, charts, specimens).

[ ] Not applicable - This study qualifies for Exempt review; there is virtually no risk to the subjects.

Because adverse events are associated with the use of a medical product or clinical test article (both of which are not incorporated into this research design) it is unlikely that one will occur. However, should it or an unanticipated event occur the PI will immediately contact her Faculty Sponsor and they will work together to address the issue. All unanticipated problems and adverse events will be reported to the Human Research Protections Program in writing within the appropriate time period (48 hours for the latter).

B. Compensation for Injury

For **Full Committee protocols**, explain how costs of treatment for research related injury will be covered.

[XX] Not applicable - This study qualifies for Exempt or Expedited review.

[ ] Subjects who are injured as a direct result of their participation in this study will be provided reasonable and necessary medical care to treat the injury at no cost to them or their insurer/third party payer. The University of California does not routinely provide any other form of compensation for injury.

[ ] Other: <Type here>

SECTION 10: PARTICIPANT COSTS

Identify and estimate those costs to be borne by subjects or their insurers, including costs of standard medical interventions or procedures.

[ ] Not applicable - This study involves no subject contact (i.e., use of existing records, charts, specimens).

[XX] There are no costs to subjects/insurers.

<Type here>

SECTION 11: PARTICIPANT COMPENSATION AND REIMBURSEMENT

If subjects will be compensated for their participation, provide detailed information about the amount and the method/terms of payment (e.g., money; check; extra credit; gift certificate). In addition:

1. Describe the schedule of compensation (e.g., at end of study; after each session/visit).
2. Compensation should be offered on a prorated basis.
3. Specify whether subjects will be reimbursed for out-of pocket expenses. If so, describe any requirements for reimbursement (e.g., receipt).

[ ] Not applicable - This study involves no subject contact (i.e., use of existing records, charts, specimens).

[XX] No compensation will be provided to subjects.

[XX] No reimbursement will be provided to subjects.

<Type here>

SECTION 12: CONFIDENTIALITY OF RESEARCH DATA

1. Explain how data will be **collected and recorded**.

Data Collection/Method of Recording (check all that apply):

[XX] Paper documents/records
[XX] Computer files/database
[XX] Audio recording

[ ] Video recording
[ ] Photographs
[ ] Biological specimens
[ ] Other(s) (specify): <Type here>

2. Indicate whether **subject identifiers** will be linked (directly or indirectly via a code) to the research data.

[ ] No Subject Identifiers will be collected
(i.e., the data are anonymous; no one, including the study team, can link subjects to their data)

[XX] Indirect link to Subject Identifiers
(i.e., a code will be assigned to the data and a key linking the code to the identity of the subjects exists)

[ ] Direct link - Subject Identifiers will be maintained with data
(i.e., personal or private information about the subjects are associated with the data)

List the direct identifiers here: <Type here>

[ ] Other (explain here): <Type here>

3. Indicate **how data will be stored, secured** including paper records, electronic files, audio/video tapes, specimens, etc.
NOTE: *The more sensitive the study data, the more sophisticated the methods should be to maintain confidentiality.*

Electronic Data (check all that apply):
[ ] Anonymous or de-identified data only
[XX] Coded data with the code key kept in separate location
[XX] Encryption or password protection software
[ ] Secure network server
[ ] Stand alone desktop computer (not connected to server/internet)
[ ] Other (specify here): <Type here>

Hardcopy Data, Recordings and Specimens (check all that apply):
[ ] Anonymous or de-identified only
[XX] Locked file cabinet or locked room at UCI/UCIMC
[ ] Locked lab/refrigerator/freezer at UCI/UCIMC
[ ] Other (specify here): <Type here>

4. **Data on portable devices:**
   - Describe the portable device(s) to be used (e.g. laptop, PDA).
   - Specify whether subject identifiable data will be stored on the device. If so, **justify why it is necessary** to store subject identifiers on the device.

Note: only the "minimum data necessary" should be stored on portable devices.

[ ] Not applicable – No study data will be maintained on portable devices.

Because this is a fieldwork-based project and the PI will be abroad for the majority of its duration, the PI must use her laptop to store data. The PI's laptop is password protected. Only the minimum data necessary will be stored on the laptop and it will not be hooked up to the internet during the time when data is stored on the device.

5. Specify who will have **access to subject identifiable data and records**.

[ ] Not applicable – No subject identifiers will be collected.

[XX] The research team, authorized UCI personnel, the study sponsor (if applicable), and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to study records to protect subject safety and welfare. Any study data that identifies the subjects will not be voluntarily released or disclosed without the subjects' separate consent, except as specifically required by law. Publications and/or presentations that result from this study will not include subject identifiable information.

[ ] Other: <Type here>

6. Explain how long the research data (hard copy documents, computer files, recordings) will be **retained** once the research has been completed (e.g., destroyed upon study completion; stored for future research; retained for a specified timeframe, etc.)

Note: If your study involves the creation of a research database, specimen repository, or you plan to share data or specimens for secondary uses or analyses, Appendix M is required.

The audio-tapes of the interviews will be transcribed within one year of the date of the interview. Within two years of the close of the project the audio-tapes will be destroyed. The audio-tapes will be kept after the transcription and until the close of the project because such things as tone of the interviewee may be significant to the findings.
All other research data will be retained for two years after the close of the project. At this time the research data will be destroyed.

7. **Certificates of Confidentiality:**
   - Specify whether a Certificate of Confidentiality (COC) has been requested from the NIH.
   - If yes, explain in what situations personally identifiable information protected by a COC will be disclosed by the UCI study team.

Note: A copy of the COC should accompany the IRB application or be provided to the IRB upon receipt.

[XX] Not applicable – No COC has been requested for this study.

<Type here>