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PSI Guidelines for Deciding Whether an Activity Requires REB Review

I. Overview

This document provides guidance to help PSI staff determine whether research activities require review by the PSI's Research Ethics Program (REP). Considerations include whether "human subjects" are involved and, if so, whether the study is "research" according to the definitions of the USG's Office of Human Research Protection (OHRP). Examples of PSI studies that require review as well as those that may not require review are provided, as well as a brief summary regarding who at PSI should make these determinations.

All PSI studies that qualify as human subjects research require review by a research ethics board, either PSI's or an alternate board. Review of a study protocol does not necessarily mean that a review takes place at a board meeting. In most cases, human subject research at PSI is considered minimal risk and classified as either exempt or expedited from full board review, which means protocols can reviewed whenever they are submitted - on a rolling basis.

The PSI REP recognizes that many organizations provide guidance about making the research/non-research determination. This document draws from various sources as well as PSI REP experience and represents PSI's procedure for making this decision. The concepts described here should be applied to all research conducted by or under the direction of PSI.

The first step in determining whether a study requires review by the Research Ethics Program is to determine if human subjects are involved. If they are, then the next step is to decide whether the study qualifies as research. If human subjects are not involved in a study, no REB review is needed, regardless of whether the study is considered research. Both of these elements are described in order below.

II. Human Subjects

OHRP defines a **human subject** as "a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual *or* identifiable private information.[1]"

Other definitions include:

a. **Intervention** includes physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Examples of interventions conducted at PSI include HIV testing, IUD insertion and drawing blood. Case control studies whether bio-medical or socio-behavioral also by definition include interventions.

[1] 45 CFR 46.102f

b. **Interaction** includes communication or interpersonal contact between investigator and subject. Surveys, interviews, and focus groups are all methods used by PSI researchers that involve interaction with subjects.
c. **Private information** is information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Examples of private information include sexual behavior and history or risky behaviors such as drug use or frequenting commercial sex workers. Private information can also be information collected for another purpose such as clinic registration forms, health history forms, and records of school grades or attendance. Identifiable information is a specific type of private information that includes first and last names, birth date, address (number, street, city), GPS coordinates of a private residence, identification number, audiotapes and photos among others[2]. See Appendix A for a more thorough list of identifying information.

Some determinations of human subjects are easy. For example, PSI TRaC studies almost always include human subjects since their methodology includes obtaining data about individuals through interaction with them. On the other hand, the phrase "about whom" in the definition of human subject can be problematic. For example, a PSI researcher enters a sales outlet, observes whether a product is available and asks the shop owner questions about the availability and sales of the product. In this case, the PSI REB may determine that this study does not involve human subjects because the information collected is not *about* the outlet worker. However, if information is collected about the owner, particularly identifiable information, the study moves into the human subjects realm.

PSI researchers often study pre-existing data either from clinic records or from previous TRaC or MAP studies. These studies do not involve direct interventions or interactions with the individuals of interest. In these cases, deciding whether human subjects are involved depends on whether the data being analyzed includes identifiable private information based on the definition provided above. If names and/or birth dates are included in the data set, then the studies include human subjects. If the data is "de-identified", then the study is usually determined not to involve human subjects. Note that identifiable clinic data should only be used if the subjects have previously given their permission for their private information to be used for research purposes. In addition the original consent document and/or donor guidelines may include time frames in which such data may be used.

III. Research

OHRP defines **research** as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge[3].

Other definitions include:

[2] Ibid.
[3] 45 CFR 46.102d

a. **Systematic**: involves processes such as control groups, random or purposeful selection of subjects, statistical tests, sampling plan, etc. to gather data.

b. **Generalizable knowledge:** results that are used to "draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program (e.g., publications or presentations)."[4] Another useful definition is new information that can be useful for understanding other populations that are similar to the participants in a particular study.

Since most PSI studies are systematic in some way, a more useful starting point is to articulate the **intent of the study**. The Centers for Disease Control (CDC) maintains that if the primary intent of the study is to generate generalizable knowledge to improve public health practice, then the study qualifies as research. The benefits of the study may or may not include study participants, but will always extend beyond the study participants, usually to society".[5]

The intent to publish the results of a study is sometimes considered sufficient to qualify a study as research. However, publication alone does not make a study research[6]. Instead, the concept of publication is linked to the generalizability component described above. If study results are generalizable because they contribute to the body of knowledge about a specific target group, product, or service, then the study is considered research regardless of whether the researchers plan on publishing the results. In many cases, researchers publish study results for the simple reason that they may be generalizable to other populations or helpful to other development actors. For example, the female condom has undergone several changes recently and PSI researchers in country X designed a study to test the acceptability of these changes among their target audience for female condoms. The researchers also planned on presenting the results of this study at an upcoming female condom conference. The PSI REB determined this study to be research because the study was adding to a body of knowledge about the changes to the product. The presentation of results at a conference was not the reason for deciding the study was research. It was, however, the byproduct of adding to the global knowledge about a newly modified product.

As shown in the above example, studies that **test new products or services** are also often considered research because their results contribute to enriched global public health knowledge about the marketing and acceptability of these new products or services. As a result, when PSI designs studies to test new products, changes to products, new counseling protocols, or methods of increasing service/product uptakes, these studies may qualify as research.

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[4] *Activities that Require IRB Review*, University California Irvine

[5] *CDC Guidelines for Defining Public Health Research and Public Health Non-Research*

[6] Amdur, Robert J. Institutional Review Board Management and Function, Jones and Bartlett Publishers, 2002. p.121.

Interestingly, the level of risk involved for study participants has no bearing on the research versus non-research determination.

Example: A PSI HIV prevention program in a capital city aims to increase knowledge of HIV prevention and use of condoms by clients of female sex workers. The program includes outreach to clients of commercial sex workers and multiple media messages targeted at clients. The study utilizes qualitative interviews and photo narratives to address specific research objectives in relation to the determinants of consistent condom use among clients of female sex workers. The data will help the platform improve communication messages targeting clients of female sex workers in the capital.

Whether the above study is research depends on how the data from the study will be used. If the data will be used solely to improve communications messages to the clients of FSWs in the capital city and is therefore not being generalized to other groups, then it is likely that this study would be considered non-research, since the data are not generalizable. If the data will be used to improve communications messages to the target group in other cities throughout the country, this data may be considered generalizable, and therefore research, since the results are being used beyond the group from whom the study was originally conducted. Similarly, if the results of the study are considered useful for other platforms or organizations implementing programs with clients of sex workers in the region or even worldwide, then this study would likely be considered research because it is adding to a body of knowledge about work with this target group globally.

The determination of research versus non-research is rarely black or white. It is nuanced and subtle. Below are some questions to help in this determination. If the answer to any of these questions is "yes", then the study is most likely research.

 Are the conclusions of the study **generalizable** beyond the population in which the data were gathered, either to other similar populations, to other geographic areas or through adding to the body of knowledge on a specific product, service, or target group?
 Will the conclusions of the study be **shared with an audience wider than program staff** through presentations and publications because of its usefulness to other program implementers? If so, are the results being shared because the results are in some way generalizable (see above)?
 Does the study evaluate or test **a new, modified, or previously untested** product or service?

Recall that the REB only reviews research related to human subjects. To help in making both the "human subject" and "research" determinations, a decision tree is included in Appendix B that summarizes the key information for both of these components.

IV. Non-Research

Non-research studies are those whose **exclusive objective** is to improve individual PSI programs. The results will not be generalized to other populations and will not be shared

outside of the program, except with the donor and Ministry of Health. The benefits of the study are primarily or exclusively for the participants/clients of a specific PSI program in a given community or country.

PSI non-research studies are usually either Quality Improvement or Information Gathering. Quality Improvement studies examine a specific PSI process and collect data to identify areas for improvement. Information Gathering is gathering information that can be used to design a study, such as identification of sites for future recruitment, review of survey items for language/clarity with local staff and/or the research population, etc.

Example: PSI researchers in country X want to undertake a brand positioning study to determine how the target population views the PSI condom in relation to other condoms on the market. Results will help the platform better define its target market, assess current brand equity, and learn more about purchasers' perceptions of different condom brands. Fifteen interviews will be conducted with men aged 18-35 in the capital city. The study will be repeated every 6 months to track changes in brand image. Results will be shared with the platform's marketing department as well as the donor funding the study/intervention.

The above example may be considered Quality Improvement since the results are exclusively for the marketing department to modify or improve the marketing of the condom brand in country X.

Example: A PSI platform has been asked by the MOH to conduct a study that will inform the country strategy on urban health, especially addressing access of the urban poor to quality reproductive and child health services. PSI will conduct a literature review, re-analyze DHS data related to the urban poor, interview government officials and/or NGO staff working in urban health, and conduct focus groups with mothers of children under five living in poor urban neighborhoods about their health seeking behaviors for their families.

The above example illustrates how many PSI studies combine research and non-research aspects in the same study. The literature review, re-analysis of DHS data and interviews with relevant officials working in urban health would likely all be considered non-research, since the intent is to contribute background information for a plan to provide quality reproductive and child health services. However, the use of focus groups to ask mothers about their personal behavior, which would then be generalized to other mothers in poor urban areas country-wide would likely be considered research. In this case, the researchers could choose between deleting the focus groups and, therefore not needing to seek REB review or submitting only the study design for the focus groups for REB review.

Example: A PSI country recently started marketing Oral Contraceptives (OCs) via retail pharmacists. The platform now wants to conduct a Mystery Client study where interviewers posing as potential purchasers ask pharmacists questions about family planning methods. The objective of the study is to assess how well pharmacists answer

questions about OCs and if they are correctly prescribing them. Results will be used to improve the OC pharmacist training and detailing program. Results will be shared with the platform department responsible for hormonal contraceptive marketing.

In this case, the study examines pharmacists' knowledge and behavior based on the training they have received from the PSI country program. Because results will only be used to improve the PSI country's training and detailing activities, it may be considered quality improvement and not research.

V. Ethical Considerations for Non-Research Activities

As stated above, the PSI REP does not have jurisdiction over non-research activities conducted by PSI or its partners. However, participants in non-research studies can be some of the least protected study participants and therefore expose themselves, and PSI, to more risk. As a result, the PSI REP strongly encourages researchers to provide participants in non-research studies the same protections as those participating in research. The same concepts of respect for persons, beneficence and justice designed to protect research participants should also apply to participants in non-research.

Some of the most important elements for protecting non-research participants include:

- Using an informed consent form that includes the same information as an IC for research participants. Most importantly, the IC should stress the voluntary nature of the study, the ability to withdraw without consequences and include a clear listing of the risks and benefits of participation. Parental consent should be sought for minors (under the age of 18), with an assent from the minor involved.
- Avoiding the collection of identifying information such as name, address, birth date, initials and GPS location, among others.
- Protecting the confidentiality of participants in the recruitment process as well as during data collection, analysis and data management.
- For mystery client surveys where informed consent documents might not be realistic, PSI programs should consider telling potential participants about the study ahead of time and specifying that the time frame of the study. Potential participants can then have the option of choosing not to be part of the study.
- Researchers should ask themselves whether the benefits outweigh the risks and whether the risks of participation are higher than those encountered by the study population in their daily lives. If this is the case, researchers should find ways to minimize those risks to the greatest extent possible.
- Researchers should be sure that they are distributing the risks and benefits of participation across as wide a population as possible and not focusing on one population segment simply because it is easier to do so.

VI. Making the Research/Non-Research Decision

Regional Researchers are responsible for making the research/non-research decision for the PSI countries under their supervision. They should follow the principles

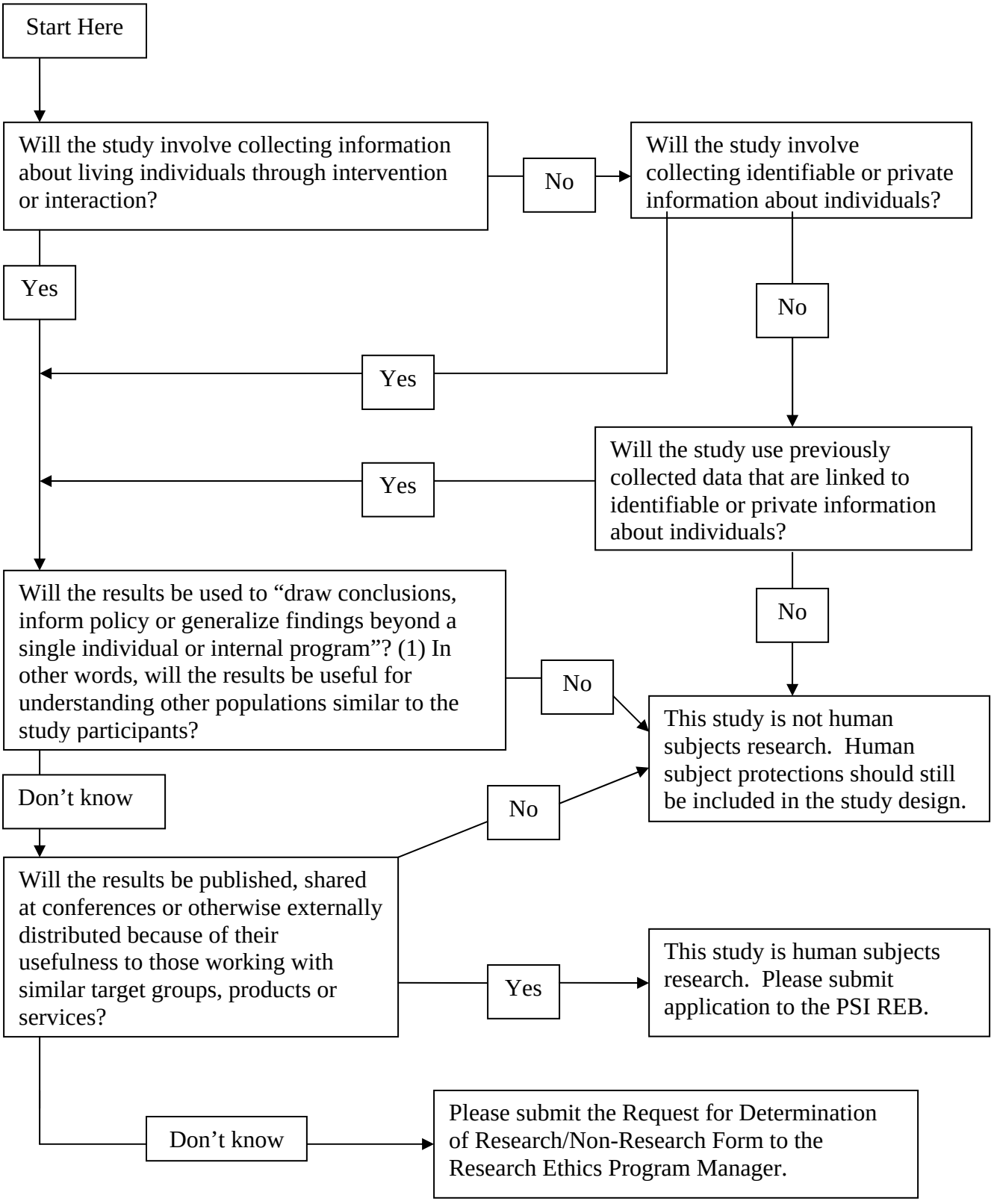
described in this document and summarized in the decision tree included in Appendix B. In cases where the Regional Researchers are not sure whether a particular research activity qualifies as research, they should submit the Request for Determination of Research or Non-Research form to the Research Ethics Program Manager, included in Appendix C.

Appendix A: Examples of Identifiable Information

- first or last name, or both
- address
- birthdate
- email address
- telephone numbers (land-line, cellular, fax, etc.)
- identification number
- medical record number
- service providers' license numbers
- vehicle license number
- account numbers (e.g., credit card)
- device identification numbers
- serial numbers
- any unique identifying numbers, characteristics, or codes (e.g., Global Positioning System (GPS) readings, unique scars or facial markings, etc.)
- Web URLs
- Internet Protocol (IP) addresses
- biometric identifiers (e.g., voice, fingerprints, wrist measurements)
- full face photographs or comparable images
- voice audio recordings

(2) List of Identifiable Information adapted from: *Is Your Activity Covered Under the Human Research Protection Program?* Office of Research Integrity and Assurance at Cornell University. http://www.irb.cornell.edu/documents/IRB%20Decision%20Tree.pdf

Appendix B: PSI Research vs. Non-Research Decision Tree



(1) *Activities that Require IRB Review*, University California Irvine
(2) Decision tree adapted from: *Is Your Activity Covered Under the Human Research Protection Program?* Office of Research Integrity and Assurance at Cornell University.
http://www.irb.cornell.edu/documents/IRB%20Decision%20Tree.pdf

Appendix C: Request for Determination of Research or Non-Research form

PSI Research Ethics Program (REP)
REQUEST FOR DETERMINATION OF RESEARCH or NON-RESEARCH
Version: August 2011

Federal regulations and PSI REB policies require REB review of research involving human subjects. Please complete and submit this form to the REP Manager for a determination of whether the proposed activities constitute Human Subject Research.

SECTION 1: CONTACT INFORMATION	
1. Regional Researcher:	
2. Regional Researcher E-mail Address:	
3. Principal Investigator:	4. Principal Investigator E-mail Address:
5. Study Title:	
6. Today's Date:	

SECTION 2: STUDY INFORMATION
1. Describe the purpose of the proposed activities. State the overall objectives and specific aims. Provide a brief description of the procedures.
2. Describe the subject population, or the type of data and/or specimens to be studied.
3. Describe how the data and/or specimens will be obtained.
4. Describe the outputs of the study and how they will be disseminated.

SECTION 3: DETERMINATION OF "HUMAN SUBJECT"

45 CFR 46.102(f):

Human subject - a *living individual* about whom an investigator (whether faculty, student, or staff) conducting research obtains: (1) data through *intervention or interaction* with the individual or (2) *identifiable private information*.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between researcher and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record information). Private information must be individually identifiable. *Individually identifiable* includes where the identity of the subject is or may be ascertained by the researcher or associated with the information.

Use the definitions above to answer the following questions.

1. Do the activities involve obtaining information about *living individuals*?
   ☐ **YES** ☐ **NO**

   1a. If "Yes" to #1, do the activities involve intervention or interaction with the individuals (i.e., prospective collection of data/specimens)?
   ☐ **YES*** ☐ **NO**

   ***If YES, the activities involve human subjects.**

2. Do the activities involve obtaining *individually identifiable* and *private* information about living individuals?
   ☐ **YES*** ☐ **NO**

   ***If YES, the activities involve human subjects.**

3. Do the activities involve analysis of existing *data/specimens* (i.e., data/specimens have been collected and are available for analysis)?
   ☐ **YES** ☐ **NO**

   3a. If yes to #3, will the *data/specimens be coded* such that a link exists that could allow the source of the data/specimens to be re-identified (i.e., key available to decipher the code)?
   ☐ **YES** ☐ **NO**

   3b. If "Yes" to #3a, is there a written agreement that prohibits the Principal Investigator and his/her research team from having access to the link?
   ☐ **YES** ☐ **NO****

   ****If you answered YES to 3 and 3a and NO to 3b, these activities involve human subjects.**

SECTION 4: DETERMINATION OF "RESEARCH"

45 CFR 46.102(d):

Research - a *systematic investigation*, including research development, testing and evaluation, *designed to develop or contribute to generalizable knowledge*.

1. Is the intent of the proposed activities to "draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program?"[7] Will the results yield new information that can be useful for understanding other populations that are similar to the study participants?
   ☐ **YES*** ☐ **NO****

   ****If NO,** please explain the intent of proposed activities and explain how the proposed activities are not intended to contribute to generalizable knowledge:

***If YES, these activities constitute research.**

SECTION 5: IS YOUR PROTOCOL HUMAN SUBJECTS RESEARCH?

The activities constitute human subjects research if based on your responses in Section 3 the activities involve human subjects **and** per your responses in Section 4 the activities constitute research. Please complete and submit an REB Application with a protocol narrative. All forms are available on the PSI website under Research Ethics Board submission forms. If you have questions or need additional guidance on the REB submission process, please contact the REP Manager.

If the activities do not appear to meet the definition of human subjects research you are not required to submit an REB application.

[7] *Activities that Require IRB Review*, University California Irvine

SECTION 6: PRINCIPAL INVESTIGATOR SIGNATURE

Principal Investigator's Signature Date

PSI REP DETERMINATION OF HUMAN SUBJECTS RESEARCH

Researchers do not complete this section. **For REP staff only**

☐ The activities as described **DO NOT** constitute Human Subjects Research. Submission of an REB Application is not required.

☐ The activities as described **DO** constitute Human Subjects Research. Submission of an REB Application **IS REQUIRED**. REB Approval must be obtained before the research can begin.

Research Ethics Program Manager Date

Document adapted from: University of California-Irvine IRB, Request for Determination of Non-human subject research, August 2010.
http://www.research.uci.edu/ora/forms/hrpp/RequestDeterminationNon-HumanSubjects.doc