OFFICE OF HUMAN RESEARCH ETHICS
Institutional Review Board

INSTRUCTIONS FOR *DETERMINATION WHETHER RESEARCH OR SIMILAR ACTIVITIES REQUIRE IRB APPROVAL* *version 30-Sep-2008*

What is the purpose of this form?

This application is to support a determination that research (or research-like activity) does not constitute human subjects research as defined by federal regulations (see also Office for Human Research Protections decision charts, August 10, 2004 OHRP guidance), or does not include certain other research-like activities that require IRB approval, either by federal regulation or University policy. In most cases, the requirement for IRB approval presents little ambiguity or difficulty; this form is intended for those cases where such determination is not immediately evident from the definitions in the federal regulations or University policy. This form may also be used when investigators require documentation that the IRB has made this determination (e.g., for funding agencies or for publication).

For which type of activities can this form be used?

- Activities that are *not* defined as "research," because they are not intended to develop or contribute to generalizable knowledge.
- Activities that are clearly "research" but do *not* involve human subjects. These include studies of existing records, data, or biological specimens for which identifying information is not available to the researcher (i.e., they are de-identified or have a coded identifier that cannot be linked back to the participants).

For which type of activities should this form **not** be used?

- Studies that use data protected under HIPAA (i.e., data that come directly from a health plan, health care clearinghouse, or health care provider).
- Studies that use data for which private information is identifiable or for which the principal investigator or research team have access to a key that links identifying information to a unique code.

How to Submit this Form

Submit two copies of this form to the IRB. Include one copy of the proposal or grant application supporting this research, if available. All application materials should be copied or printed on one side only. Address for all applications and other correspondence:

IRB
CB# 7097, Medical Building 52
105 Mason Farm Road
Chapel Hill, NC 27599-7097

If the IRB determines that your project does constitute human subjects research, you will be required to complete the "Application for IRB Approval of Human Subjects Research" available from the Office of Human Research Ethics website. The IRB will notify you of its determination.

You do not need to include documentation of ethics training when you submit this form.

OFFICE OF HUMAN RESEARCH ETHICS
Institutional Review Board

DETERMINATION WHETHER RESEARCH OR SIMILAR ACTIVITIES REQUIRE IRB APPROVAL

Version 30-Sep-2008

Part 1. Contact Information, Agreements, and Signatures

Title of Study: Timeliness and Perception in Online Disclosure

Date:

Name and degrees of Applicant: Jacob Kramer-Duffield
Department: School of Information and Library Science Mailing address/CB #: 3360
UNC-CH PID: Pager:
Phone #: Fax #: Email Address:

For trainee-led projects: __ undergraduate _X_ graduate __ postdoc __ resident __ other
Name of faculty advisor: Jane Greenberg
Department: School of Information and Library Science Mailing address/CB #: 3360
Phone #: Fax #: Email Address:

Name of funding source or sponsor (*please do not abbreviate*):
_X_ not funded __ Federal __ State __ industry __ foundation __ UNC-CH
__ other (specify):
For industry sponsored research (if applicable):
Sponsor's master protocol version #: Version date:
Investigator Brochure version #: Version date:
Any other details you need documented on IRB approval:

RAMSeS proposal number (from Office of Sponsored Research):

Applicant: I will notify the IRB if the scope of the activity changes in such a way that the answers on this form are no longer valid. I will ensure that all collaborators, students and employees assisting in this project are informed about these obligations. All information given in this form is accurate and complete.

_____ _____
Signature of Applicant Date

Faculty Advisor if Applicant is a Student or Trainee: I accept ultimate responsibility for ensuring that this project complies with all the obligations listed above for the Applicant.

_____ _____
Signature of Faculty Advisor Date

Part 2. Description of Research or Similar Activities

2.1. **Brief Summary of Purpose and Rationale**. Provide a *brief* non-technical description of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words. *Please reply to each item below, retaining the subheading labels already in place, so that reviewers can readily identify the content.*

Purpose: This study examines the effects of user perceptions of timeliness, audience and data lifecycle factors in online disclosure of various types of information.

Participants: Participants will be users of Amazon's "Mechanical Turk" service for the anonymous answering of simple questions in online form

Procedures (methods): Procedures will involve the use of Amazon's Mechanical Turk system for the answering of simple questions

2.2. **Which of the following describes your proposed activity?**

	Yes	No
2.2.1. Secondary analysis of existing data or specimens, deidentified or coded?	___	_X__
2.2.2. Program evaluation?	___	_X__
2.2.3. Class projects for educational purposes only?	___	_X__
2.2.4. QI/QA for internal purposes?	___	_X__
2.2.5. Center or core grants (to establish infrastructure)?	___	_X__
2.2.6. Training grants?	___	_X__
2.2.7. Demonstration projects?	___	_X__
2.2.8. Case study (publication of clinical scenario that has already occurred)?	___	_X__
2.2.9. Other? Explain Use of Amazon's Mechanical Turk program for anonymous answering of simple questions online	_X__	___

2.3. **Generalizable Knowledge.** Generalizable knowledge might include information presented to a broader audience or published with the intent of drawing scientific conclusions or increasing the body of scientific knowledge. This would not typically describe projects that are intended solely for internal assessment purposes, such as quality improvement/assurance, and program evaluations. Will the proposed activity result in the development of or contribution to generalizable knowledge?

_X__ yes ____ no If no, please explain.

2.4. **Living Individuals.** Are you planning to obtain data from or about living individuals?

_X__ yes ____ no Please explain.

2.5. **Direct Interaction with Individuals.** Will you be collecting data via direct interaction with individuals (any contact with subjects including questionnaires, interviews, focus groups, observation, treatment interventions, etc.)?

___ yes _X__ no

2.6. **Description of Existing Records, Data, Human Biological Specimens**. What existing records, data or human biological specimens will you be using? *(indicate all that apply)*:

	Yes	No
2.6.1. a. Data already collected from another research study? b. If yes, was applicant involved in the original collection? If yes, please explain role:	___ ___	_X__ ____
2.6.2. a. Patient specimens (tissues, blood, serum, surgical discards, etc.)? b. If yes, has the purpose for which they were collected been met before removal of any excess?	___ ___	_X__ ___
2.6.3. Data already collected for administrative purposes?	___	_X__
2.6.4. Medical records data?	___	_X__
2.6.5. Electronic data from a clinical (i.e., not a research) database?	___	_X__
2.6.6. Publicly available data?	___	_X__
2.6.7. Other? Explain:	___	_X__

If you have answered "yes" to any of the items 2.6.1 through 2.6.7, provide a description of the data you propose to use, describing the type of data, how they were collected (including consent procedures), and where they currently reside.

2.7. **Private Information.** Private information includes information about behavior that occurs in a context that an individual can reasonably expect will not be made public (e.g., a medical or school record). Public information might include information that is publicly available or from observation of public behavior (e.g., seatbelt use, use of bicycle lanes, etc.). Are the data for your project private?

___ yes _X__ no If no, explain: The data gathered will have only the barest demographic elements (age, sex) and the researchers will not have access to personally identifiable data regarding the users of Amazon's Mechanical Turk system who participate in this study

2.8. **HIPAA.** Do any of these data come directly from a health plan, health care clearinghouse, or health care provider? (See http://www.unc.edu/hipaa/index.htm for more about HIPAA.)

___ yes _X__ no

2.9. **Identifiers in Existing Data.** Do the data you will receive have any of the following identifiers?

__ No _**X**_ Yes *If yes, check all that apply*:

a. __ Names

b. __ Telephone numbers

c. __ Any elements of dates (other than year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death. For ages over 89: all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 and older

d. __ Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three digits of a zip code

e. __ Fax numbers

f. __ Electronic mail addresses

g. __ Social security numbers

h. __ Medical record numbers

i. __ Health plan beneficiary numbers

j. __ Account numbers

k. __ Certificate/license numbers

l. __ Vehicle identifiers and serial numbers (VIN), including license plate numbers

m. __ Device identifiers and serial numbers (e.g., implanted medical device)

n. __ Web universal resource locators (URLs)

o. __ Internet protocol (IP) address numbers

p. __ Biometric identifiers, including finger and voice prints

q. __ Full face photographic images and any comparable images

r. _X_ Any other unique identifying number, code, or characteristic, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher

2.10. **Coded Data.** Coded data are those for which identifying information (see the list in 2.9) that would enable the investigator to readily ascertain the individual's identity has been replaced with a number, letter, symbol, or combination thereof (i.e., a code) that cannot be linked to the original individual.

2.10.1 Are the data coded? ___ yes _X__ no

2.10.2. Will you have access to a key that deciphers the code, enabling linkage of identifying information to private information or samples? ___ yes _X__ no

► **If you have answered "yes" to 2.10.2 you must apply for IRB approval. Please complete the form "Application for IRB Approval of Human Subjects Research" available from the Office of Human Research Ethics website.**

If you have answered "no" to 2.10.2, identify the mechanism which precludes your access to the codes and include a copy of any agreements or documents that explain these protections:

	Yes	No
2.10.2.1. Data use agreement with data and code custodian (agreement prohibiting the release of the key to decipher the code to the applicant under any circumstances)?	___	_X_
2.10.2.2. Data are publicly available?	___	_X_
2.10.2.3. Honest broker (centralized custodian who controls data and will not release codes or IDs)?	_X__	___
2.10.2.4. Other. Explain _____	___	___

► **If the answers to the questions above do not direct you to apply for IRB approval using the form "Application for IRB Approval of Human Subjects Research," submit this completed form to the IRB for determination if your activity requires further IRB review and approval.**