OFFICE OF HUMAN RESEARCH ETHICS
Institutional Review Board

APPLICATION FOR IRB APPROVAL OF
HUMAN SUBJECTS RESEARCH
Version June 25, 2009

Part A.1. Contact Information, Agreements, and Signatures

Date: June 8, 2010

Title of Study: Contextual Authority Tagging: Expertise Location via Social Labeling

Name and degrees of Principal Investigator: Terrell Russell
Department: School of Information and Library Science Mailing address/CB #:
UNC-CH PID: 7014-80158 Pager:
Phone #: xxx-xxx-xxxx Fax #: Email Address: tgr@unc.edu

For trainee-led projects: __ undergraduate _X_ graduate __ postdoc __ resident __ other
Name of faculty advisor: Deborah Barreau
Department: School of Information and Library Science Mailing address/CB #:
Phone #: 919-966-5042 Fax #: Email Address: barreau@ils.unc.edu

Center, institute, or department in which research is based if other than department(s) listed above:

Name of Project Manager or Study Coordinator (if any):
Department: Mailing address/CB #:
Phone #: Fax #: Email Address:

List **all other project personnel** including co-investigators, and anyone else who has contact with subjects or identifiable data from subjects. **Include name, location (UNC or specific outside location), role and email address for each person who should receive electronic copies of IRB correspondence to PI.**

Name of funding source or sponsor (*please do not abbreviate*):
__ not funded __ Federal __ State __ industry __ foundation __ UNC-CH
__ other (specify):

For external funding, RAMSeS proposal number (from Office of Sponsored Research):

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:

Checklist of Items to Include with Your Submission

Include the following items with your submission, where applicable.

- Check the relevant items below and include one copy of all checked items 1-11 in the order listed.
- Also include two additional collated sets of copies (sorted in the order listed) for items 1-6.

Applications must "stand alone" and should provide all information requested, i.e., complete answers must be contained in the application. While you may reference other documents with supporting information, do not respond solely by stating "see attached."

Applications will be returned if these instructions are not followed.

Check	Item	Total No. of Copies
□	1. This application. One copy must have original PI signatures.	3
□	2. Consent and assent forms (include DHHS-approved sample, when one exists), fact or information sheets, phone and verbal consent scripts.	3
□	3. HIPAA authorization addendum to consent form.	3
□	4. All recruitment materials including final copies of printed advertisements, audio/video taped advertisements, scripts, flyers, letters, and emails.	3
□	5. Questionnaires, focus group guides, scripts used to guide phone or in-person interviews, etc.	3
□	6. Documentation of reviews from any other committees (e.g., Clinical and Translational Research Center (CTRC), Oncology Protocol Review Committee, or local review committees in Academic Affairs).	3
□	7. Protocol, grant application or proposal supporting this submission, if any (e.g., extramural grant application to NIH or foundation, industry protocol, student proposal). This must be submitted if an external funding source or sponsor is checked on the previous page.	1
□	8. Addendum for Multi-Site Studies where UNC-CH is the Lead Coordinating Center.	1
□	9. Data use agreements (may be required for use of existing data from third parties).	1
□	10. Only for those study personnel *not* in the online UNC-CH human research ethics training database (http://cfx3.research.unc.edu/training_comp/): Documentation of required training in human research ethics.	1
□	11. For drug studies, Investigator Brochure if one exists. If none, include package insert for previously approved uses..	1

Principal Investigator: I will personally conduct or supervise this research study. I will ensure that this study is performed in compliance with all applicable laws, regulations and University policies regarding human subjects research. I will obtain IRB approval before making any changes or additions to the project. I will notify the IRB of any other changes in the information provided in this application. I will provide progress reports to the IRB at least annually, or as requested. I will report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects. I will follow the IRB approved consent process for all subjects. I will ensure that all collaborators, students and employees assisting in this research study are informed about these obligations. All information given in this form is accurate and complete.

_____ _____

Signature of Principal Investigator Date

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

_____ _____

Signature of Faculty Advisor Date

Note: The following signature is not required for applications with a student PI.

Department or Division Chair, Center Director (or counterpart) of PI: (or Vice-Chair or Chair's designee if Chair is investigator or otherwise unable to review): I certify that this research is appropriate for this Principal Investigator, that the investigators are qualified to conduct the research, and that there are adequate resources (including financial, support and facilities) available. If my unit has a local review committee for pre-IRB review, this requirement has been satisfied. I support this application, and hereby submit it for further review.

_____ _____

Signature of Department Chair or designee Date

_____ _____

Print Name of Department Chair or designee Department

Part A.2. Summary Checklist *Are the following involved?*

	Yes	No
A.2.1. Existing data, research records, patient records, and/or human biological specimens?	__	_X_
A.2.2. Surveys, questionnaires, interviews, or focus groups with subjects?	_X_	__
A.2.3. Videotaping, audiotaping, filming of subjects, or analysis of existing tapes?	_X_	__
A.2.4. Do you have specific plans to enroll subjects from these vulnerable or select populations:		
a. UNC-CH students or UNC-CH employees?	__	_X_
b. Non-English-speaking?	__	_X_
c. Decisionally impaired?	__	_X_
d. Patients?	__	_X_
e. Prisoners, others involuntarily detained or incarcerated, or parolees?	__	_X_
f. Pregnant women?	__	_X_
g. Minors (less than 18 years)? ***If yes***, give age range: to years	__	_X_
A.2.5. a. Are sites outside UNC-CH engaged in the research?	__	_X_
b. Is UNC-CH the sponsor or lead coordinating center for a multi-site study?	__	_X_
***If yes*,** include the Addendum for Multi-site Studies.		
If yes, will any of these sites be outside the United States?	__	__
If yes, is there a local ethics review committee agency with jurisdiction? (provide contact information)	__	__
A.2.6. Will this study use a data and safety monitoring board or committee?	__	_X_
If yes: UNC-CH NC TraCS DSMB? (must apply separately)	__	__
Lineberger Cancer Center DSMC?	__	__
Other? Specify:	__	__
A.2.7. a. Are you collecting sensitive information such as sexual behavior, HIV status, recreational drug use, illegal behaviors, child/physical abuse, immigration status, etc?	__	_X_
b. Do you plan to obtain a federal Certificate of Confidentiality for this study?	__	_X_
c. Is this research classified (e.g., requires security clearance)?	__	_X_
A.2.8. a. Investigational drugs? (provide **IND #**)	__	_X_
b. Approved drugs for "non-FDA-approved" conditions?	__	_X_
All studies testing substances in humans must provide a letter of acknowledgement from the UNC Health Care Investigational Drug Service (IDS).		
A.2.9. Placebo(s)?	__	_X_
A.2.10. Investigational devices, instruments, machines, software? (provide **IDE #**)	__	_X_
A.2.11. Fetal tissue?	__	_X_
A.2.12. Genetic studies on subjects' specimens?	__	_X_
A.2.13. Storage of subjects' specimens for future research? ***If yes**, see instructions for* Consent for Stored Samples.	__	_X_
A.2.14. Diagnostic or therapeutic ionizing radiation, or radioactive isotopes, which subjects would not receive otherwise? ***If yes**, approval by the* UNC-CH Radiation Safety ***Committee** is required.*	__	_X_
A.2.15. Recombinant DNA or gene transfer to human subjects? ***If yes**, approval by the* UNC-CH Institutional Biosafety ***Committee** is required.*	__	_X_
A.2.16. Does this study involve UNC-CH cancer patients? ***If yes**, submit this application directly to the* Oncology Protocol Review Committee.	__	_X_
A.2.17. Will subjects be studied in the Clinical and Translational Research Center (CTRC) or is the CTRC involved in any other way with this study? If yes, obtain the CTRC Addendum *and submit completed application (IRB application and Addendum) directly to the CTRC. The CTRC includes facilities located on the 3rd floor of the Main Hospital (formerly GCRC) and Ground floor Burnett-Womack (formerly CCCT).*	__	_X_
A.2.18. Will gadolinium be administered as a contrast agent?	__	_X_
A.2.19. Will subjects' Social Security Number (SSN) be collected for:		
a. processing payments greater than $200 per year, to support IRS reporting (see also B.6)?	__	_X_
b. processing payments of any amount through UNC-CH Accounts Payable?	__	_X_
c. use as a unique identifier for study tracking purposes for national registry or database?	__	_X_

Part A.3. Conflict of Interest Questions and Certification

The following questions apply to **all investigators and study staff** engaged in the design, conduct, or reporting results of this project **and/or their immediate family members.** For these purposes, "family" includes the individual's spouse and dependent children. "Spouse" includes a person with whom one lives together in the same residence and with whom one shares responsibility for each other's welfare and shares financial obligations.

A.3.1. Currently or during the term of this research study, does any member of the research team or his/her family member have or expect to have:		
(a) A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with the sponsor of this study?	__ yes	_X_ no
(b) A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with an entity that owns or has the right to commercialize a product, process or technology studied in this project?	__ yes	_X_ no
(c) A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with an entity engaged in the performance of this project as a subcontractor, sub-recipient or vendor?	__ yes	_X_ no
(d) A board membership of any kind or an executive position (paid or unpaid) with the sponsor of this study or with an entity that owns or has the right to commercialize a product, process or technology studied in this project?	__ yes	_X_ no
A.3.2. Has the University or has a University-related foundation received a cash or in-kind gift from the sponsor of this study for the use or benefit of any member of the research team?	__ yes	_X_ no
A.3.3. Has the University or has a University-related foundation received a cash or in-kind gift for the use or benefit of any member of the research team from an entity that owns or has the right to commercialize a product, process or technology studied in this project?	__ yes	_X_ no

If the answer to ANY of the questions above is *yes*, the affected research team member(s) must complete and submit the form, which is accessible online at http://coi.unc.edu. List name(s) of all research team members for whom any answer to the questions above is *yes*:

_____

Certification by Principal Investigator: By submitting this IRB application, I (the PI) certify that the information provided above is true and accurate regarding my own circumstances, that I have inquired of every UNC-Chapel Hill employee or trainee who will be engaged in the design, conduct or reporting of results of this project as to the questions set out above, and that I have instructed any such person who has answered "yes" to any of these questions to complete and submit for approval a Conflict of Interest Evaluation Form. I understand that as Principal Investigator I am obligated to ensure that any potential conflicts of interest that exist in relation to my study are reported as required by University policy.

_____ _____

Signature of Principal Investigator Date

Faculty Advisor if PI is a Student or Trainee Investigator: I accept ultimate responsibility for ensuring that the PI complies with the University's conflict of interest policies and procedures.

_____ _____

Signature of Faculty Advisor Date

Part A.4. Questions Common to All Studies

For all questions, if the study involves only secondary data analysis, focus on your proposed design, methods and procedures, and not those of the original study that produced the data you plan to use.

Complete answers must be provided. While you may reference other documents with supporting information, do not respond solely by stating "see attached."

A.4.1. **Brief Summary**. 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: To validate and verify the usefulness of a new technique, Contextual Authority Tagging, for expertise location among members of an organization.

Participants: Groups of professional knowledge workers, estimated to be 80 participants in total, with a maximum of ~20 groups of ~8 participants for a total of 160 people.

Procedures (methods): This research will use custom social labeling software to conduct a Delphi study of five rounds among the members of each group of 8-10 participants. There will be an accompanying survey. Some participants (perhaps 10%) will be interviewed to provide additional insight.

A.4.2. **Purpose and Rationale**. Provide a summary of the background information, state the research question(s), and tell why the study is needed. If a complete rationale and literature review are in an accompanying grant application or other type of proposal, only provide a brief summary here. If there is no proposal, provide a more extensive rationale and literature review, including references.

This research is designed to validate and verify the usefulness of a new technique for expertise location among members of an organization. Expertise location has been a part of the knowledge management toolkit for some time but has largely been based on existing documents and recorded correspondence. This research investigates the possibility that other members of an organization may be able to identify the areas of expertise of a particular group member, as well. Claims of authority that come from a group of others are harder to centrally fabricate and/or manage and therefore provide a stronger aggregate credential than self-claims. Additionally, information from the heads of others may be more forward-looking than the information recorded in existing documents and therefore more useful to managers and other planning personnel.

This research aims to answer the following two questions: 1) Does Contextual Authority Tagging work? and 2) Is Contextual Authority Tagging acceptable within an organization? The first question gets at whether the technique is viable and a group can know what a group member knows. The second question addresses whether group members are comfortable being labeled by one another, whether they believe the information that is gathered, and whether the gathered information is useful or new.

A.4.3. **Subjects.** *You should describe the subject population even if your study does not involve direct interaction (e.g., existing records).* Specify number, gender, ethnicity, race, and age. Specify whether subjects are healthy volunteers or patients. If patients, specify any relevant disease or condition and indicate how potential subjects will be identified. Researchers are reminded that additional approvals

may be needed from relevant "gatekeepers" to access subjects (e.g., school principals, facility directors, hospital or healthcare system administrators).

This research will be conducted with groups of professionals within organizations approached and recruited by the researcher. These groups will be composed of knowledge workers rather than manual laborers. Eight to ten groups of roughly ten professionals each will be recruited and involved in the study for an estimated total of eighty participants. As the process is largely automated and online, the number of groups could easily approach 20 with little extra work on the part of the researcher. 20 groups of 8 participants would total 160 people. These participants will have no particular target gender, ethnicity, race, or age and will be healthy participants as far as the research is concerned.

A.4.4. **Inclusion/exclusion criteria.** List required characteristics of potential subjects, and those that preclude enrollment or involvement of subjects or their data. Justify exclusion of any group, especially by criteria based on gender, ethnicity, race, or age. If pregnant women are excluded, or if women who become pregnant are withdrawn, specific justification must be provided.

Inclusion will be limited only in that the participants are a member of a selected organization or group and consider themselves coworkers or colleagues with the other members of their organization. There are no listed exclusion criteria.

A.4.5. **Full description of the study design, methods and procedures.** Describe the research study. Discuss the study design; study procedures; sequential description of what subjects will be asked to do; assignment of subjects to various arms of the study if applicable; doses; frequency and route of administration of medication and other medical treatment if applicable; how data are to be collected (questionnaire, interview, focus group or specific procedure such as physical examination, venipuncture, etc.). Include information on who will collect data, who will conduct procedures or measurements. Indicate the number and duration of contacts with each subject; outcome measurements; and follow-up procedures. If the study involves medical treatment, distinguish standard care procedures from those that are research. If the study is a clinical trial involving patients as subjects and use of placebo control is involved, provide justification for the use of placebo controls.

The research study design is based on the Delphi model. There will be an accompanying survey and select follow-up interviews. The Delphi model consists of an iterated query of anonymous experts usually until a consensus emerges or little or no new information is obtained. This research places colleagues in the role of expert(s) and custom software handles the questions and answers.

Members of a group will be asked about their own and then their colleagues' areas of expertise. Using free text, the participants will tag, or label, these areas of expertise. These tags will be aggregated by the software to produce a "group" list to accompany each member's "self" list. Each round of the Delphi will produce this pair of lists for each group member. In each round, the participants will have access to their own unique pair of lists and can reflect on what the group has said about them and how they are perceived. The study will last for five rounds. The rounds will be spaced over the course of up to two weeks. Please see the attached screenshots of the pilot study.

A follow-up survey will be administered to each participant to address parts of the second research question regarding the technique's acceptability. Please see the attached survey questions.

Participants will be asked at the end of the survey whether they would like to be interviewed. Roughly ten percent of the participants will be interviewed for twenty minutes each to provide additional

insight and color to the survey data. If more than ten percent of participants are willing to be interviewed, the researcher will select first for coverage from different groups, then randomly within groups. Please see the attached interview questions.

The text labels that are collected from the software will be analyzed in two ways to determine "similarity" between the "self" and the "group" lists. The first method will be automatic and consist of an algorithm that uses the WordNet database to provide semantic similarity analysis. The second method will use Amazon's Mechanical Turk service to provide semantic similarity comparison scores of the two lists. Both of these methods will only have two lists of words as inputs and carry no personally identifiable information.

A.4.6. **Benefits to subjects and/or society.** Describe any potential for direct benefit to individual subjects, as well as the benefit to society based on scientific knowledge to be gained; these should be clearly distinguished. Consider the nature, magnitude, and likelihood of any direct benefit to subjects. If there is no direct benefit to the individual subject, say so here and in the consent form (if there is a consent form). Do not list monetary payment or other compensation as a benefit.

The potential for direct benefit to the participants is moderate, but interesting. Insight into how others perceive one's areas of expertise and skill sets is sometimes very hard to come by and this technique aims to pull some of the tacit information within organizations up to the surface to make them more explicit. Self-awareness of skill sets, professional strengths, and areas of relative expertise could be of significant benefit to any particular group member.

The benefit to society may not be visible for some time. This research could validate that a group's opinion of a particular other can be measured and holds value. By measuring what a group thinks an individual knows about, other systems could be more confident when calculating reputation scores or making question routing or team building decisions.

A.4.7. **Full description of risks and measures to minimize risks.** Include risk of psychosocial harm (e.g., emotional distress, embarrassment, breach of confidentiality), economic harm (e.g., loss of employment or insurability, loss of professional standing or reputation, loss of standing within the community) and legal jeopardy (e.g., disclosure of illegal activity or negligence), as well as known side effects of study medication, if applicable, and risk of pain and physical injury. Describe what will be done to minimize these risks. Describe procedures for follow-up, when necessary, such as when subjects are found to be in need of medical or psychological referral. If there is no direct interaction with subjects, and risk is limited to breach of confidentiality (e.g., for existing data), state this.

This research, by allowing direct description of participants' areas of expertise by other participants, includes the slight risk of psychosocial harm that is already present in the workplace. By inviting participants to label each others' areas of expertise, participants may be embarrassed by the omission of important skill sets or the inclusion of things not related to the workplace. These minimal risks are already part of a modern workplace, but could be exacerbated by making these labels explicit and shared. The risk mentioned here is minimized by reminding the participants that these labels are recorded and visible for the purpose of sharing and discourse. The researcher assumes these labels will remain on-task and largely professional in nature.

The consent document (in the form of a click-through and separate downloadable file) will point out that this type of information flow is expected and that the participants should keep this in mind when participating. The participants will know that the labels are aggregated (and somewhat anonymous) but only within the small group of their coworkers. Additionally, it is expected that the participants

will continue to work with one another after the conclusion of the study and therefore have incentive to remain within the behavioral norms of the existing workplace while participating in the study.

A.4.8. **Data monitoring and analysis.** Tell how the qualitative and/or quantitative data will be analyzed. Explain how the sample size is sufficient to achieve the study aims. This might include a formal power calculation or explanation of why a small sample is sufficient (e.g., qualitative research, pilot studies). Describe the provisions for monitoring the data to ensure the safety of participants. These plans could range from the investigator monitoring subject data for any safety concerns to a sponsor-based DSMB, depending on the study.

The labels that are returned by the participants about their group members' areas of expertise will be grouped and then analyzed for similarity over time. Each group member's “self” list and “group” list will be compared semantically and evaluated for similarity. This will be handled by two different methods, automatic and human-judged. These two methods will then be compared against each other as well.

Each group will have on the order of ten participants and will therefore provide moderate statistical power at the group analysis level using ANOVA to show differences between rounds. Combining the different groups, if appropriate, will provide even greater power to show an effect for the entire study.

A.4.9. **Will you collect or receive any of the following identifiers?** Does not apply to consent forms.

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

a. _**X**_ 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. _**X**_ Electronic mail addresses

g. __ Social security numbers

h. __ Medical record numbers

i.

j. __ Health plan beneficiary numbers

k. __ Account numbers

l. __ Certificate/license numbers

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

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

o. __ Web universal resource locators (URLs)

p. __ Internet protocol (IP) address numbers

q. __ Biometric identifiers, including finger and voice prints

r. __ Full face photographic images and any comparable images

s. __ 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

A.4.10. **Identifiers in research data**. Are the identifiers in A.4.9 above linked or maintained with the research data?

_X_ yes __ no

The names, or identifiers, used in this study will be stored in a separate table from the tagging data within the database. These names will consist of first and last names of the participants and will be stored in the database only so the other members of the group can successfully identify and reference each other during the study. Email addresses will be collected and stored in the same separate table as the names. The email addresses are necessary to communicate with the participants throughout the duration of the study. A participating member of a single group can only see other members of his/her group (his/her coworkers).

A.4.11. **Confidentiality of the data**. Describe procedures for maintaining confidentiality of the data you will collect or will receive. Describe how you will protect the data from access by those not authorized. How will data be transmitted among research personnel? Where relevant, discuss the potential for deductive disclosure (i.e., directly identifying subjects from a combination of indirect IDs).

The data is collected directly by the software and stored directly into the local mysql database. The names of the participants are kept in separate tables from the tagging data and are only retained so that the other members of the group can identify each other during the study. Email addresses are kept in the same separate tables and stored for communication and coordination purposes. The names and emails will be destroyed after the data collection phase. The database is only accessible to the researcher via unix login and password.

Aggregate tagging data about each participant will obviously be available to the participants during the study, as a feature of the study itself. Additionally, aggregate tagging data will be made available to the respective participating organizations at the end of the study. No attribution of tags will be available within the aggregated data.

Survey data will be collected via the Qualtrics survey software licensed to the Odum institute at UNC-CH. The survey data will be downloaded at the end of the survey to the researcher's local computer for analysis.

Interview data will be collected by the researcher and kept locally. Only anonymized illustrative quotations and general themes will be used in the published research.

A.4.12. **Data sharing.** With whom will *identifiable* (contains any of the 18 identifiers listed in question A.4.9 above) data be shared outside the immediate research team? For each, explain confidentiality measures. Include data use agreements, if any.

_X_ No one
__ Coordinating Center**:**
__ Statisticians**:**
__ Consultants**:**
__ Other researchers**:**
__ Registries**:**
__ Sponsors:
__ External labs for additional testing:
__ Journals:
__ Publicly available dataset:
__ Other:

A.4.13. **Data security for storage and transmission**. Please check all that apply.

For electronic data stored on a desktop computer:
__ Secure network _X_ Password access __ Data encryption __ Password protected file(s)
__ Other comparable safeguard (describe):

For portable computing devices/external storage devices (e.g. laptop computer, PDA, CDs, memory sticks):
_X_ Power-on password __ Automatic log-off __ Data encryption __ Password protected file(s)

__ Other comparable safeguard (describe):

For hardcopy data (including human biological specimens, CDs, tapes, etc.):
_X_ Data de-identified by research team (stripped of the 18 identifiers listed in question A.4.9 above)
_X_ Locked suite or office __ Locked cabinet
__ Data coded by research team with a master list secured and kept separately
__ Other (describe):

A.4.14. **Post-study disposition of identifiable data or human biological materials**. Describe your plans for disposition of data or human biological specimens that are identifiable in any way (directly or via indirect codes) once the study has ended. Describe your plan to destroy identifiers, if you will do so.

The only identifiable information from A.4.9 are the names and email addresses affiliated with each participant during the study. These will be destroyed (deleted) once the data collection is complete.

Additionally, group affiliation information will be stored for each participant, for data sorting purposes. This group name will also be destroyed at the end of the study.

No other identifiable information is collected or affiliated with individual participants.

Part A.5. The Consent Process and Consent Documentation (including Waivers)

The standard consent process is for all subjects to sign a document containing all the elements of informed consent, as specified in the federal regulations. Some or all of the elements of consent, including signatures, may be altered or waived under certain circumstances.

- If you will obtain consent in any manner, complete **section A.5.1**.
- If you are obtaining consent, but requesting a waiver of the requirement for a signed consent document, complete **section A.5.2**.
- If you are requesting a waiver of any or all of the elements of consent, complete **section A.5.3**.
- If you need to access Protected Health Information (PHI) to identify potential subjects who will then be contacted, you will need a *limited waiver of HIPAA authorization.* This is addressed in section B.2.

You may need to complete more than one section. For example, if you are conducting a phone survey with verbal consent, complete sections A.5.1, A.5.2, and possibly A.5.3.

A.5.1. **Describe the process of obtaining informed consent from subjects**.
Describe who will be obtaining consent (or permission) and from whom. Include discussion, as relevant, any waiting period between the initial consent discussion and obtaining consent, and steps that will be taken to minimize coercion or undue influence. If children will be enrolled as subjects, describe the provisions for obtaining parental permission and assent of the child. If decisionally impaired adults are to be enrolled, describe the provision for obtaining surrogate consent from a legally authorized representative (LAR). If non-English speaking people will be enrolled, explain how consent in the native language will be obtained. Address both written translation of the consent and the availability of oral interpretation. It is expected that the information in the consent document(s) will be communicated to participants or their LAR. *After you have completed this part A.5.1, if you are not requesting a waiver of any type, you are done with Part A.5.; proceed to Part B.*

The researcher will be obtaining informed consent from each participant. The consent form will be completed at the beginning of the first round of Delphi-style iterations and will be at the bottom of the initial welcome screen. Each participant will be allowed to remove him/herself from the study at any time and no coercion will be used to initiate participation. All participants will be in the majority and should have no impairments requiring surrogate consent.

The consent form will be in the form of a click-through and will be recorded in the database along with other information about each participant. The consent factsheet will also be available for separate download.

A.5.2. **Justification for a waiver of *written* (i.e., signed) consent**. *The default is for subjects to sign a written document that contains all the elements of informed consent.* Under limited circumstances, the requirement for a signed consent form may be waived by the IRB if either of the following is true. *Choose only one:*

a. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., study topic is sensitive so that public knowledge of participation could be damaging). *Participants should be asked whether they want documentation linking them with the research and the participants' wishes will govern whether they sign the form.* Note: This justification cannot be used in FDA- __ yes _X_ no

regulated research. _X_ yes __ no
Explain.

b. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (e.g., phone survey).
Explain. The research will be conducted entirely online and the attached online consent form should be sufficient to obtain informed consent.

If you checked "yes" to either (and you are not requesting a waiver in section A.5.3) consent must be obtained orally, by delivering a fact sheet, through an online consent form, or be incorporated into the survey itself. Include a copy of the consent script, fact sheet, online consent form, or incorporated document.

→ If you have justified a waiver of written (signed) consent (A.5.2), you should complete A.5.3 *only* if your consent process will not include all the other elements of consent.

A.5.3. **Justification for a full or partial waiver of consent.** *The default is for subjects to give informed consent.* A waiver might be requested for research involving only existing data or human biological specimens (see also Part C). More rarely, it might be requested when the research design requires withholding some study details at the outset (e.g., behavioral research involving deception). In limited circumstances, parental permission may be waived. This section should also be completed for a waiver of HIPAA authorization if research involves Protected Health Information (PHI) subject to HIPAA regulation, such as patient records.

__ Requesting **waiver of some elements** (specify; see SOP 28 on the IRB web site):
__ Requesting **waiver of consent entirely**
If you check either of the boxes above, answer items a-f.. To justify a full waiver of the requirement for informed consent, you must be able to answer "yes" (or "not applicable" for question c) to items a-f. **Insert brief explanations that support your answers.**

a. Will the research involve no greater than minimal risk to subjects or to their privacy? __ yes __ no
Explain.

b. Is it true that the waiver will *not* adversely affect the rights and welfare of subjects? *(Consider the right of privacy and possible risk of breach of confidentiality in light of the information you wish to gather.)* __ yes __ no
Explain.

c. When applicable to your study, do you have plans to provide subjects with pertinent information after their participation is over? *(e.g., Will you provide details withheld during consent, or tell subjects if you found information with direct clinical relevance? This may be an uncommon scenario.)* __ yes __ not applicable
Explain.

d. Would the research be impracticable without the waiver? *(If you checked "yes," explain how the requirement to obtain consent would make the research impracticable, e.g., are most of the subjects lost to follow-up or deceased?).* __ yes __ no
Explain.

e. Is the risk to privacy reasonable in relation to benefits to be gained or the __ yes __ no

importance of the knowledge to be gained?
Explain.

If you are accessing patient records for this research, you must also be able to answer "yes" to item f to justify a waiver of HIPAA authorization from the subjects.

f. Would the research be impracticable if you could not record (or use) Protected Health Information (PHI)? *(If you checked "yes," explain how* not *recording or using PHI would make the research impracticable).* __ yes __ no
Explain.

Part B. Questions for Studies that Involve Direct Interaction with Human Subjects

→ ***If this does not apply to your study, do not submit this section.***

B.1. **Methods of recruiting.** Describe how and where subjects will be identified and recruited. Indicate who will do the recruiting, and tell how subjects will be contacted. Describe efforts to ensure equal access to participation among women and minorities. Describe how you will protect the privacy of potential subjects during recruitment. *For prospective subjects whose status (e.g., as patient or client), condition, or contact information is not publicly available (e.g., from a phone book or public web site), the initial contact should be made with legitimate knowledge of the subjects' circumstances. Ideally, the individual with such knowledge should seek prospective subjects' permission to release names to the PI for recruitment. Alternatively, the knowledgeable individual could provide information about the study, including contact information for the investigator, so that interested prospective subjects can contact the investigator.* Provide the IRB with a copy of any document or script that will be used to obtain the patients' permission for release of names or to introduce the study. Check with the IRB for further guidance.

Participants will be recruited based on their membership or employment at institutions or organizations of interest. The researcher will employ snowball sampling and reach out to a personal network of friends and friends of friends within industry to find interested organizations. Once a connection has been made within an organization, scheduling discussions will occur to determine how best to plan five rounds of participation over the course of a few weeks. Women and minorities should be represented proportionally as they are in the industry of the participating organizations.

The organizations enrolled should be diverse across industries but employ knowledge workers rather than physical laborers.

Please find attached the information sheet that will be distributed to prospective participants and organizations.

B.2. **Protected Health Information (PHI).** If you need to access Protected Health Information (PHI) to identify potential subjects who will then be contacted, you will need a *limited waiver of HIPAA authorization*. If this applies to your study, please provide the following information and complete Section C.

a. Under this limited waiver, you are allowed to access and use only the minimum amount of PHI necessary to review eligibility criteria and contact potential subjects. What information are you planning to collect for this purpose?

b. How will confidentiality/privacy be protected prior to ascertaining desire to participate?

c. When and how will you destroy the contact information if an individual declines participation?

B.3. **Duration of entire study and duration of an individual subject's participation, including follow-up evaluation if applicable.** Include the number of required contacts and approximate duration of each contact.

The duration of the entire study should be no more than two to three weeks. A participant will complete five rounds of social labeling, the survey at the time of the end of the last round, and potentially a

short interview with the researcher within a few days of the last round. The length of time between rounds will be as per the arrangement between the organization and the researcher, but is expected to average around two weeks in total.

B.4. **Where will the subjects be studied?** Describe locations where subjects will be studied, both on and off the UNC-CH campus.

The participants can participate from anywhere, but they will probably be at work, situated among the others that they are labeling. They could also be at home, not on work hours, if they so choose. The software can be accessed from any networked computer with a standard web browser. The researcher will not meet or speak with any participants directly except for the initial set up for each organization and during the selected follow-up interviews.

B.5. **Privacy.** Describe procedures that will ensure privacy of the subjects in this study. Examples include the setting for interviews, phone conversations, or physical examinations; communication methods or mailed materials (e.g., mailings should not indicate disease status or focus of study on the envelope).

The bulk of the communication between researcher and participants will be online via custom software and the survey tool hosted by Qualtrics.com. Coordination and reminder notifications will occur over email. Interviews will be conducted over the phone and recorded for transcription purposes. Participants who are interviewed will be able to select their environment and may choose to be out of the office when speaking to the researcher.

B.6. **Inducements for participation.** Describe all inducements to participate, monetary or non-monetary. If monetary, specify the amount and schedule for payments and if/how this will be prorated if the subject withdraws (or is withdrawn) from the study prior to completing it. For compensation in foreign currency, provide a US$ equivalent. Provide evidence that the amount is not coercive (e.g., describe purchasing power for foreign countries). Be aware that payment over a certain amount may require the collection of the subjects' Social Security Numbers. If a subject is paid more than $200.00 per year, collection of subjects' Social Security Number is required (University policy—see SSN Guidance) using the Social Security Number collection consent addendum found under forms on the IRB website (look for Study Subject Reimbursement Form).

There are no monetary inducements to participate in this study. Participants will potentially gain some insight into their coworkers and colleagues estimates of their areas of expertise, both by seeing what is listed as well as seeing what is not listed. This insight may be considered an inducement.

B.7. **Costs to be borne by subjects.** Include child care, travel, parking, clinic fees, diagnostic and laboratory studies, drugs, devices, all professional fees, etc. If there are no costs to subjects other than their time to participate, indicate this.

There are no costs to participate other than time. As any time used for this study will probably be taken from work hours, the participants need to weigh this consideration when deciding to participate. Of course, participation could also occur away from work and not on work hours, if deemed appropriate.