1. Contacts and Title

1. Principal Investigator:

   Ann Johnson
   Email: ann.johnson@hsc.utah.edu
   Training CoI Date: 8/16/2012 SM 5/8/2014

   a. Position of Principal Investigator:
      - Faculty
      - Student
      - Staff
      - Resident/Fellow
      - Other

      If Other, describe:

   b. Will the Principal Investigator consent participants? ☐ Yes ☐ No

2. Contact Person(s) (if different from the PI):

   Name Email Training
   There are no items to display

3. Internal Staff and Sub-Investigator(s) (Within the University of Utah):

   Name Email Training Obtaining Consent CoI Date
   There are no items to display

4. External Sub-Investigator(s) (Investigators outside the University of Utah):

   Last Name First Name Affiliation
   There are no items to display

5. Faculty Sponsor (if needed):

   Stephen Alder

6. Guests:

   Last Name First Name E-Mail
   There are no items to display

7. What type of application is being submitted?

   New Study Application (or Amendment/Continuing Review)

8. Title Of Study:

   Perceptions and attitudes about the use of language translation and interpretation in the human subject research setting

9. Study Purposes and Objectives:

   In the United States, the inability to speak English is a growing contributor to health disparities through diminished access to necessary health care services. As clinical research is frequently becoming the setting for health care services, understanding the current practices and perceptions regarding the use of translation and interpretation services in clinical research is an important step toward initiating change and improving access for all patients.
The purpose of this project is

1. To implement a survey for assessing the perceptions and attitudes of clinical and translational research investigators and their staffs regarding the use of language translation and interpretation services at academic research institutions.
2. To gain additional information about perceptions and attitudes through in-depth interviews.

10. Background and Introduction:

Currently, there is very little centralized, publicly available information regarding the policies and procedures followed by academic medical centers in terms of language translation and interpretation services for research. While the federal laws and regulations governing both clinical health care and clinical research specify the standards academic medical centers must follow, the regulations are silent regarding the procedures that should be used to accomplish compliance with the requirements. Institutional review boards (IRB) are charged with the task of enforcing the translation and interpretation requirements for clinical research and institutional policies and procedures have also been created to address the issue; however, a national standard does not exist for the content of the policies and procedures, nor for the decision-making process of IRBs. Thus, the quality of these policies and procedures may vary between institutions.

Recognizing this potential variation, a study of online IRB policies and procedures from thirty top-ranked medical schools and research institutions in the U.S. was published in 2006.[1] The results from this study identify the lack of published guidance about the IRB’s interpretation of federal regulation as well as the lack of published guidance about the IRB’s requirements for translation of informed consent documents and other study-related documents. This study is useful in demonstrating part of the problem institutions face when attempting to adhere to federal law and regulation. However, this study did not include a review of institutional policies and procedures outside of the IRB. It also did not describe if online policies and procedures promoted any translation and interpretation services that were available to researchers at each site.

### 3. Participants

1. **Ages of Participants:**  
   18 and older  
   (Consent form needed)

2. **Specific age range of participants (e.g., 7-12 years old, 60+, etc.):**  
   18+ years

3. **Indicate any vulnerable participant groups (other than children) included:**  
   Students, staff, or faculty of the research institution  
   If "Other", please specify:

   **If "None" and no children are involved, answer the following question.**  
   Has the participant selection process overprotected potential subjects who are considered vulnerable so that they are denied opportunities to participate in research?  
   - Yes  
   - No

4. **Number of participants to be enrolled during the entire study:**  
   **At Utah:** 5-10 interview participants; 100 survey participants  
   **All Centers:** 20-30 interview participants; 500 survey participants

5. **Characteristics of Participants/Inclusion Criteria:**  
   Clinical researchers and clinical research support staff (i.e. study coordinators, research assistants, etc.) who conduct research that involves direct contact with participants.

6. **Participant Exclusion Criteria:**  
   None

7. **Is a substantial percentage of the participant population anticipated to be non-English speaking?**  
   - Yes  
   - No

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**Vulnerable Populations**

**Justification Requirements for the Inclusion of Vulnerable Populations**

1. **How does the nature of the research require or justify using the proposed subject population?**  
   The proposed project will inquire about the perceptions and attitudes of researchers and research staff who are employees of the University of Utah. This is the subject populations that would/does utilize language and translation services for the research studies they are conducting.

2. **Would it be possible to conduct the study with other, less vulnerable subjects?**  
   - Yes  
   - No  
   If yes, justify the inclusion of vulnerable subjects:

3. **Is this population being included primarily for the convenience of the researcher?**  
   - Yes  
   - No  
   If yes, explain:

4. **Does the scientific merit of the study warrant the inclusion of subjects who may either be susceptible to pressure or who are already burdened?**  
   - Yes  
   - No
4. Study Information

1. Design of Study (select all that apply):
   - Survey/Questionnaire Research
   - Interviews and Focus Groups
   - If Other, describe:

2. Does your study involve the use of any placebo?
   - Yes
   - No

3. Length of entire study, from initiation through closeout: 1 year

4. How will participants be recruited or identified for inclusion in the study?
   a. Select all methods that will be used:
      - In-person contact (e.g., patients, students, etc.)
      - Referrals
      - Written advertising (flyers, brochures, website postings, newspaper ads, etc.)

   b. Describe the recruitment/participant identification process in detail (e.g. who will review charts or records, who can refer participants to the study, where will flyers be posted, how often will recruitment letters be sent, when will follow-up phone calls be made, etc.):

   Clinical researchers and clinical research support staff will be recruited through key contacts at several institutions. Email announcements for the survey will be sent by these key contacts (the PI will not have direct access to email lists). Email announcements will be written specific to each group/institution sending out the survey invitation and will be provided to the IRB via an amendment once written.

   All interview participants will be recruited through referral by key contacts and through the survey participant pool - an invitation for interview participation will be included at the end of the survey. Survey participants may choose to provide their name and contact information for participating in the follow-up interview.

5. How will consent be obtained?
   - Informed Consent Process (with or without a document)

6. Describe all the procedures chronologically, from screening/enrollment through study closeout, which will be completed in the research project.
   **Survey Procedures**
   All surveys will be completed online. The survey asks 5 questions about the participant's attitude, behavior, and experience surrounding the issue of providing language services for non-English speaking research participants. It is anticipated that the survey will take 10-15 minutes to complete.

   1. A recruitment email will be sent out through key institutional contacts, notifying potential participants about the survey.
   2. Participants will access the survey via a hyperlink in the recruitment email.
   3. Participants will read the consent cover letter on the first page of the electronic survey. The participant clicks "Continue" in order to provide their consent and complete the survey.
   4. The participant reads the introductory synopsis on the second page of the survey.
   5. The participant completes the survey.
   6. The participant completes the optional form for participating in a follow-up interview.

   **Interview Procedures**
   All interviews will be completed in-person, via email, or via telephone. The interview is open-ended and asks many in-depth questions about the participant's attitude, behavior, and experience surrounding the issue of providing language services for non-English speaking research participants. It is anticipated that the interview will take 30-60 minutes to complete.

   1. The PI will contact the participant via email or telephone.
   2. The PI will discuss the interview process with the participant using the interview consent script.
   3. The participant will indicate via email or telephone if he/she gives consent.
   4. The PI will arrange for the interview at a time and location of convenience for the participant.
   5. The interview will be conducted in an open-ended fashion.
7. Are all procedures for research purposes only (non-standard or non-standard of care procedures)?
   - Yes
   - No
   If no, list the procedures that are performed for research purposes only (non-standard or non-standard of care procedures):

8. Is there a safety monitoring plan for this study?
   - Yes
   - No

9. Provide a summary of the statistical methods, data analysis, or data interpretation planned for this study. Factors for determining the proposed sample size (e.g., power) should be stated.
   Surveys will be analyzed using descriptive statistics. Open-ended answers will be coded for themes and then analyzed. Comparisons between groups will be made using chi-square or Fisher exact test.
   Interviews will be analyzed using qualitative methods, involving thematic coding. Common themes will be described.

Consent Process

1. The following investigators and internal staff will obtain consent (as indicated on the Contacts and Title Page):
   Ann Johnson
   List by name, role, and affiliation any others who will obtain consent (e.g. Dr. John Smith, Co-Investigator, etc.).
   Surveys: Participants will self-consent online via an electronic consent.
   Interviews: Ann Johnson

2. Describe the location(s) where consent will be obtained.
   Surveys: Online
   Interviews: at a location convenient for the participant.

3. Describe the consent process(es), including the timing of consent. Describe whether there is a waiting period between the consent process and obtaining consent from the participant (i.e., any time between informing participants and actually obtaining consent).
   Surveys: Online, prior to completing the survey.
   Interviews: Interviews will be conducted over a 2-3 month period and anyone considering participation will have this amount of time to make a decision and schedule the interview. The participant will be able to contact the PI at anytime to ask questions. The PI will contact the participant based upon contact information provided by the participant for this purpose. The majority of consent processes will be conducted between the PI and participant via email or telephone; very few will happen in person. After consent is provided, the interview will be scheduled.

4. Describe what measures will be taken to minimize the possibility of coercion or undue influence.
   It will be emphasized throughout the process that participation is voluntary.
   The interview will have no influence on the participants’ employment status or research status at their respective institutions. Completion of the survey will also not affect employment status or research status.

5. Describe the provisions that are made to allow adequate time to exchange information and questions between the investigator and participant.
   Interviews will be conducted over a 2-3 month period and anyone considering participation will have this amount of time to make a decision and schedule the interview. The participant will be able to contact the PI at anytime to ask questions. Participants will be encouraged to have an open dialogue with the PI during this time.

6. Will a legally authorized representative (LAR) be used?
   - Yes
   - No
   If yes, describe when the use of an LAR might arise in this study population and what the frequency of an LAR will be during the enrollment period.

7. Will a language other than English be used to obtain consent?
   - Yes
   - No
   If yes, complete the following:
   a. Please indicate which form will be used:
      There are no items to display
      If using the short form, please provide justification for why a full, translated consent document will not be used:

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IRB_00051476
Created: 8/7/2011 5:20 PM
PI: Ann Johnson  PhD, MPH
Submitted: 7/9/2012
Title: Perceptions and attitudes about the use of language translation and interpretation in the human subject research setting
b. Describe whether translation services will be used for the consent process and how the consent process will be conducted?

If yes, complete the following:

- Explain why the waiver of consent documentation is being requested.
  Considering that consent processes will happen online, via email, or over the phone, it would be more hassle and burdensome for the researcher and the participants to obtain signatures. The study procedures are minimal risk and generally a signed consent document is not required for interview or survey participation outside of the research setting. Participants will also be given written information about the study.

- Justification for the waiver is one of the following:
  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.

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5. Data Monitoring Plan

1. Privacy Protections: Privacy refers to persons and to their interest in controlling access of others to themselves. Privacy can be defined in terms of having control over the extent, timing and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. What precautions will be used to ensure subject privacy is protected?
   
   Select all that apply:
   - The research intervention is conducted in a private place
   - Discussing the study with participants individually instead of in front of a group
   - Allowing for anonymous submission of surveys and questionnaires

2. Confidentiality Precautions: Confidentiality is an extension of the concept of privacy; it refers to the subject's understanding of, and agreement to, the ways identifiable information will be stored and shared. Identifiable information can be printed information, electronic information or visual information such as photographs. What precautions will be used to maintain the confidentiality of identifiable information?
   
   Select all that apply:
   - Storing research data on password protected computers or in locked cabinets or offices
   - Participant identifiers will be stored separately from the coded, participant data
   - Destroying photos, audio tapes, or video tapes at the end of the study

   Other or additional details (specify):
   - Interviews:
     - Data from individual interviews will be transcribed in an anonymous fashion and identifiable information will be stored separate from the study data. Audiotapes and field notes will be stored in a locked office and destroyed at the end of the research study. Transcripts will be stored on a password-protected and encrypted computer at the University of Utah.
   - Surveys:
     - Surveys can be submitted anonymously (unless the participant would like to engage in a follow-up interview), such that data will be de-identified when analyzed by the researcher.

3. Will photos, audio recordings, or video recordings, or medical images of participants be made during the study?
   - Yes  ☑ No

   If yes, describe the recording/images and what will become of them after creation (e.g., shown at scientific meetings, stored in the medical/research record, transcribed, erased, etc.):
   - All recordings will be transcribed and then destroyed at the end of the study.

4. How will study data and documentation be monitored throughout the study?
   
   Select all that apply:
   - Periodic review of informed consent documentation
   - Periodic review of the transfer/transcription of data from the original source to the research record

   Other additional details (specify):

5. Who will be the primary monitor of the study data and documentation?
   
   Select all that apply:
   - Principal Investigator

   Other or additional details (specify):
6. How often is study data and documentation monitoring planned (e.g., monthly, twice a year, annually, after N participants are enrolled, etc.)?

The data will be monitored once prior to final data cleaning and analysis.

6. Risks and Benefits

1. Describe the reasonable foreseeable risks or discomforts to the participants:

None of the participants are anticipated to be vulnerable to coercion or undue influence while participating in the study.

There may be minimal risks to participants who participate in the interviews, including a loss of privacy while sharing personal opinions and beliefs about language translation and interpretation, and a potential loss of confidentiality if study data were to be compromised or breached.

Completion of the surveys may also involve the risk of loss of confidentiality. Such risks may cause the participants to feel uncomfortable; however, protections are in place to ensure that these risks are minimized.

2. Describe the potential benefits to society AND to participants (do not include compensation):

There are no anticipated benefits to individual participants; however, it is anticipated that the results of this study will benefit the institutions who are collaborating, providing feedback about the perceptions at their institutions.

3. Are there any costs to the participants from participation in research?

[ ] Yes [ ] No

If yes, specify:

4. Is there any compensation to the participants?

[ ] Yes [ ] No

a. If yes, answer the following:
   Specify overall amount:

b. Specify when participants will be paid (e.g. at each visit, at end of study, etc.):

c. If applicable, please specify payment by visit or other time interval (e.g. $10 per visit, etc.):

d. If applicable, explain plan for prorating payments if participant does not complete the study:

7. HIPAA and the Covered Entity

1. Does this study involve Protected Health Information (PHI) or de-identified health information?

[ ] Yes [ ] No

a. If yes, select the method(s) of authorization that will be used:
   De-identified

   If needed, select De-Identification Form:

b. If yes, will PHI be disclosed outside the Covered Entity?

   [ ] Yes [ ] No

   If so, to whom?
   And for what purposes?

2. Does this study involve any of the following:

   a. The investigational use of a drug?
8. Resources and Responsibilities

1. State and justify the qualifications of the study staff:

The PI has been trained in research design and has an intimate background in human subject research protections.

2. Describe the training that study staff and investigators will receive in order to be informed about the protocol and understand their research-related duties and functions:

The PI is responsible for all study procedures and has been trained to perform these procedures. The PI has completed human subject research training (CITI, U of Utah RATS courses, PRIM&R conference attendance).

3. Describe the facilities to be used for the research activities (e.g. hospitals, clinics, laboratories, classrooms/schools, offices, tissue banks, etc.):

The information collected in the study will be stored at the University of Utah Research Administration Building. The survey is created using the LimeSurvey program available through the U of Utah College of Social and Behavioral Science, and survey information is stored on University servers. The interviews conducted in-person will be performed at a site of the participant’s choosing.

4. Describe the medical or psychological resources available at this site (and other participating sites, if applicable) that participants might require as a consequence of the research. If not applicable, please state.

N/A
Documents and Attachments

If any of your documents (such as investigational brochures, sponsor protocols, advertisements, etc.) are not available in an electronic format, please scan and save them as PDF files or contact our office for assistance.

**Naming Documents:** Please use the title field to clearly indicate the content of each form. The name you enter will be listed on your approval letter. Use names that will differentiate from earlier versions.

Examples:
- Consent Document Control Group 04/14/05
- Consent Document Treatment Group 4/14/05
- Sponsor Protocol 04/14/05 Version 2
- Assent Document (Highlighted Changes)

Apple/Macintosh Users: MS Word documents must have a .doc file extension. See ERICA home page for instructions.

Print View: IRB Draft Protocol Summary

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Consent Documents, Consent Cover Letters, Consent Information Sheets, Consent Scripts, etc.:

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Surveys, Questionnaires, Interview Scripts, etc.:

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Full Protocol (company protocol, sponsor protocol, investigator-initiated protocol, etc.):

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Investigational Brochure (IB) for Investigational Drug or Drug/Device Package Insert:

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Literature Cited/References:

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Principal Investigator's Scholarly Record (CV/Resume):

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Faculty Sponsor's Scholarly Record (CV/Resume):

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Other Stamped Documents:

Only attach documents here as directed by the IRB, such as the Data/Information Request Form for UUHSC EDW.

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Recruitment Materials, Advertisements, etc.:

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PI: Ann Johnson  PhD, MPH  
Submitted: 7/9/2012  
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Finish Instructions

1. To view errors, select the "Hide/Show Errors" option at the top or bottom of the page. If you have errors on your application, you won't be able to submit it to the IRB.
2. Selecting the Finish button will NOT submit the application to the IRB. You MUST select the "Submit" option on the workspace once you've selected the "Finish" button.
3. If your study has a faculty sponsor: Once the PI submits the application, it will be sent to the faculty sponsor for final approval. The IRB cannot review the study until the faculty sponsor submits the application to the IRB.