UMKC
Office of Research Services

5. Obtaining Consent from Research Subjects

5.1. Policy

No investigator conducting research under the auspices of the institution may involve a human subject in research without obtaining the legally effective consent of the subject or the subject's legally authorized representative unless a waiver of consent has been approved by the IRB in accordance with section 5.4 of these procedures. Except as provided in section 5.4.8, consent must be documented by the use of a written consent form approved by the IRB. The IRB will evaluate both, as applicable, the consent process and the procedures for documenting consent to ensure that adequate consent is obtained from participants. The following procedures describe the requirements for obtaining consent from participants in research under the auspices of the institution.

Regulations & Guidance: DHHS 45 CFR 46.116; FDA 21 CFR 50.20; AAHRPP II.7.A.

5.2. Definitions

The following definitions apply throughout this Guidance document:

Legally Authorized Representative (LAR): DHHS regulations define a LAR as an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

FDA regulations define a LAR as an Individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research

Regulations and Guidance: DHHS 45 CFR 46.102(i); FDA 21 CFR 50.3(l)

5.3. Basic Requirement

Consent must be obtained by the PI (or properly trained designee) prior to entering or enrolling a subject into an IRB-approved study and/or conducting any study related procedures required by the protocol, unless consent is waived by the IRB.

If someone other than the PI conducts the interview and obtains consent from subject, the PI needs to formally delegate this responsibility, and the person so delegated must have received appropriate training to perform this activity. The person so delegated must be knowledgeable about the research to be conducted and the consenting process, and must be able to answer questions about the study. These consent requirements are not intended to preempt any applicable Federal, state, or local laws that require additional information to be disclosed for consent to be legally effective.

Sample or draft consent documents may be developed by a sponsor or cooperative study group. However, the IRB-of-record is the final authority on the content of the consent document(s) that is presented to the prospective study subjects.

Regulations & Guidance: DHHS 45 CFR 46.116; FDA 21 CFR 50.20.

5.4. Procedures

5.4.1. Securing and Documenting Consent

A PI is required to obtain legally effective consent from a subject or the subject's LAR. [DHHS 45 CFR 46.116; FDA 21 CFR 50.20; AAHRPP II.7.D]. When consent is required, it must be sought prospectively, and properly documented. [DHHS 45 CFR 46.117; FDA 21 CFR 50.20]. The requirement to obtain the legally effective consent of Individuals before involving them in research is one of the central protections provided for by the Federal regulations and the UMKC IRB.

The consent process involves three key features:

- Disclosing to the prospective human subject information needed to make a decision;
- Facilitating the understanding of what has been disclosed; and
- Promoting the voluntariness of the decision about whether or not to participate in the research.

Consent is more than just a signature on a form. It is a process of information exchange to include reading and signing the consent document. The consent process is the critical communication link between the prospective human subject and an investigator, beginning with the initial approach of an investigator and continuing through the completion of the research study. Investigators must have received the appropriate training and be knowledgeable about the study protocol in order that they may answer questions to help provide understanding to the study participant or potential study participant. The exchange of information between the investigator and study participant can occur via one or more of the following modes of communication, among others; face to face contact, email; mail; telephone; or fax.

5.4.2. Consent Process

Consent must be obtained under the following circumstances:

- Consent may only be obtained from subjects who have the legal and mental capacity to give consent. For subjects without that capacity, consent must be obtained from a LAR. See section 6.2.5.1 for details regarding additional requirements for Individuals with impaired decision making.
- The consent process shall be sought under circumstances that provide the subject (or LAR) with sufficient opportunity to consider whether or not to participate.
- The consent process shall be sought under circumstances that minimize the possibility of coercion or undue influence. Coercion occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast often occurs through an offer of an excessive or inappropriate reward or overture in order to obtain compliance.
- The consent information must be presented in language that is understandable to the subject (or LAR). To the extent possible, the language should be understandable by a person

who is educated to an 8th grade level and layman's terms shall be used in the description of the research.

- For subjects whose native language is not English, consent must be obtained in a language that is understandable to the subject (or LAR). In accordance with this policy, the IRB will typically require the consent process include a translator when the prospective subject does not understand the language of the research personnel tasked with obtaining consent. The translator may be asked to sign the approved translated consent form as the witness.
- The consent process may not include any exculpatory language through which the subject is made to waive, or appear to waive any of the subject's legal rights or through which the investigator, the sponsor, the institution or UMKCs employees or institutional agents are released from liability for negligence, or appear to be so released. [DHHS 45 CFR 46.116; FDA 21 CFR 50.20].
- The PI is ultimately responsible for ensuring that each prospective subject is adequately informed about all aspects of the research and understands the information provided. However, the IRB, the research investigators and the research staff all share in the responsibility of ensuring that the consent process is adequate.
- Federal regulations do not specify how far in advance of study entry a subject can provide consent. The amount of time required by a subject to make a decision would presumably depend upon the nature of the study, taking into consideration the degree of risk, potential benefits, alternatives, and desire to consult with family. It may be prudent to reiterate information contained in the consent document with the research subject prior to initiating any research procedures.

Regulations & Guidance: DHHS 45 CFR 46.109(b); 45 CFR 46.116; FDA 21 CFR 50.25; 21 CFR 56.109(b); OHRP Guidance on Exculpatory Language in Informed Consents; FDA Information Sheets: A Guide to Informed Consents; AAHRPP II.7.C.

5.5. General Requirements for Informed Consent

Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

Except for broad consent obtained in accordance with paragraph (d) of this section:

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

5.5.1. Basic Elements of Consent

To be valid, the consent process must provide the following basic elements of information to potential subjects:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental and done for research purposes;
- A description of any reasonably foreseeable risks or discomforts to the subject including privacy risks (legal, employment, etc.);
- A description of any benefits to the subject or to others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject must be maintained;
- For FDA-regulated studies, the possibility that the FDA may inspect the records needs to be included in the statement regarding subject confidentiality.
- For FDA-regulated studies subject to posting on clincaltrials.gov the following statement is required to be placed in the consent form:
- A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time."
- For research involving more than minimal risk, an explanation as to the availability of medical treatment in the case of research-related injury, including who will pay for the treatment and whether other financial compensation is available;

- An explanation of whom to contact on the research team for answers to pertinent questions about the research or to voice concerns or complaints about the research, and whom to contact in the event of a research-related injury to the subject;
- Contact information for the IRB to obtain answers to questions about the research; to voice concerns or complaints about the research; to obtain answers to questions about their rights as a research participant; in the event the research staff could not be reached; and in the event the subject wishes to talk to someone other than the research staff ;
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
- One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
- A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
- A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Regulations & Guidance: DHHS 45 CFR 46.116(b); FDA 21 CFR 50.25(a); OHRP Guidance on Exculpatory Language in Informed Consents; FDA Information Sheets: A Guide to Informed Consents; AAHRPP II.7.A.

5.5.2. Additional Elements of Consent to be Applied, as Appropriate

- Additional situational-specific elements that a consent should include are:
- A statement that the particular treatment or procedure may involve risks to the subject, which are currently unforeseeable (e.g., include when the research involves investigational test articles or other procedures in which the risks to subjects are not well known);
- A statement that if the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable (e.g., include when the research involves pregnant women or women of child bearing potential and the risk to fetuses of the drugs, devices, or other procedures involved in the research is not well known.);
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research (e.g., include when withdrawal from the research is associated with adverse consequences);
- Procedures for orderly termination of participation by the subject (e.g., include when the protocol describes such procedures);

- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject (e.g., include when the research is long term and interim information is likely to be developed during the conduct of the research);
- The approximate number of subjects involved in the study (e.g., include when the research involves more than minimal risk);
- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Investigational New Drug applications (IND) submitted to FDA are not required to contain a copy of the consent document. For significant risk devices, the consent document is considered to be a part of the investigational plan in the application for an Investigational Device Exemption (IDE). Any substantive changes to the document made by an IRB must be submitted to the FDA (by the sponsor) for review and approval.

Regulations & Guidance: DHHS 45 CFR 46.116(c); FDA 21 CFR 50.25(b).

5.5.3. Documentation of Consent

Except as provided in section 5.4.8, consent must be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's LAR at the time of consent. A copy of the signed and dated consent form must be given to the person signing the form.

All subjects should be afforded the opportunity to discuss the consent document in addition to reading and signing the consent document. In addition to signing the consent document, the subject or representative should enter the date of signature on the consent document to permit verification that consent was actually obtained before the subject began participation in the study. If the consent is obtained on the same day as the subject's involvement in the study begins, the subject's medical records/source documentation should document that consent was obtained prior to participation in the study. A copy of the consent document should be provided to the subject, a copy placed in all of the appropriate health records, and the original signed consent document should be retained in the study records. It is not required that the subject's copy be a signed copy, although a photocopy with a signature is strongly preferred.

The IRB may require a witness to sign and date the consent document as necessary to protect the rights and welfare of human subjects in research.

5.5.3.1. Short Form Consent Documentation

For the short form of consent documentation, the IRB determines that the regulatory criteria for use of the short form of consent documentation are met.

- The consent document states that the elements of disclosure required by regulations have been presented orally to the subject or the subject's legally authorized representative.
- A written summary embodies the basic and appropriate additional elements of disclosure.
- There will be a witness to the oral presentation.
- For subjects who do not speak English, the witness will be conversant in both English and the language of the subject.
- The subject or the subject's legally authorized representative will sign and date the consent document.
- The witness will sign both the short form and a copy of the summary.
- The person actually obtaining consent will sign a copy of the summary.
- A copy of the short form and IRB-approved consent document will be given to the subject or the subject's legally authorized representative.
- A copy of the summary will be given to the subject or the subject's legally authorized representative.

5.5.3.2. Consent – Version Control

A primary concern of the consent process is how to ensure the most recent approved consent is in use. Version control helps distinguish multiple draft versions from the final version, helps research teams keep documentation straight and may serve as a reminder of expiration date (if that information is maintained on the consent).

Version control will be maintained by the use of information maintained in the footer of each page of the consent form. At the time of submission, researchers will enter a version date in the footer of the consent form. Updated consent forms will receive an updated version as submitted by the Principal Investigator. In addition to version date control, the most recent approved version of the consent form will be marked as "Current approved" and found in chronological order within the "Attached files" section of eCompliance.

The footer contains the following information:

IRB ID:
Version Date:

The IRB-approved version of all consent forms must be free of tracked changes.

Regulations & Guidance: DHHS 45 CFR 46.109(c); 45 CFR 46.117; FDA 21 CFR 50.27; AAHRPP II.7.D.

5.5.4. Consent Monitoring

In reviewing the adequacy of consent procedures for proposed research, the IRB may on occasion determine that special monitoring of the consent process by an impartial observer (consent monitor) is required in order to reduce the possibility of coercion and undue influence, ensure that the approved consent process is being followed, or ensure that subjects are truly giving consent.

Such monitoring may be particularly warranted for:

- High risk studies;
- Studies that involve particularly complicated procedures or interventions;
- Studies involving highly vulnerable populations (e.g., ICU patients, children);
- Other situations when the IRB has concerns that consent process is not being conducted appropriately.
- Monitoring may also be appropriate as a corrective action where the IRB has identified problems associated with a particular investigator or a research project. If the IRB determines that consent monitoring is required, the IRB Chair and the RCO Director will develop a monitoring plan and submit it to the IRB for approval. The consent monitoring may be conducted by IRB staff, IRB members or another party, either affiliated or not with the institution. The PI will be notified of the IRB determination and the reasons for the determination. Arrangements will be made with the PI for the monitoring of the consent process for a specified number of subjects. When observing the consent process, the monitor will determine:
  - If the consent process was appropriately completed and documented;
  - If the participant had sufficient time to consider study participation;
  - If the consent process involved coercion or undue influence;
  - If the information was accurate and conveyed in understandable language; and
  - If the subject appeared to understand the information and gave their voluntary consent.
  - Following the monitoring, a report of the findings will be submitted to the IRB, which will determine the appropriate action to be taken.

5.5.5. Waiver or Alteration of Consent

An IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above; or waive the requirements to obtain consent, provided the IRB finds and documents that:

- The research involves no more than minimal risk to the subjects;
- The research could not practicably be carried out without the requested waiver or alteration;

- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

In addition, an IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of consent; or waive the requirements to obtain consent, provided the IRB finds and documents that:

- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
- Public benefit or service programs;
- Procedures for obtaining benefits or services under those programs;
- Possible changes in or alternatives to those programs or procedures; or
- Possible changes in methods or levels of payment for benefits or services under those programs.
- The research could not practicably be carried out without the waiver or alteration.

FDA regulations do not provide for waivers of informed consent except in emergency situations (see section 7.1.5 and 7.1.9.6).

Regulations & Guidance: DHHS 45 CFR 46.116; FDA 21 CFR 50.23; AAHRPP II.7.E; II.7.F.

5.5.6. Waiver of Documentation of Consent

The IRB may waive the requirement for the PI to obtain a signed consent form for some or all subjects if it finds any of the following:

- That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
- That 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; or
- If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB requires the PI to provide, in the application materials, a written summary of the information to be communicated to the subject. The IRB

will consider requiring the investigator to provide subjects with a written statement regarding the research.

Regulations & Guidance: DHHS 45 CFR 46.109(c); 45 CFR 46.117; AAHRPP II.7.E.

5.5.7. Obtaining Consent from Non-English-Speaking Subjects

The concept of "consent" requires that it be obtained in a language the subject understands. The research study and all other elements of consent must be explained fully to subjects in a language they understand by either a member of the research team qualified to obtain consent or a translator who speaks both English and a language in which the subject is fluent.

There are two possible situations involving non-English-speaking subjects — (1) the PI knows prior to submitting the protocol application that he or she may be enrolling one or more subjects who do not speak English; or (2) the PI identifies after IRB approval of the protocol application one or more potential subjects who do not speak English. The requirements for each situation differ slightly.

5.5.7.1. Translation processes:

The IRB must approve all foreign language versions of written or oral consent documents and all survey instruments as a condition of approval. The translation process for IRB approval can be carried out in one of the following ways:

- A two-way process where, first, there is a forward translation from English to non-English by a translator fluent in both languages, followed by a back-to-English translation by a second bilingual translator who has not seen the original English consent form. The PI and the IRB then assess the adequacy of the non-English translation by comparing the two English versions. The IRB must approve the translation as accurate before it can be used to enroll subjects. This method is preferred, particularly for protocols and consent forms that are somewhat complex, difficult to understand, etc.
- A one-way translation of the English version into the non-English version which is certified as accurate by a translator who is certified to be a translator for that language. Under this process, the IRB will accept a certified translation for review and approval without requiring a back-to-English translation.

If the protocol and the English versions have been approved already by the convened IRB, translation(s) may be reviewed and approved by the Chair of the IRB or the Chair's designee. However, if an additional risk for the non-English-speaking subject is identified, the translation(s) should be referred to the convened IRB for review and approval. The IRB must approve all translated versions of the consent form and recommends that the written translation be done by a certified translator. However, the IRB will consider, on a case-by-case basis, allowing other translators to perform this function with verification that the translation is an accurate and acceptable presentation of the entire English version.

PI plans to enroll non-English-speaking subjects before submitting protocol application:

If it is known in advance that a potential subject or a significant percentage of the prospective subjects does not speak English, a written consent form in the language of the consenting subject(s) must be submitted to the IRB as part of the protocol application.

The English consent form should be translated into the appropriate foreign language for review and approval by the IRB, preferably by the two-way process described above in 1. Translated versions of research instruments must also be provided to the IRB for their review and approval before they can be used.

If convenient for investigators, the translation and back translation of the approved consent form may be submitted as an amendment to the IRB and approved before a research subject is authorized to use the translated consent form or participate in the research protocol.

PI identifies potential non-English-speaking subjects after IRB approval of protocol application:

If the majority of anticipated research subjects are English speakers, but the PI identifies for enrollment an Individual who does not speak and read the language of the approved consent form, he or she may use the IRB-approved "consent short form" in the language that the subject knows fluently in cooperation with a translator who speaks English and the language of the research subject. A short form template is provided on the IRB website. Consent short forms may be used with a translator's oral explanation of consent information to obtain consent from non-English speaking subjects in a study when the majority of subjects are English speakers, as an alternative to translated consent forms.

While the institution provides versions of the approved short form in a number of languages on the IRB website, the PI is responsible for identifying and using the services of a translator. For minimal-risk research, a family member who speaks the research subject's native language and is fluent in English may generally serve as translator. However, the research staff should use some sensitivity when a teenager is being asked to serve as a translator for a study where it may be embarrassing for them to serve as the interface between the subject and the research team. In no case should children under the age of 13 be used as translators.

If the PI finds that he or she is using the consent short form in the same language frequently (for approximately 4 or more subjects), the PI should have the full length consent form translated and approved by the IRB.

Roles in the process of obtaining consent of non-English speaking subjects:

The IRB may require that a minimum of two persons fulfill the following three roles.

The translator and the witness, if applicable, each must be fluent in the language being used by the person obtaining consent (generally, English) and the language of the research subject.

> **Translator**: the translator gives an oral presentation to the subject or representative in a language in which they are fluent, describing the content of the English-version consent form. The translator can be related to or closely associated with the subject or representative if that is acceptable to them. If the translator is a member of the research team, he or she may also serve as the person obtaining

the consent, but an Independent person fluent in both languages must then serve as the witness. As appropriate, the translator signs the English consent form and the translated form or the consent short form, which should state that the translator has explained all details in the English consent form to the subject and has communicated any questions from the subject to the research team.

Witness: the witness can be related to or closely associated with the subject or representative if that is acceptable to them. The witness may serve as the person obtaining consent, but may not then serve as the translator. The witness certifies that an oral presentation was made to the subject or representative in a language understandable to them and described accurately the content of the English-version consent form. As appropriate, the witness signs the English consent form and the translated form or the consent short form, which should state that the witness observed that the translator's presentation of the English consent form details to the subject or representative was complete and understandable to them.

Person obtaining consent: the person obtaining consent may not be related to or closely associated with the subject or legally authorized representative. The function of the person obtaining consent is to supervise the consent process and to be able to answer any questions about the study posed by the subject or representative. The person obtaining consent may serve as the translator or witness, but not both. As appropriate, the person obtaining consent signs the English consent form and the translated form or the consent short form. As appropriate, the research subject signs and receives a copy of the consent form or the short form.

Oral consent: Where oral consent is appropriate, as set forth in section 5.4.6, a translator fluent in both English and the subject's language should translate the IRB-approved English consent form orally to the subject in front of a witness. The IRB may require that the translator be a non-research team member. The translator may serve also as the witness, if appropriate.

Questionnaires:

Written questionnaires: when subjects who do not understand English are involved in studies that require answering questionnaires, the questionnaires must be translated into a language that those subjects understand, while maintaining the same format. Furthermore, the translated questionnaires must convey the same meaning as the original English versions. Otherwise, the responses of non-English speakers will not be comparable to those of English speakers. The translation process shall be the same one-way or two-way process described above in section 1.

Verbal questionnaires: verbally-administered questionnaires shall be the same for English and non-English speakers in both content and format. The PI may select one of these two translation options:

Verbal administration: the questionnaire does not require a written translation. Instead, it will be verbally administered by a person who is fluent in both languages.

Written translation: the questionnaire will be translated into a language understandable to the subject by the two-way process. The translated questionnaire must be administered verbally by a person who is fluent in the subject's language, but this person need not be fluent in English.

Other documents:

If the research involves the use of oral scripts, educational materials, advertisements, or other documents in addition to the consent forms and questionnaires, the PI must describe in the protocol the measures that will be taken by the research team to ensure that the information contained in those documents will be conveyed to the subjects in an understandable way. Under normal conditions, translated copies should be submitted to the IRB for review and approval. The extensive use of a translator to work with the research subject in order to communicate the information in the materials is an acceptable alternative to providing translated documents.

5.5.8. Exempt Studies Utilizing an Information Script from Non-English-Speaking Subjects

By definition, "exempt" research is exempt from the requirement for a signed consent form. Nevertheless, the ethical principles listed in the Belmont Report, particularly the discussion of the first principle, respect for persons, emphasizes the importance of ensuring that subjects are fully informed about the nature of the research project so that they can make an informed decision to participate or not. An Information Script provides this type of information.

Chronological steps when submitting an Exempt protocol:

1. Submit the English version of the Information Script and any other documents participants will interact with during the course of their participation in the study.
2. Submit the English-language documents to a translator for translation and have them sign a translator certification form. Exempt studies do not require back translations. To determine who can act as Translator, see Table 1 below.
3. Submit the translated documents and signed translator certification form.
4. Wait for the Research Compliance Office to respond indicating the documents have been accepted and can now be used.

Additional Considerations: Some study designs may benefit from the addition of an Interpreter (i.e., focus groups, interviews). If you plan to use an Interpreter during the course of the study this should be described in the application. To determine who can act as Interpreter, see Table 2 below.

TABLE 1: WHO CAN ACT AS THE TRANSLATOR?

- This individual must read, speak, and write the native language and English.

	Exempt	Expedited - No Clinical Procedures	Expedited - Involves Clinical Procedures	Full Board
Fluent Study Team Member	Yes	No	No	No
Non-Certified Translator Who is Not Part of the Study Team	Yes	Yes	No	No
Certified Translator Who is Not Part of the Study Team	Yes	Yes	Yes	Yes

TABLE 2: WHO CAN ACT AS THE INTERPRETER?

- Must read, speak, and write the native language and English
- Is available to answer Participants' questions at any stage of the study

	Exempt	Expedited - No Clinical Procedures	Expedited - Involves Clinical Procedures	Full Board
Family Member of Participant	No	No	No	No
Fluent Study Team Member	Yes	No	No	No
Bilingual Individual Who is Not Part of the Study Team	Yes	Yes	No	No
Bilingual Clinical Staff Who is Not Part of the Study Team	Yes	Yes	Yes	Yes
Medical Interpreter Who is Not Part of the Study Team	Yes	Yes	Yes	Yes

Approved by: Yusheng Liu, PhD
Name of University Institutional Official

March 9, 2022

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Signature of University Institutional Official Date