

Translation of Informed Consent Documents

Approval Date

March 21, 2023

Effective Date

January 1, 2024

Last Revision Date

March 13, 2023

Responsible Party

SDSU Research Support Services and the SDSU IRB

Scope and Audience

SDSU Principal Investigators conducting human subjects research.

Additional Authority

45 CFR 46, 21 CFR 50, 56

1. Policy Purpose

To ensure that informed consent is obtained in a language that is understandable by potential research participants.

2. Policy Statement

Translation of informed consent documents that reflect the study population that the PI wishes to recruit for participation is required at all review levels. If the PI does not employ a certified translator, they must provide evidence in the form of a statement about their level of proficiency in the language and their experience in translating documents from English into the foreign

language relevant to a study population. They must attest that they are the individual who translated the informed consent document(s), and that they have the expertise to do so. At the time of IRB submission all consents and relevant study documents must be submitted in English. Translations of IRB-approved documents must be submitted as an amendment.

3. Definitions

Proficient [regarding translations]: The ability to translate documents well due to education, training, experience, and practice. An advanced knowledge of the language the document is to be translated to as well as an advanced knowledge of the language to be translated from. Proficiency requires an in-depth cultural knowledge including understanding cultural idioms, and the ability to communicate effectively in writing as demonstrated by knowledge of grammar rules, punctuation rules which may differ in foreign languages.

Certified translator: An individual who has passed a certification exam to verify their translation skills.

Certified translation: One where a translator or another reviewer provides a [written] statement, in addition to the translated document. The statement which includes:

- A statement of the translator's qualifications.
- A statement affirming the completeness and accuracy of the document.
- Identification of the translated document and language.
- The translator's name, signature, and date.

<https://www.atanet.org/client-assistance/what-is-a-certified-translation>

IRB Review levels: There are three levels of review, exempt, expedited, full board.

- **Exempt:** The human subjects research proposal meets criteria to be reviewed under 45 CFR 46.104
- **Expedited:** The human subjects research proposal meets the criteria to be reviewed under 45 CFR 46.110.
- **Full Board:** The human subjects research proposal does not meet the criteria to be reviewed at 45 CFR 46.104 or 45 CFR 46.110.

4. Forms

See links at the end of this document.

5. Frequently Asked Questions

Information may be posted on the IRB webpage—date to be determined.

6. Related Information

1. American Translators Association: [Language Services Directory – American Translators Association \(ATA\) \(atanet.org\)](https://www.atanet.org/)
 2. [SAN DIEGO TRANSLATION CENTER](https://www.sandiegotranslationcenter.com/)
 3. San Diego Translation and Interpretation Services: [Translators-USA](https://www.translators-usa.com/)
 4. [AML Global](https://www.amlglobal.com/)
 5. [Corporate Translations](https://www.corporatetranslations.com/)
 6. [LinguaLinx](https://www.lingualinx.com/)
 7. [Transperfect Translations](https://www.transperfecttranslations.com/)
 8. [Accredited Language Services](https://www.accreditedlanguageservices.com/)
 9. Executive Linguist Agency, Inc: [Translation Service](https://www.translation-service.com/)
 10. [Interpreters Unlimited Group](https://www.interpretersunlimitedgroup.com/)
 11. [TranslationServices.com](https://www.translation-services.com/)
-

Last Review Date

March 21, 2023

Revision History