ORLANDO HEALTH®

1414 Kuhl Ave.
Orlando, Florida 32806
321.843.7000

Type of Policy:	***PROTECTION OF HUMAN RESEARCH PARTICIPANTS***	Category:	**Institutional Review Board (IRB)**

Title:	***Translation of Study Documents***	Policy #:	**0330-1022**
		Replaces #:	
Page:	1 of 2	Developed By:	Orlando Health Institutional Review Board (IRB)
Issue Date:	4/14/2015	Approved By:	
Revision Dates:	2/12/18, 1/7/19, 4/5/21, 5/14/24, 7/15/25		Philip Giordano, MD Institutional Official **SIGNATURE ON FILE**

I. PURPOSE: To establish the requirements for written translation of study documents from the English language to another language.

II. DEFINITIONS:
Please refer to the IRB Definition Policy

III. POLICY:
It is the policy of the Orlando Health IRB that informed consent forms and study related documents should be translated into a language comprehended by research subjects (participants if a researcher intends to enroll subjects (participants) who do not have adequate skills in reading English, but are fluent in reading another language.

IV. PROCEDURE:

A. Costs of Translation: If the study is funded, the costs of translation should be covered by the Sponsor whenever possible.

B. Translation process

1. The English version of approved study documents, including informed consent documents, should be approved by the IRB before the documents are translated into languages other than English. This is to avoid having to pay extra translation fees if the IRB requests changes to the English version of the document. Exceptions may be made for items (such as patient diaries, wallet cards, letters to patients, information sheets, etc.) that are not likely to require modification by the IRB. NOTE: If translating informed consent documents, use the most current "clean" Word version for the translation; do not use the IRB approved stamped PDF version.
2. Investigators may not use the translated documents until they are approved by the IRB.
3. Written translations must be accompanied by a verification statement including the following information:
   a) Date of the translation
   b) Statement that the translation is true, accurate, and correct to the best of the translator's knowledge and ability.
   c) Qualifications and/or credentials of the person responsible for the translation (i.e., translator or designee)
   d) Signature of the person responsible for the translation (i.e., translator or designee)

C. Required documents for IRB submission

1. A completed "Information Only/"Other" Submission Report" and/or the appropriate IRB-related form
2. IRB-approved or IRB approvable English version of the document(s) that have been translated
3. The translated version of the document(s)
4. The translator verification statement

D. Approval process

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1. The IRB staff will confirm that all required documents are included in the submission.
2. The IRB Chairperson or designee will acknowledge or approve the submission in IRBNet, as appropriate for the materials submitted.
3. The translated version of the consent document(s) will be stamped "Approved" with the effective date. For other documents not requiring a stamp, the list of approved items will be provided in the approval letter. In some cases, IRB staff may provide an approval or acknowledgment stamp on translated documents other than the consent form, if appropriate.
4. IRB staff will publish the approvals/acknowledgments in IRBNet.

V. DOCUMENTATION:

A. Information Only/"Other" Submission Report Form

VI. REFERENCES:

A. 21 CFR 50.20, 21 CFR 50.27, 45 CFR 46.116, 45 CFR 46.117
B. OHRP and FDA Guidance Documents

VII. ATTACHMENTS:

A. None.