

## SHORT FORM USE UPDATE

As part of the most recent update to the Human Research Protections Program (HRPP) Standard Operating Procedures (SOPs), Hackensack Meridian Health's stance on the use of short forms (Section 11.6) has been altered to promote more objectivity and clarity, and to ensure equitable autonomy and process with regard to the consent process for non-English speaking research participants.

The Office of Human Research Protections (OHRP) states: "Where informed consent is documented in accordance with 46.117(b)(1), the written consent document should embody, in language understandable to the subject, all elements necessary for legally effective informed consent. Subjects who do not speak English should be presented with a consent document written in a language understandable to them. OHRP strongly encourages the use of this procedure whenever possible."

The following applies to all studies taking place at HMH, both when HMH IRB is the IRB of record and when the study relies on an external IRB of record.

As such, the revised SOP limits the use of the short form process to situations when **both** are true:

- A full-length version of the consent form in a language understandable to the subject is not available, and
- It is in the subject's best medical interest to be enrolled in the research before a translated consent form can be obtained.

If there is no direct medical benefit to the subject by being enrolled in the study, the consent form must first be translated into the language that the patient can read prior to enrollment.

Additionally, if a short form is used, the subject or their LAR **must** be reconsented with the current IRB-approved consent form in a language understandable to the subject within 60 (business) days or at the first visit after receipt of the translated consent form (whichever is less).

If the Principal Investigator anticipates that a study is likely to enroll more than a few participants who speak the same non-English language, the consent should be translated and submitted upfront.

\*Any study that was previously approved to include a short form that would, under this policy revision, not be permitted to use this process is grandfathered in and may continue to use a short form. If more than a few participants are enrolled who speak the same non-English language, please consider having the consent form translated into that non-English language for future enrollment.

\* For translation of a consent form into a non-English language, please email Jessica Ansbach or Elizabeth Lind in Language Services: [Jessica.Ansbach@hmhn.org](mailto:Jessica.Ansbach@hmhn.org) or [Elizabeth.Lind@hmhn.org](mailto:Elizabeth.Lind@hmhn.org)