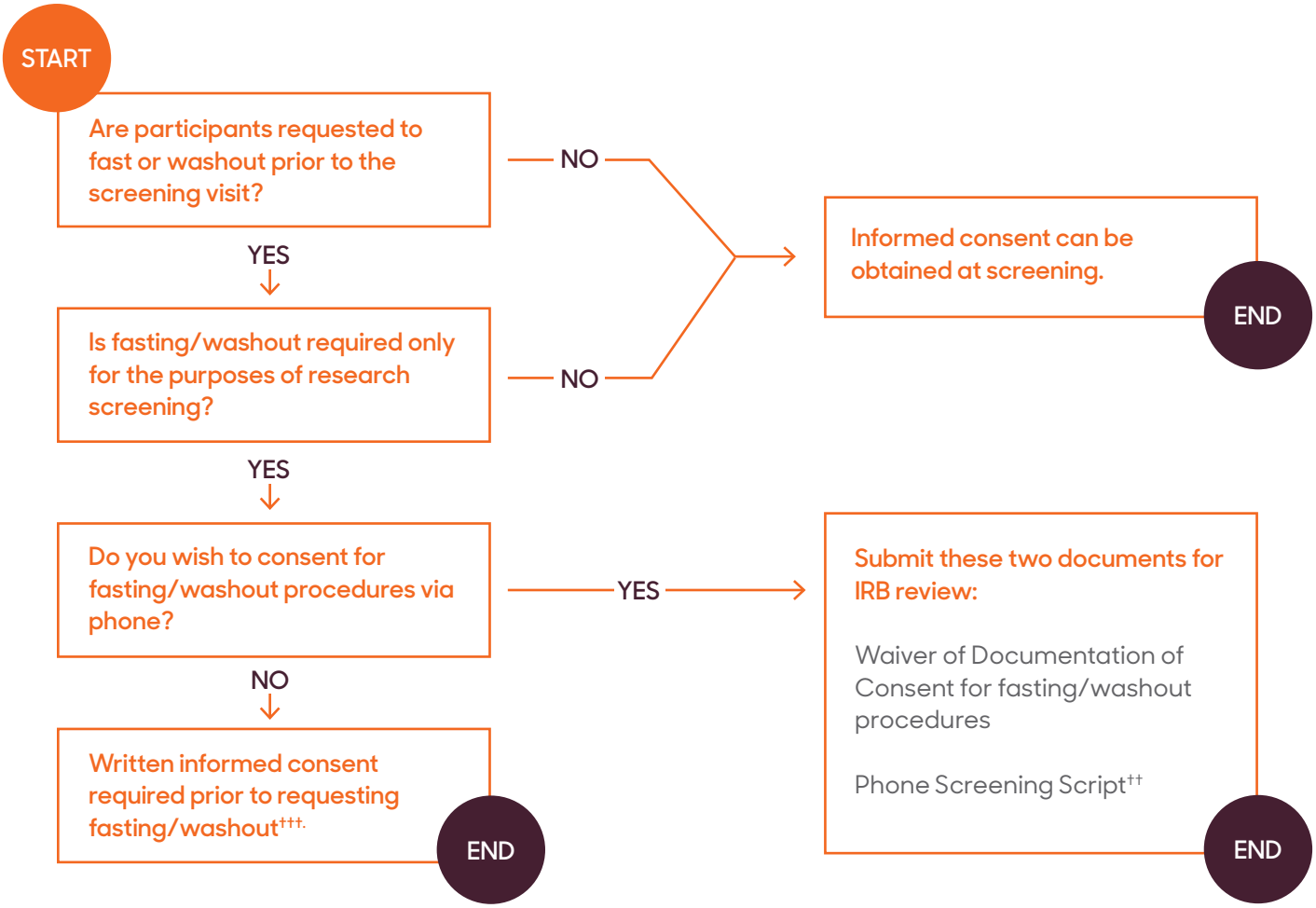
Researcher's Guide to Screening: Assessing Consent Needs For Fasting and Washout

In general, a participant cannot be asked to undergo a study procedure before study staff have obtained and documented informed consent.

Occasionally, however, a participant must fast and/or temporarily withhold regular medications (washout) prior to a first study visit, in preparation for certain clinical tests to help determine eligibility for the research†. If this is the case for your study, please refer to the chart below to ensure your consenting plan meets regulatory requirements.



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† What is the source of this information?

This document is based on the FDA Information Sheet, Screening Tests Prior to Study Enrollment, available at: http://www.fda.gov/RegulatoryInformation/Guidances/ucm126430.htm (accessed 07/17/15).

Please note:
This document is intended to address FDA-regulated research only. The Common Rule has a different definition of "human subject" (see 45 CFR 46.102(f)). As a result, research regulated under the Common Rule may require consent under more circumstances, such as screening questionnaires that collect identifiable private information.

†† What should be included in a phone screening script?

The phone screening script must explain the research screening and ask whether the participant agrees to fast and/or washout. Risks of fasting and/or washout must be included, along with all basic elements of consent.

If applicable, HIPAA elements may also need to be incorporated into a phone screening script. It remains the obligation of a site to determine if and how the HIPAA privacy rule applies to its research activities.

For more information about HIPAA related to research activities, please visit: http://www.hhs.gov/ocr/privacy/hipaa understanding/special/research/research.pdf

††† If written informed consent is required prior to fasting or washout, must the protocol be revised?

If written informed consent is necessary prior to fasting or washout, the protocol should be revised or clarified to address the timing of consent.

For example, the protocol may be revised either to explain that written consent will be obtained prior to the screening visit, or to add an initial screening visit where all screening procedures are done except the fasting blood draw and washout

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