Effective 11.30.20

Columbia University

IRB Guidance on Home Study Visits Conducted by Home Healthcare Agencies

Home healthcare agencies ("HHAs") may be contracted by Columbia or by an external study sponsor to conduct study visits in the homes of research participants.

The involvement of HHAs must be described in the protocol and consent document(s) that are submitted to the IRB, including such factors as whether the home visits are optional or required, the procedures that will be performed by the HHAs, and the measures that are in place to safeguard the confidentiality of participant data by the HHA representatives, e.g., while in transit or stored by the HHA.

Federal regulations for the protection of human subjects in research at 45 CFR 46, which apply to federally funded research, require IRB approval for all institutions engaged in *research* that involves *human subjects*, each as defined therein. HHAs that provide services *only* for research studies and interact with study participants are considered to be engaged in human subjects research. Columbia University applies the federal regulations for the protection of human subjects at 45 CFR 46 to all *research* that involves *human subjects*, regardless of funding source. Accordingly, when HHAs provide services that constitute engagement for non-federally funded research, IRB approval for such services is required.

IRB approval of the HHA's engagement for a study at a Columbia site may be provided by an external IRB, in which case documentation of such approval is required, or by a Columbia IRB as part of a sponsor's protocol for such study. Columbia may serve as the reviewing IRB for all sites or for Columbia sites only. In the latter situation, the IRB determination letter should include a statement that HHA activities are covered only for the study being reviewed and, if applicable, for Columbia sites only. When Columbia is the reviewing IRB for non-Columbia study sites, IRB approval for the external sites includes approval of the HHAs.

Columbia investigators are responsible for ensuring that instructions to the HHAs are clearly communicated and that documentation of, and follow-up to, procedures performed during home study visits are equivalent to the documentation and follow-up that would occur for procedures performed by Columbia personnel on-site. Best practices include:

- Communication between Columbia researchers and the HHA representative before and after each visit;
- Communication between Columbia researchers and participants about the impending home study visit and feedback after the visit; and
- Attention to data security, e.g., how participant data is transferred/transported.

HHA representatives are not investigators and should not be listed on FDA Form 1572 filed by a Columbia investigator. Columbia delegation of authority logs should not include HHA representatives, although research records must clearly document by whom each study procedure is performed, whether by Columbia personnel or HHA representatives.

When a HHA is contracted directly by a study sponsor, the sponsor is responsible for ensuring that the HHA meets all applicable requirements such as licensing and credentialing, and is trained on the study protocol.