**Guidance of the Use of External Home Health Services**

1. If at all possible, try to keep the home health agency “not engaged” in research. Engaged means they will conduct any activities that are dictated by the protocol. They may be “not engaged” if they are conducting activities they would normally conduct for **non-research** purposes. However, a home health agency that primarily supports research is automatically engaged.
2. The contract must limit VUMC’s obligations to the procedures to be conducted at VUMC. The portion of the protocol being performed at participant’s homes must be excluded from the scope of work for VUMC to perform.
3. The sponsor or group engaging the home health services for the study must agree: i) to indemnify VUMC for any damages that arise from the portions of the study being performed at participant’s homes; ii) to expressly release VUMC from all responsibility/liability for any actions of the home health agency; and iii) to obligate the home health agency to maintain all patient information in confidence.

For Your General Information

VUMC IRB cannot serve as the IRB of Record for any home health agency assigned by a sponsor or CRO. The VUMC IRB approval letter must indicate that the approval is limited to procedures performed at VUMC.

The home health agency must not be listed on the 1572 of any study, this indicates the PI is responsible. If federally funded, the home health agency must have a Federalwide Assurance.

The home health agency must consent for their part, separate from the study, if applicable.