**Home Study Visit checklist – Supplement to Research Protocol**

Home study visits may be conducted by Columbia personnel, a Home Health Agency (HHA) or, rarely and for safety reasons only, by a medical device manufacturer. The IRB Position Statement about use of Home Health Agencies, and applicable contractual and other requirements, can be found on the HRPO/IRB website [here](https://research.columbia.edu/sites/default/files/content/HRPO/Home%20Study%20Visits%20Conducted%20by%20Healthcare%20Agencies%20final.pdf).

1. This form should be completed to provide additional information to the IRB about procedures performed at the research subject’s home.
2. The completed form should be attached in the print menu in Rascal before submitting the event (e.g., new protocol, modification, renewal).
3. Include the following statement in the procedure page of the Rascal form, in response to the following question “Is there an external protocol that describes ALL procedures in this study?”: “*Home visits will be performed by [insert: Name of Home Health Agency or Manufacturer; or “Columbia personnel”]. The Home Study Visit checklist was completed and is attached in the print menu*.”
4. If home visits are proposed with a modification or at the time of renewal, update the Summary of Modification to reflect this and select the “Procedures” option under the Modification information page.

For shaded cells, no response is required.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Question** | **Yes** | **No** | **Response** |
| 1 | Protocol number: |  |  |  |
| 2 | PI Name: |  |  |  |
| 3 | Home visits to be conducted by: |  |  | Columbia personnel  HHA hired by Columbia (provide name of HHA):  HHA hired by external sponsor ( provide name of HHA):  Manufacturer representative (provide name of manufacturer): |
| 4 | Are home visits optional? |  |  |  |
| 5 | Why are home study visits proposed? |  |  |  |
| 6 | What study procedures will be conducted in home visits? |  |  |  |
| 7 | If a HHA or manufacturer will conduct the home visits: Are all procedures to be conducted also conducted by the HHA or manufacturer in non-research situations? |  |  |  |
| 8 | What is the risk level of study procedures to be conducted in home visits? |  |  | No greater than minimal risk  Greater than minimal risk |
| 9 | Do study procedures to be conducted in home visits involve radiation exposure or other hazardous material procedure/exposure? If yes, describe and complete the appropriate Rascal Appendix. |  |  |  |
| 10 | If home visits will be conducted by a HHA or manufacturer, is IRB approval for the HHA/manufacturer’s services at CU sites for this study included in the submission to the IRB? |  |  | ☐ N/A; services are provided by Columbia personnel .  ☐ N/A; services are routine procedures performed by the HHA or manufacturer for non-research purposes, therefore the HHA/manufacturer is not engaged in the research.  ☐ Yes (documentation should be attached to the Rascal submission)  ☐ No; the HHA is contracted by the study sponsor, and Columbia will provide IRB review and oversight for the HHA as part of the protocol.  ☐ No; the HHA is contracted by Columbia and the HHA will rely on Columbia for IRB review through the terms of a reliance agreement. |
|  |  |  |  |  |

Signature on this form by the study PI or designee confirms the following:

* There is a plan in place for training personnel conducting home visits.
* There a plan in place for monitoring the conduct of home visits, including communication between the CU PI or designee and the personnel conducting home visits.
* Study records will include documentation of home study visits, including procedures performed and name of person conducting procedures.
* The consent form describes the home visits and, if optional, includes a requirement for subject initials or signature for this option.
* All personnel conducting procedures will be appropriately qualified and, as applicable, credentialed or licensed. This is the responsibility of the PI if not covered in an applicable agreement or contract.

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Signature of PI or designee Date