***Example of a Home Visit Protocol:***

The following protocol is implemented to standardize safety for study home visits or visits in the community.

The study will conduct home visits for data collection to provide convenience for participants around family schedules (e.g., early morning fasting blood draws) and because visits for the follow-up primary outcome data collection time point have more than one interaction (e.g. repeated blood pressure measurement). When there is already a scheduled clinic visit during the data collection window, we will plan to perform data collection before or after that encounter. However, home visits will still be needed per the above and to ensure high study follow-up. Safety of participants and staff collecting the information are high priority.

We follow these procedures:

1. Study staff schedule a day/time for the home visit with the study participant.
2. Decide which staff will complete the home visit. It is best to have two staff.
3. The study participant is contacted as a reminder either the evening before, if an a.m. visit, or the morning of, if a p.m. visit.
4. Appropriate COVID-19 screening questions are asked by phone. If there is concern for anyone in the home being ill, appropriate referrals are made and the visit is postponed.
5. For confirmed visits, staff and supervisor will have the address and the time of the home visit and know the approximate time it will take to complete the visit.
6. If the study visit is not confirmed, the staff will try again to contact. After two contact attempts and no response before the attempted travel time, the team will not attempt the visit and will re-schedule once they establish contact.
7. Prior to entering the home or community site (e.g., library) to complete the home visit:
	1. Check surroundings to ensure staff feel safe
	2. The staff contact another team member not on the visit so the team knows where the staff member conducting the home visit is. This typically is the study coordinator or study director.
8. During the visit, conduct planned data collection procedures as efficiently as possible while maximizing the comfort and safety of the participant.
9. Appropriate personal protective equipment is used for study staff and provided for (e.g., masks) for the participant and household members who will be in the room. Other up-to-date COVID-19 related guidance is followed (e.g., asking about symptoms, taking temperature with touchless thermometer)
10. After the visit, the study team removes all study equipment and supplies used during the visit including any disposable items such as alcohol pads, gloves, etc.
11. Once data collection staff complete the visit and are safely in their vehicles they will contact the study coordinator or study director letting them know the visit was completed.
	1. If the expected time to conduct the visit passes without hearing from the data collection team, the study coordinator will contact the staff conducting the visit to check in on progress and timeline until completion. If contact is not established, the study coordinator will implement other procedures (i.e. check in with study participant, contact principal investigator).

9.   As soon as the visit is complete and staff are at their work spaces, they will document information about the study visit on study forms including time spent completing the visit, all those the study team interacted with such as the study participant, guardian, parent, etc. Study data collected, if not collected electronically, is entered into the study database. All study visit attempts including those where contact was not made (i.e., participant was not home) are tracked.

For home visits with participants under the age of 18, the parent/guardian is the point of contact and must be present during the visit.

Gail Daumit, MD, MHS Principal Investigator

Joseph Gennusa, PhD, RDN, LDN Research Program Manager II