Data and Safety Monitoring Plan. A data and safety monitoring plan has been developed to ensure and maintain the scientific integrity of our research study and to protect the safety of the participants. Although the risks associated with our proposed research are minimal and are not expected to occur, utmost care and concern will be taken to ensure participant safety. Our plan includes the development of a small Data and Safety Monitoring Board (DSMB). A statistician and doctorally prepared nurse practitioner will meet once in year one and once in year 02 and more often if there is an investigator-identified concern.

The DSMB will objectively examine project data and assess whether participants are experiencing risks or health problems at a rate greater than expected to occur by chance. DSMB members will look for changes in blood pressure (BP) and cardiovascular morbidity and mortality in both treatment groups. If DSMB members note a rise in BP in any of the treatment groups to above baseline levels, or has other concerns, they will contact the Principal Investigator and meet with the investigators to discuss their concerns and appropriate remedies. Specifically, monitoring will include: (a) monitoring of adverse events (i.e., checking to determine if the observed frequency and type of events exceeds the expected in the population); (b) ensuring that recruitment is on target (i.e., examining that the expected and actual numbers of participants entered into the study to date are close to target and that the number of participants assigned to the experimental interventions is as expected); and (c) ensuring that retention rates remain high.

Adverse event data will be reviewed in the context of information about hypertension, the number of participants accrued at the time of the review versus total number of participants to be recruited in the study, and group assignment. Reports of adverse events will include the proportion and number of participants who reported a particular problem, severity of the adverse events during a specific time frame, or relative to time patterns. Adverse events are to be ascertained at the 3 month follow-up date.

Participants in each intervention group and their healthcare providers will be informed in writing of all potential hypertensive urgencies or emergencies, and of depression greater or equal to a score of 20 as measured by the BDI-II, in order to allow for appropriate treatment as soon as possible. The following list describes the criteria that will be used to determine adverse events, the need for additional safety measures, or the need to stop the trial.

- Dropout from one study group is four times greater than the dropout rate from the other group. Attrition from each study group is expected to be equal.
- Less than 1 person recruited per month for two consecutive months. The monthly target recruitment goal is 12.
- Unresolved equipment failures greater or equal to 50% of the telemonitoring intervention group. Since telemonitoring is a fairly new technology some equipment failures are expected.
- Adverse health event (death, stroke, myocardial infarction) rates in the telemonitoring (TM) intervention group two-fold greater than adverse health event rates in the usual care (UC) group.
- Mean level of depression in either group greater or equal to a score of 20 as measured by the BDI-II. For either treatment group, a rise in the mean systolic blood pressure (SBP) greater or equal to 20 mm Hg or a rise in mean diastolic blood pressure (DBP) greater or equal to 10 mm Hg that is maintained over a 6-month period.
• A rise in an individual participant's SBP to greater than 180 mm Hg or a rise in an individual participant's DBP to greater than 105 mm Hg.
• Differential change in SBP and DBP between groups.

**A Data Safety and Monitoring Committee**

Once a year the committee will meet and our data manager will submit current data for their objective review. These data will include changes in BP and cardiovascular morbidity and mortality in both groups. If the committee notes a rise in BP in either the MI group or the LI group to above baseline levels, or has other concerns, the chair will contact the Principal Investigator and meet with the investigators to discuss their concerns and appropriate remedies.

Chair:
Josef Coresh, MD, PhD, Associate professor of Epidemiology, Medicine and Biostatistics, the Johns Hopkins Medical Institutions.

Members:
Lawrence Appel, MD, MPH, Associate Professor of School of Medicine, the Johns Hopkins University.
Micheal Klag, MD, MPH, Professor of School of Medicine, the Johns Hopkins University.
Donald Steinwachs, PhD, Chairman of Department of Health Policy and Management, School of Public Health, the Johns Hopkins University.
Peter Beilenson, MD, MPH, Commissioner of Health for the City of Baltimore
Arlene Butz, ScD, RN, Associate Professor of School of Medicine, the Johns Hopkins University.
Neil Powe, MD, MBA, Professor of School of Medicine, the Johns Hopkins University.

**Advice Dr. Milton Friedman sent me the first time I was planning a DSMB.**
The NIH policy is that a Data and Safety Monitoring Plan is required for clinical trials. Further information can be found on the web at [http://www.nhlbi.nih.gov/funding/policies/dsm-12.htm](http://www.nhlbi.nih.gov/funding/policies/dsm-12.htm). Components of a monitoring plan can include:

- procedures for obtaining and analyzing data on potential adverse events
- evaluating the quality of the data being collected
- monitoring recruitment and retention rates
- reviewing interim efficacy data to determine if the study has answered the research question early.

Monitoring is used to determine what corrective actions, if any, are needed and to determine if a study should be stopped early either because of safety or efficacy issues.
List the potential adverse events that you will actively monitor and have a specific form for reporting them. The events to be selected should be those that are potential adverse effects of the intervention being tested. For example, a study of physical activity intervention would monitor potential adverse events related to physical activity including musculoskeletal injuries, heart attacks, and any hospitalizations. Study participants can be specifically asked at regular intervals if they had had any of these events. One thing we have learned from some studies is that it is useful to ask about the potential adverse events at baseline to get a "background level" that can be used for comparison of the followup rates, particularly for lifestyle studies.

The rate of events should be compared between the intervention and control arms at regular intervals, say twice a year, and reviewed by persons outside the study so that the investigators and staff remain blinded to ensure lack of bias. The reviewers would then provide feedback and recommendations to the investigators. The reviewers could also look at efficacy data, and you could conduct efficacy monitoring by standard methods, e.g., the O'Brien Fleming method.

In addition to monitoring adverse events by randomized arm, monitoring for individual adverse events, regardless of arm, can be a component of the plan. Such monitoring enables the investigators to identify adverse events and then deliver corrective actions. For example, in a study of diabetes treatment, monitoring for multiple severe hypoglycemia events can occur, and patients with multiple events could have their case reviewed by an expert in diabetes and recommendations provided to prevent future events.

Monitoring for recruitment and retention includes comparing the recruitment rate to predetermined goals and evaluating rates of followup with a goal of 100%. Monitoring data quality includes obtaining information on accuracy of any tests and completeness and timeliness of data collected.

You may want to establish an investigator-appointed Data and Safety Monitoring Board (DSMB) (see the website http://www.nhlbi.nih.gov/funding/policies/dsmb_est.htm). Such a board can review all aspects of the monitoring mentioned above. I recommend establishment of such a board; investigators have found them quite useful in addition to fulfilling the NIH policy on monitoring. DSMB members can be selected to be knowledgeable about the topic area under study, which has advantages over using an IRB for this purpose. In addition, the board can provide advice regarding other aspects of the study, such as recruitment approaches. It could be a small number of people, and could be local people, or could be convened by conference call, so does not have to be costly.