Agency for Healthcare Research and Quality (AHRQ): Standardizing Antibiotic Use in Long-Term Care Settings (SAUL) Study
Response to OMB comments

1. It seems that more than 12 facilities will need to be recruited to complete the administrator interviews (Supporting Statement A (SSA), bottom of page 4, number 2) in order to properly match enough facilities to control v. experiment groups. This should be reflected in the burden statement.

Please note that the sampling procedures are described in Supporting Statement B (SSB), page 3, number 1. As described, approximately 77 facilities will be included in the sampling frame from which 12 facilities (six matching facilities) will be selected that meet the eligibility criteria. All of the items on which we will match are publically available from the North Carolina licensing agency and will not depend on data gathered in the administrator interview. Recruitment and assignment into control versus treatment groups will occur prior to the administrator interview; data from this interview will not be used to assign facilities to control versus treatment.

We will not need to screen communities (i.e., nursing homes) for selection since the screening criteria is public data, and all communities are participants in the Collaborative Studies of Long-Term Care (CS-LTC), a research consortium that was formed by Drs. Zimmerman and Sloane (principal and co-principal investigators) and colleagues in 1996 and now consists of almost 700 settings in 14 states. At the present time, the CS-LTC includes 161 settings in North Carolina, of which 77 are within 50 miles of UNC. Thus, there are ample sites suitable for participation. If there is more than one eligible facility (based on publically reported data), we will randomly order the eligibles and approach them in that order.

We will not contact the facilities until it is time to recruit them. Our only pre-participation (screening) question will be to ask the administrator if he/she is interested in participating in the study. Although it is difficult to predict how many facilities we will have to approach to obtain a sample of 12 communities, in the last project, all but one facility initially approached agreed to participate. Since all facilities that we will contact are participants in the CS-LTC, we expect nearly 100 percent participation rate.

2. In SSA page 5, number 6, the statement suggests that "…data collection will not impose a burden on the facility staff..." Even though the information will be collected by the researchers rather than facility staff, this collection will still place a burden on the facility in order to obtain consent, deal with privacy issues, etc. OMB suggests that this sentence be removed. Yes, the sentence is removed.

As suggested, we have removed the sentence referred to above, from Supporting Statement A (SSA), page 5, number 6.

3. In SSB, page 4, number 2, the statement suggests that resident/patient identifiers will not be collected. However, SSA page 8 lists a series of identifiers (resident ID, age, sex, marital status, etc). Please clarify. Also, is marital status necessary to include?

As recommended, we will drop marital status from our analyses since it is not necessary. Also, to clarify, the project is not collecting direct identifiers; rather, resident IDs will be investigator-assigned "dummy identifiers." We are not collecting items considered "protected health information (PHI)" such as resident names medical record number, date of birth, social security number, or home address. The resident ID is not, in fact, a facility assigned ID; rather it is an investigator-assigned "dummy identifier." Resident name, room number, facility-assigned IDs, or other direct identifiers will not be linked to the data. In addition, we are reducing the detail in other demographic variables. For example, age 89 and over will be top-coded into a group of 90 and over and marital status will not be collected.

4. In SSB, page 7, the statement suggests that program staff may "fine-tune" the survey questions based on the first 10 responses. Please remember that any substantive changes to the survey will require OMB approval.

Noted; we do not expect to make any substantive changes to the protocols, but if we do, we will submit for OMB approval.