QUALITY CONTROL PROTOCOL FOR THE CLINICAL EXAMINATION RECORDERS

1. Initial Certification of Recorders

Before the start of the study, each recorder will record examination results on the teleforms for a minimum of 6-8 subjects. For efficiency, these can be accomplished while the clinical staff is conducting their preliminary examinations (see "Quality Control Protocols for the Clinical Examination" section).

The purpose of the initial certification is to ensure that the recorders at each clinic understand how to use the teleforms, become familiar with the layout of the forms, can keep pace and maintain communication with the clinical examiner, and can identify the items on the teleform that may be particularly prone to recording error. For each of the 6-8 examinations, the Study Coordinator or Project Director at each site and the recorder both will complete the teleforms. At the conclusion of each examination, the Study Coordinator or Project Director will review the completed teleform with the recorder. At that time and as necessary, the protocol will be reviewed and questions about marking the teleforms answered.

If new study staff is hired during the course of the project, this process must be completed.

2. Ongoing Quality Control

The purpose of ongoing quality control is to ensure that the information resulting from the clinical examinations is recorded correctly and reliably throughout the study period. The ongoing quality control will be accomplished with duplicate examinations—that is, 2 recorders will complete teleforms for the same examination. The quality control process will ensure that reliability between recorders remains high throughout the study period. The goal is for the recording process to be error free, so that the potential error inherent in the clinical exam is not magnified.

2.1 Number of Duplicate Examinations

During the first month of the study, duplicate examinations will be completed on 3-4 participants for each recorder. For each duplicate examination, either 2 recorders or a recorder and the Study Coordinator/Project Director will be paired. At the conclusion of the clinic visit, the teleforms will be reviewed by the Designated Reviewer (see below). The goal is for the recorded scores on each measure to be the same and for the total fraction of discrepancies to be no more than 0.05%. The first set of duplicate examinations for each recorder must be completed within 30 days of the initial certification.

After the first 30 study days, each recorder will complete 2 duplicate examinations per month for the remainder of the study period. It should be noted that the recorder duplicate examinations must be scheduled with MrOS participants who are not being re-examined as part of the clinical quality control. The data system can accommodate only 1 set of duplicate measures per participant.

2.2 Items to be Assessed

The duplicate examination will include all items on the clinical examination form including measures of gingival index and plaque index.

2.3 General Procedure

The study coordinator or project director at each site will schedule the duplicate examinations for each recorder. Again, the recorder duplicate examinations should be scheduled for MrOS participants who are not being re-examined as part of the clinical quality control. The study coordinator will assign one recorder to fill in the bubble marked 'first' on the teleforms and the other recorder to fill in the bubbly marked 'repeat' on the teleforms. Both sets of teleforms should then be faxed to the Coordinating Center according to standard protocols.

At each site, a Designated Reviewer will be identified. The primary responsibility of the designated reviewer is to compare the teleforms and address sources of discrepancies so that recording error is minimized. The Designated Reviewer can be a co-investigator, project director, or study coordinator. After the exam is completed, the Designated Reviewer will compare the two sets of teleforms, identify the most obvious errors, if any, between the recorders, and review the discrepancies with the recorders for that examination. The teleforms **should not** be altered or corrected during or after this review.

2.4 Example Schedule of Duplicate Examinations in first 30 days

Example: 3 recorders (R1, R2, R3) and 1 study coordinator (S1)

Pairs (primary recorder/second recorder):
R1/S1, R1/R2, R1/R3
R2/S1, R2/R1, R2/R3
R3/S1, R3/R1, R3/R2

Duplicate Examinations: 3 per recorder

Schedule in the first 30 days:

Monday	Tuesday	Wednesday	Thursday	Friday
R1/S1		R2/R1		R3/S1
	R1/R2		R2/R3	
R3/R2	R2/S1			R1/R3
		R3/R1		

3. Reporting Results

Study personnel at Administrative Center will summarize data from the recorder duplicate examinations at regular intervals and will present the information during regularly scheduled conference calls.