

QUALITY CONTROL PROTOCOLS FOR THE CLINICAL EXAMINATION

1. Initial Certification of Clinical Staff

Before the start of the study, each clinical staff person will examine a minimum of 10 subjects using the MrOS Dental Study protocols. The purpose of this exercise is to assure that the examiner understands and is comfortable with the study protocols. These 10 examinations will be observed by the site's quality assurance periodontist (UAB: Dr. Guers, OHSU: Dr. Madden) and any questions regarding the protocols will be brought to the Dental Study Advisory Committee for clarification. The teleforms from these examinations will be mailed to the Administrative Center at OHSU for review. If new clinical staff are hired during the course of the study, this process must be repeated. The initial examinations may be completed on either males or females age 60 years or older.

During the first month of the study, cross-site quality assurance visits will be completed. During this visit, the quality assurance reviewer will monitor the clinical exams to assure that protocols are being followed.

2. On-Going Quality Control

2.1 Number of Duplicate Examinations

During the first month of the study, duplicate examinations will be completed on 10-20 study participants (depending upon the level of agreement between the examiner and the "gold standard"). The goal is to have a Kappa score of ≥ 0.80 for each of the two periodontal measures – pocket depth and clinical attachment loss. In addition to the Kappa score, the mean difference in the measures between the clinical examiner and the "gold standard" should be ≤ 0.5 mm. After the first month, duplicate examinations will be completed on 4-5 study participants each month. The duplicate exam must be completed within 30 days of the initial examination.

NOTE: If a site has more than one clinical examiner, each examiner must complete duplicate examinations. The goal is to complete duplicate examinations on 5 percent of the study participants seen by each examiner per month.

2.2 Items to be Assessed

The duplicate examination will include all items on the clinical examination forms (pages 1-11), with the exception of the gingival index and plaque index on page 3 (because these measures can differ from day to day).

2.3 General Procedure

The examiner will complete the full clinical assessment per study protocols. After completing the assessment, the participant will be asked if they are willing to be reexamined by the site's periodontist to assure that the examiner is obtaining reliable data. If the participant agrees, the "gold standard" for the site will reexamine the participant (this can occur on the same day or within 30 days of the initial examination). The "gold standard" will review the findings with the examiner and address any discrepancies.

For the repeat exam, clinics should complete pages 1-11 of the Dental Exam TELEforms making sure that the REPEAT bubble on the top of the form is marked. Since the gingival index and the plaque index cannot be repeated, these bubbles should be left blank on the repeat exam TELEform (page 3). All other repeat exam TELEforms should be completed in their entirety. The missing and implant bubbles should be filled when appropriate.