

## **DURHAM VAMC INFORMED CONSENT STATEMENTS FOR PROCEDURES INVOLVING IONIZING RADIATION IN CLINICAL INVESTIGATIONS**

The DVAMC Radiation Safety Committee has adopted the following requirements relative to expressing radiation dosage to patients or research subjects who are participating in clinical or basic human research.

- a. The investigator shall calculate the anticipated radiation dosage as effective dose equivalent and the dose to the critical organ (where appropriate). Calculation should include the dose from the initial administration and, if applicable, quarterly and yearly cumulative exposures due to subsequent procedures.***

The calculated dose should be expressed both as an absolute quantity (mrem) and as a fraction or multiple of the natural background radiation, or a fraction or multiple of the applicable FDA limits for investigational radioactive drugs or the United States Nuclear Regulatory Commission (NRC) occupational dose limits, whichever is most appropriate to the circumstances of the study population and the study characteristics. The expression of dosage is not restricted to the preceding suggested formats. However, any expression of radiation dose must assist the subject in making an informed value judgment as to the magnitude of the component of risk attributable to ionizing radiation. Investigators may contact the Radiation Safety Officer for assistance in supplying the appropriate dose information and for templates of the appropriate wording for subject consent forms for a variety of diagnostic procedures.

**If you need additional assistance in preparing your radiation risk statement, contact Walter (Buddy) Furr (Walter.Furr@med.va.gov or 919-416-5851) or Wendy Woehr (Wendy.Woehr@va.gov, ext. 4888).**