The following links provide important information about human use of investigational agents.

FDA Guidances
http://www.fda.gov/cder/guidance/guidance.htm

Exploratory IND:
www.fda.gov/cder/guidance/6384dft.pdf

Traditional IND: IND content and format for Phase 1 studies
www.fda.gov/cder/guidance/phase1.pdf -

Developing Medical Imaging Drug and Biological Products
Part 1: Conducting Safety Assessments:
www.fda.gov/cder/guidance/5742prt1.pdf
Part 2: Clinical Indications:
www.fda.gov/cder/guidance/5742prt2.pdf
Part 3: Design, Analysis, and Interpretation of Clinical Studies
www.fda.gov/cder/guidance/5742prt3.pdf

Radioactive Drug Research Committee (RDRC) Program
www.fda.gov/Cder/regulatory/RDRC