Purpose: To ensure that all BSOM clinical, research and teaching facilities allow for health compliance with federal and state requirements regarding Infection Control and Radiation and Biological Safety, and that employee, patient and public safety is protected.

A. **Review of all projects in planning phase (Pre-design for new facility construction, and when drawings are available for either new construction or renovation or lease of existing facility.) is requested for:**

1. **Clinical sites** of all types where **direct patient care** will be provided:
   a. New construction, leasing, build to lease, expansion of clinical services into existing nonclinical space, etc. OR
   b. If construction or renovation will impact an existing clinical operation – e.g., by demolition of a common wall or roof or interruption of utility or HVAC service then review of plans for containment and continued safe operation and infection control in the affected clinic is required.

2. Any project on a room or facility which will use **Radioactive materials or sources**, or equipment that generates radiation for diagnostic, treatment or research use (includes Ionizing and Non Ionizing radiation) OR

   Relocates such equipment OR

   Occurs immediately **adjacent/physically contingent†** to a room or facility where ionizing radiation is used or generated.

3. Any project to construct a **laboratory (clinical or research)** in which infectious microorganisms or recombinant DNA will be used in a way that requires containment greater than hazard level 2 OR

   which requires installation of a Biological Safety cabinet, OR

   Any construction or renovation work which will be conducted immediately **adjacent/physically contingent†** to such space.

4. Any project to be performed in any clinical site where **high risk immunosuppressed patients** are seen. OR

   **Any work of any type located adjacent/physically contingent†** to a clinical site where immuno compromised patients are seen. OR

   Any work conducted that **shares a ventilation system with an area that sees high risk patients who are highly immunosuppressed**.

   Current high risk clinical sites include: Leo Jenkins Cancer Center (entire building, both floors), Transplant Surgery clinic, Pediatric Hematology Oncology, and adult and pediatric Infectious Disease clinics where AIDS patients are treated.

5. Any project conducted in an Animal Housing room or facility OR adjacent/physically contingent to an Animal Housing room or facility.

6. Any renovations in areas which **previously** housed activities using Radioactive materials, or infectious microorganisms immediately prior to planned work, to verify lack of contamination.

B. **Notification for post construction walk-through prior to opening for patient care or laboratory use is required for:**

1. All new clinical sites
2. All new areas using radiation or radioactive materials (including non ionizing radiation, such as lasers)
3. All new laboratories using a Biological Safety Cabinet

†Located adjacent/physically contingent = sharing a common wall or ceiling/plenum system or floor/ceiling combination or where work in one clinic or unit will physically penetrate the perimeter of another.

*Prospective Health = Radiation Safety, Biological Safety, Infection Control, Biomedical Waste Management, Employee Health
+ If ECU architects or Group Practice Administration are managing the process, they will contact Prospective Health directly; however, submission of this form by the responsible department is required to facilitate the review process.
Appendix: Form for Risk Assessment: Content of Prospective Health Review of New Physical Facilities

Print this form, complete it, and fax or email (shipleys@ecu.edu) to the Office of Prospective Health 744-2417

A. Infection Control Review of Plans for New BSOM Clinical Construction, Renovation or Leasing

1. Nature of Site
   - New Construction
   - Renovation of BSOM Occupied Clinic, Specify Locale ________________________
   - Renovation of Vacant BSOM Space, Specify Locale ________________________
   - Lease of clinic space without modification by BSOM
   - Lease of clinic space with construction/renovation per BSOM requirements

2. What types of Patients will be seen there? (Adults/ pediatrics/ primary care/ sub-specialty?)
   _______________________
   a. Are any patients immunosuppressed due to Neoplasm, Chemotherapy or Immune suppressant drugs, or Metabolic Disease? ___Yes ___No
   b. Will patients with respiratory disease (fever and/or cough) be seen? ____Yes ____No
   c. Will patients with fever and rash be seen? ____Yes ____No

3. Procedures Planned:
   - Endoscopy Outpatient
   - Surgical Procedures
   - Minor Surgery
   - Laser Use
   - Point of care or CLIA waived Laboratory Procedures (*)
   - Immunizations/injections
   - Pelvic Exams
   - Rectal Exams
   - Phlebotomy
   - Bronchoscopy
   - Other ________________________

4. Special Sterilization/Disinfecting Procedures
   - Autoclave
   - Glutaraldehyde or Other Chemicals
   - Other ________________________

5. Special Areas:
   - Pharmacy (Any chemotherapy or onsite drug compounding? ____Yes ____No)
   - X-rays
   - Other Radiological/Nuclear Medicine
   - Laboratory Specify ________________________
   - Other Onsite Diagnostics_____________________

6. Biomedical Waste Collection:
   a. Is there a central site that will accommodate a waste cart and its movement in and out of the building during clinic hours? (This central site will be used to store the accumulation of red bags until pickup.) ____Yes ____No
   b. Will there be sharps boxes for needle/ lancet disposal? ____Yes ____No
7. General Infection Control Principles:
   A. Individual red bags of biomedical waste at non-Brody clinics should be removed from exam room receptacles by clinic staff and placed in central waste cart for pickup.
   B. Sinks for handwashing in each exam or treatment or procedure room or lab
   C. Separate clean and dirty areas for reused equipment/instruments, especially if sterilization is planned.
   D. Increased ventilation and containment for chemical sterilization
   E. Negative pressure isolation rooms are required for bronchoscopy and endoscopy. At least one negative pressure exam room is required in clinics that evaluate or treat airborne diseases, e.g. chicken pox, measles or TB may be part of differential diagnosis.
   F. Any renovations, no matter how minor, occurring in clinics while immune suppressed patients are seen in immediate or adjacent area must consult Infection Control Policy/FSSP.
   G. Space for storage of contaminated linen until collected by laundry, segregated from clean storage of materials and supplies
   H. Adequate storage of clean equipment and supplies, off floor and away from splash or water spray; linen stored covered.

B. Radiation Safety Review of Clinical Space or Laboratory (clinical or scientific research space) Construction, Renovation, Leasing, and Relocation

1. Will radiation (ionizing or nonionizing) be used for treatment or diagnosis? (This includes x-rays. Gamma rays, microwaves, infrared devices, etc.) Yes_____ No_____; specify __________________________

2. Will radionucleotides or radioactive materials be used for research or clinical purposes? Yes_____ No_______

3. Will radiation-producing devices be installed, or moved physically/relocated? Yes_____ No____

4. Will construction occur adjacent to an area using ionizing radiation? Yes___ No___

C. Biological Safety Review of Research Laboratory Space Construction, Renovation, and Relocation

1. Will Research be conducted with infectious microorganisms or with recombinant DNA? Yes____ No____

2. Will aerosols be created? Yes_____ No____

3. Will Biological Safety Cabinets be installed, removed or relocated? Yes__ No__

4. Will use of micro-organisms or recombinant DNA require special containment i.e.? BL-3 or BL-4, due to risk group classification or a genetic procedure covered by NIH guidelines? Yes_____ No____

5. Will construction or renovation occur adjacent to an area with a Biological Safety cabinet or a BL-3 or greater laboratory? Yes___ No ___

6. Will Research using Laboratory Animals be conducted? Yes____ No_____

7. Will construction occur adjacent to a laboratory animal facility? Yes_____ No___

Return this form to Office of Prospective Health, 188 Warren Bldg, or fax to Paul Barry, MD, MPH or Sharon Shipley, RN, 744-2070.

Name: ________________________________

Department: __________________________

Phone Number: __________________________