

**EXAMPLE:** This is the Statement of Work used in the Video tutorial and is intended to serve as an example only.

**Description:**

This work involves the design, synthesis, and testing of new radiotracers that target neuro-receptors with known or suspected involvement in human cognitive disorders, including schizophrenia. These ligands will be radiolabeled with a variety of isotopes, allowing for their use in both PET and SPECT imaging systems....

**Processes:**

The processes involved include:

- a) computer-assisted design of the ligands to target specific brain receptor subtypes to pre-select for structures with the highest potential for high affinity, specificity and stability;
- b) synthesis of these new compounds with both stable and radioactive isotopes;
- c) in vitro and in vivo binding studies to determine the pharmacokinetic;
- d) performing imaging studies with the best candidates to validate their properties in whole body studies....

**Materials used:**

Potentially hazardous materials used in these experiments fall within three major categories:

- Chemical
  - Chemical hazards are those common to organic synthesis, included the use of corrosive, reactive and toxic chemicals, toxic gases, and flammable solvents.
- Radiological,
  - Radiological hazards include the use of both cyclotron and commercially available radionuclides, and X-ray via CT scanners.
- Biological.
  - Biological materials include animal and human cell lines and tissues....

**Equipment:**

In addition to the usual equipment involved in synthesis and testing of radiotracers (HPLC, gamma counters, cell harvesters), imaging experiments will involve the use of CT/SPECT and PET systems.

**More Detail**

**The use of either pyrophoric or water reactive materials** must be carried out following exact protocols. The procedures for the use of pyrophoric chemicals are lengthy and detailed. The Bldg 55 SOP for their use is attached below (*Pyrophoric Use in Bldg 55 Chemistry Labs*). One must be checked on this SOP by the Activity Lead before starting work with pyrophoric materials.

**Water reactive materials** are used in the synthesis of precursors. They will only be used in the chemical hood in 55-118. Specific PPE, listed in the Control section of this Activity Description, must be employed when water reactives are used. All glassware and tools must be oven-dried prior to use (oven is in 55-118). All flammable and combustible materials must be removed from hood prior to use of water reactives. Since hydrogen gas is a common product of reaction with water, all sources of ignition must be removed prior to the use of water reactive chemicals.

**Alkali metals (Na, K) and t-butyl lithium are used** for the production of precursors used in the production of the radiotracers. The general approaches to the creation of the serotonin and dopamine analogs is attached in the *Organic Synthesis Procedures* SOP. Variations from these SOPs should be documented in your lab notebooks, and discussed with the Activity Lead prior to initiation of the work. Specific steps with high risk include.....

### **Limits**

Work with pyrophorics, toxic gases, water reactive materials, and radioisotopes requires specific OJT, and should not be attempted until fully approved by the Activity Lead.

This Activity does not cover, nor authorize, the use of the Bldg 56 cyclotron for the production of  $^{11}\text{C}$ - and  $^{18}\text{F}$ -positron emitting isotopes, nor the transfer of the isotopes from Bldg 56 to Bldg 55. Those processes are covered under other Activities, and a worker must be authorized under those Activities to perform those tasks.

While the use of the Bldg 55 CT/SPECT and CT/PET are involved in this protocol, workers must also be authorized under separate Activities for SPECT and PET work before using the imaging equipment.

### **Further details**

Radiosynthesis steps with dispersible materials should always be performed in the lead-lined Berkeley Boxes located in 55-118 to reduce exposure and achieve ALARA. Once the radiotracers have been produced, small aliquots (under  $50\ \mu\text{Ci}$ ) may be used in the hood in 55-116 for tissue and cell binding studies...

Biological materials used include commercially purchased (frozen) rodent brain tissue, commercially available animal and human cell lines, human blood drawn from healthy volunteers, and rodent animal models for imaging studies. These materials will be used in binding studies using rodent tissue extracts and a cell harvester binding apparatus, and in stability, uptake, clearance and metabolism studies with both animal and human cells. Rodent models will be used for imaging studies. It should be assumed that all human cells are potentially contaminated with bloodborne pathogens, and Universal Precautions (described in Control section) taken to insure infections do not occur.

### **Other Equipment**

The radiometric monitoring equipment attached to the HPLC system is pressure sensitive, so HPLC pressures should not exceed the levels listed on the side of each monitor. If a new column or set up is being used, the rad-detectors should be bypassed by turning the valve located just prior to the rad monitor.

### **Additional Waste Handling**

Nitric Acid is used in the preparation of glassware used in the radiotracer synthesis. It is neutralized immediately after use as described in the attached *Nitric Acid Neutralization Procedure* SOP. Only those workers who have been specifically approved by the Activity Lead may carry out this process.