**Radiochemistry Core Guide to Radiotracer Development**

**Key Contact Personnel:**

Adam Rosenberg (adam.j.rosenberg@vumc.org), Phone: 5-0929

Todd Peterson (todd.e.peterson@vumc.org), Phone: 2-2648

**Purpose:** This guide serves as a step-by-step guide for researchers to use when developing new radioisotopes/radiopharmaceuticals from the VUIIS Radiochemistry Core.

This document is divided into four possible types of development:

1. Development of radiotracers in common use.
2. Development of radiotracers published in the literature, but not in common use.
3. Development of radiotracers from a concept or idea.
4. Translation of an established radiotracer for human use.

**Key Requirements/Policies:**

1. To begin the development process, you must have an active iLab Account. Speak to your business administrator to obtain an account.
2. An active center number must be in iLab and associated with the PI interested in the development.
3. ***Important****: If you are planning to propose the use of a radiotracer in a grant application or similar proposal, please contact us at least four weeks prior to final submission to obtain the most up-to-date budgetary pricing. Though non-binding and subject to revision, this estimate will reflect the cost to produce the tracer at the time of proposal submission.*

**Definitions:**

1. Simple Radiotracers: Radiotracers that are well developed and prepared at multiple productions sites are considered to be in common use. Typically, these radiotracers will have well-established methods of production on automated synthesis modules.
2. Complex Radiotracers Use: Radiotracers that are produced only at a small number of production sites or that require specialized methods of production fall into the complex category. Development of these radiotracers may require extended development or purchase of specialized equipment.

**Development Process**

**Development of Simple Radiotracers**

1. To commence the developmental process the requestor should go to the VUIIS Radiochemistry Core iLab page and select “New Radiotracer Production Request (Project Request)”.
2. Complete the form as indicated and submit the request to the radiochemistry core.
3. Within two business days you will be contacted by the Radiochemistry Core to schedule a meeting to further develop the project parameters.
4. A quote will be generated for the cost of the development including: QC (quality control) development, process development, radiochemistry developmental productions and purchase of any materials not currently stocked by the radiochemistry core. For a well-established radiotracer produced on the same type of equipment available to the radiochemistry core, one (1) to five (5) developmental productions are typically required.

**Development of radiotracers published in the literature, but not in common use**

1. To commence the developmental process the requestor should go to the VUIIS Radiochemistry Core iLab page and select “New Radiotracer Production Request (Project Request)”.
2. Complete the form as indicated and submit the request to the radiochemistry core.
3. Within two business days you will be contacted by the Radiochemistry Core to schedule a meeting to further develop the project parameters and discuss the feasibility.
4. If at the specified meeting it is decided to move the project forward, a quote will be generated for the cost of the development including: QC (quality control) development, process development, radiochemical synthesis methods, radiochemistry developmental productions and purchase of any materials not currently stocked by the radiochemistry core. For this type of development significant efforts might be required, and if the precursor is not commercially available it will need to be sourced. The radiochemistry core will work closely with the investigator and provide regular updates.

**Development of radiotracers from a concept or idea**

1. To commence the developmental process the requestor should go to the VUIIS Radiochemistry Core iLab page and select “New Radiotracer Production Request (Project Request)”.
2. Complete the form as indicated and submit the request to the radiochemistry core.
3. Within two business days you will be contacted by the Radiochemistry Core to schedule a meeting to further develop the project parameters and feasibility.
4. The radiochemistry core will work with the investigator to determine the optimal approach to developing the requested radiotracer.
5. Once an approach has been determined a quote will be generated for the investigator’s approval outlining the costs of the requested development.

**Translation of an established radiotracer for human use**

1. To begin the translation into human use of a radiotracer that the Core already produces, the requestor should go to the VUIIS Radiochemistry Core iLab page and select “New Radiotracer Production Request (Project Request)”.
2. Complete the form as indicated and submit the request to the radiochemistry core.
3. Within two business days you will be contacted by the Radiochemistry Core to schedule a meeting to further develop the project parameters.
4. The radiochemistry core will work with the investigator to determine the optimal approach for translating the radiotracer into human subjects. This will involve addressing regulatory requirements for: production of the radiotracer under cGMP procedures, application to the FDA for regulatory approval, as well as other potential hurdles.
5. Once an approach has been determined a quote will be generated for the investigator’s approval outlining the costs of the requested development.