UTSouthwestern Medical Center Radiology Title: Cyclotron Project Intake Evaluation	SOP.029.A024 Version Number: 0	Effective Date: 10/16/18 RAD Mission: Cyclotron Operations
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1.0 Purpose

1.1 The purpose of this Standard Operating Procedure (SOP) is to build a two-step process for the intake of new radiotracer relevant service or investigational projects, clinical trials, and research programs with respect to the financial sustainability as well as scientific merits.

2.0 Responsible

2.1 Project Intake Evaluation Committee and Cyclotron and Radiochemistry Program's Regulatory Affairs Officer (RAO)

3.0 Schedule

3.1 Every time a new idea is developed that involves PET radiotracers produced at the cyclotron facility.

4.0 References

4.1 Not applicable

5.0 Equipment and Materials

5.1 Presentation Template for Cyclotron Project Intake

6.0 Procedure

6.1 The Principal Investigator (PI) notifies the Cyclotron and Radiochemistry Program (CRP) for their new idea involving radiotracers.

6.1.1 To initiate discussions and to arrange a meeting with the CRP, contact the Regulatory Affairs Officer at: Marianna.Dakanali@utsouthwestern.edu (or Cyclotron@utsouthwestern.edu).

6.2 Project evaluation by CRP team

6.2.1 CRP will determine the chemistry, financial and regulatory feasibility of the project.

6.2.1.1 If the CRP determines that the project is not feasible the process is completed, and the project is denied.

6.2.1.2 If the CRP determines that there are the necessary resources for the project, the study team will proceed to the planning phase, section 6.3.

6.3 Planning Phase

6.3.1 During this phase the PI and the study team will be engaged in discussions with other clinicians/scientists to finalize the details of the project.

6.3.2 Items to be discussed and finalized during this phase are:

6.3.2.1 The synthesis of the radiotracer and the imaging protocol. If the use of the radiotracer is reported before, the team must collect as much information for the synthetic route and the imaging protocol as possible.

6.3.2.2 If this is a first in human use of the radiotracer, the imaging protocol, dosimetry, toxicology and pharmacology, as well as the regulatory approach need to be determined.

6.3.2.3 The role of each investigator must be clarified and responsibilities must be assigned.

6.3.2.4 The requirement for additional resources if necessary must be identified.

6.4 Evaluation of Academic Opportunities

6.4.1 The evaluation committee reviews all details and identifies if there is an academic opportunity for the Nuclear Medicine division, the CRP, the Radiology Department and/or UT Southwestern Medical Center.

6.4.1.1 If it is concluded that no academic opportunities exist, CRP will provide core facility services to the project.

6.4.1.1.1 Cost recovery plans will be prepared.

6.4.1.1.2 Payment options will be arranged.

6.4.1.2 If it is concluded that there are academic opportunities, the project will continue to full project intake evaluation, as described in section 6.5.

6.5 Project Intake Evaluation

6.5.1 The study team will prepare a presentation of the project and will present their idea and project planning to the evaluation committee.

6.5.1.1 The evaluation committee consists of the Department of Radiology's Vice Chair for Research and at least another two members based on their expertise related to the topic of the proposed project.

6.5.1.2 Individuals are invited as members of the committee by the Vice Chair of Research.

6.5.1.3 The Vice Chair of Research decides the number of committee members per case/project.

6.5.2 The evaluation committee will evaluate the hypothesis, innovation, research plan of the proposal and will give a written review.

6.5.3 The committee will determine the financial responsibilities.

6.5.4 The committee will provide an overall Priority Score.

6.6 Upon completion of the process the committee will submit their evaluation to the CRP's Steering Committee for review and approval.

6.7 Upon the decision made by the steering committee the project will be either added to CRP's operation's calendar or sent back to the requestor for revision.

6.7.1 If the project involves human subjects, once it is approved, it will be assigned to CRP's Regulatory Affairs Office to evaluate the clinical readiness of the project (see SOP 029.A23).

7.0 Acceptance Criteria

7.1 All CRP projects have been evaluated by the Project Intake Committee.

8.0 Revision History

Version	Date	Reason for Revision
0	10/16/18	New SOP