

Biomedical Imaging Research Core (BICOR)

Intake Form, Unlisted tracer or Development Project

Project Information

- Title of project _____
- Project acronym _____
- Project start date _____
- Projected duration _____

Principal Investigator

- Name _____
- Address _____

- Email _____
- Mass DPH, Controlled Substance License Number _____

Account information

- Project number _____
- Partner's PeopleSoft Account Number _____
- Account end date _____
- Contact for invoicing if not PI _____
- Invoice address _____

- Invoice email _____
- Source of funding _____

Tracer Information

- Radioisotope _____
- Compound _____
- Human Use* _____
- Required Strength _____ - mCi
- Required Concentration _____ -mCi/mL
- Number of Doses _____

*In the case of investigational radioactive drugs for human use, the nuclear pharmacy requires an investigator's protocol for the preparation of radioactive drugs (if applicable), a copy of the Human Use Committee Approval, a copy of the approved patient consent form, and a letter from the sponsor indicating that the physician requesting the radioactive drug is a qualified investigator and the PI's Mass DPH Controlled Substance License number.

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Background

- Novel Tracer _____ Literature Tracer _____
 - Target _____
 - List principal papers for existing knowledge:
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Scope of work

- Precursor source/develop
 - _____
 - Reference standard source/develop
 - _____
 - Radiolabeling synthesis route and equipment
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Quality control procedure development

- Appearance _____, Radionuclidic identity _____, Radiochemical purity _____, Chemical purity _____
- Pyrogen _____, Sterility _____, pH _____, Potency/concentration _____
- Maximum injectable volume _____, Bioreactivity _____, Stability _____

Documents

- Manufacturing instruction _____, Batch record _____, CMC _____, IUCOC _____
- RDRC _____, IND _____
- Use protocol _____, SB sheets (material control) _____, COA _____

Budget*

- Anticipated development cost _____
- Anticipated tracer lot cost _____

* A budget spreadsheet detailing estimated costs should be attached.