**FAPI PROJECT REQUEST**

The aim of this document is to assess the scope of work and support needed for a clinical study.

This document will be assessed internally by Isotopia scientific team, and the medical director and feedback will be provided in up to 4 weeks.

* Should the request be approved, A copy of the Helsinki committee\ MOH will be required.
* A copy of the IRB or IACUC (or applicable documentation) approval will be required to commence research.
* A signed Term sheet will be required with Isotopia Molecular Imaging for the use of FAPI-2286 tracers.

**GENERAL INFORMATION** Please fill out below:

|  |  |
| --- | --- |
| INSTITUTION NAME AND ADDRESS |  |
| TYPE OF INSTITUTION (University clinic, research center, municipal hospital, private center, other) |  |
| PLACE OF RADIOPHARMATICAL PRODUCTION (Hospital, external supplier, other) | Isotopia Molecular Imaging |
| POINT OF CONTACT NAME |  |
| POINT OF CONTACT ADDRESS (If different from above) |  |
| POINT OF CONTACT EMAIL |  |
| DIAGNOSTIC OR THERAPEUTIC USE |  |
| PRECLINICAL OR CLINICAL USE |  |
| SINGLE OR MULTIPLE LOCATIONS |  |
| DESCRIPTION OF FUNDING SOURCE |  |
| TARGET EXECUTION DATE  |  |
| TARGET COMPLETION DATE |  |
| ATTACHMENTS (Protocoles, data, publications etc.) |  |

**PROJECT TITLE:**

**DESCRIPTION OF WORK:** (Introduction of Research Subject: list/attach separately if multiple)

Please provide a summary of the project, including, but not limited to:

1. Project Details (including primary and secondary objective, data analysis methods, and schedule)
2. Scientific Value (including scientific relevance of the project with respect to innovations and originality)
3. Project Feasibility (including available staff and technical resources as well as documented expertise on the subject)
4. Other info. The amount of detail is under PI discretion; however, a brief statement of the idea will not be considered sufficient for approval.

**AUTHORS/PIs, SPONSORS, AFFILIATES:** (Please list all applicable)

Please provide information on the PI’s (and any significant contributors') background and expertise for completing the research proposed. CVs are appreciated, but not required.

**RESEARCH INSTITUTION(S):** Please list all applicable:

Please provide information on the facilities and equipment that are available for completing the research proposed.

**APPLICABLE LICENSE(S):** Please list all applicable:

Please provide a copy of any locally required licenses to produce and or use FAPI, e.g. RAM license, marketing/manufacturing license in accordance with national regulations. If you do not have a copy of the licenses, please make note that you will provide prior to starting the study.

**FUNDING/GRANT(S):** Please list all applicable:

Please provide enough information to assess the ability of the PI to complete the research.

A willingness to commit funds will not be considered sufficient for approval.

**Isotopia Molecular Imaging INTERNAL USE ONLY**

|  |  |
| --- | --- |
| DATE RECEIVED FOR SCIENTIFIC REVIEW  |  |
| PROJECT REFERENCE NUMBER |  |
| APPROVED BY |  |
| DATE APPROVED  |  |

**NOTE:**

Isotopia Molecular Imaging reserves the right to accept or deny the request of any person or entity interested in using its licensed product or products listed above. Decisions will be at the sole discretion of the Isotopia Molecular Imaging Scientific Advisory Board (SAB).