



## **Preliminary Investigator Initiated Study Concept Submission Terms and Conditions**

This preliminary concept form is intended to determine if the proposed Investigator Initiated Study (IIS) concept/study idea aligns with Istari Oncology, Inc. (“Istari”) areas of scientific interest and warrants submission of a full IIS application (“Application”).

The IIS Review Committee will review the submission, request additional information, if required, and decide if submission of a full application is warranted.

The submission of this concept form does not grant the requestor any rights in or to any intellectual property associated with the submission, the concept, or any products which are or may be manufactured, owned, or sold by Istari or use of such products. Submission of the Application does not obligate Istari to approve, in whole or in part, any applications, protocols, hypotheses, ideas or suggestions contained therein, and Istari may deny any such request in its sole and absolute discretion.

**Note:** Investigator understands and acknowledges any information disclosed in the concept form or Application is nonconfidential, nonproprietary, with no restrictions on use; and Istari and its principals, employees, designees and affiliates (collectively “Representatives”) are not bound by any obligations of confidentiality and restricted use regardless of how such information is marked by Investigator. Istari, and its Representatives are not liable for any real or perceived loss resulting from the submitters voluntary and non-required disclosure of proprietary information with the IIS concept submission.

## **CONCEPT SUBMISSION FORM**

**In as few words as possible in the spaces provided, please describe your study proposal, addressing the key points below.** To avoid delays in the evaluation process, complete, accurate and detailed information is required. Concept forms with insufficient information will either be denied or will require resubmission.



1. Indicate which of the following are being proposed and *briefly* describe the nature of the study:

Clinical study (involving active recruitment of subjects); specify all that apply:

Observational  Interventional  Other (specify):

Briefly describe:

Translational research: specify if based on existing or newly collected laboratory or clinical samples (if clinical, the subjects consented to the research outlined in the proposal or propose plan for waiver of consent, etc.).

Briefly describe:

Nonclinical or Animal Investigations/proof-of-concept studies for future clinical applications or those proposing investigations that may yield critical mechanistic or other insight or other.

Briefly describe:



2. Importance/rationale behind the proposed research:

3. Key Study Objectives and associated Endpoints:

4. Proposed Methodology/General Investigational Plan:

5. Describe qualifications/ability to carry out proposed research (investigative team, facilities, patient population or specialty clinic, etc.):



6. Estimated timeline from finalization of contracts and all protocols, etc. (assuming accepted), to study start and study completion (ie, final report submitted):

7. Support Requested:

a) Nonfinancial support requested (if requested; note all that apply):

Access to Istari investigational product (PVSRIPO)

Access to Istari clinical or nonclinical samples (tissue, blood, data, etc.); specify:

Access to Istari clinical or non-clinical data (specify):

Other (specify):

b) Financial Support (if requested): Specify the Total Budget being requested, inclusive of overhead (if any):

c) Note the payment schedule and specify estimated financial support needed at:

a. Start up

b. By quarter for duration of study

8. Support Provided: if applicable, please specify the source and nature of any potential additional support (financial w/ \$ amounts or other) that may be provided by the investigator, institution, or other parties to conduct the proposed research (eg, grants, institutional or departmental funds, other biotech/pharma companies, etc.):

9. Specify any other information relevant to the proposed concept.



Name of overall study director/sponsor investigator:

Title:

Relevant degrees/certificates:

Affiliation:

Address:

Phone #(s):

Email:

2-3 best days/times for meetings:

Administrative Assistant (as applicable): Name, Phone, Email:

Planned key sub-investigators, collaborators, and/or consultants (if any): List name(s), degrees/affiliations, email addresses:

**Required Acknowledgement:**

By ticking the box below and signing, you acknowledge that you understand and agree with all stated terms and conditions and are authorized to submit the concept. Accept terms and conditions:

Signed:

Title:

Date:

Tick

Printed Name: