**AstraZeneca – National Cancer Institute (NCI)**

**Cancer Therapy Evaluation Program (CTEP) and Formulary**

**Non-clinical Request Form**

**Confidential information:** Please include only **non-confidential information** in the concept proposal. If confidential data exists that would strengthen the proposal, the author may indicate that confidential information is available to share under a Confidential Disclosure Agreement (CDA). If AstraZeneca finds the non-confidential Concept Proposalsufficiently interesting, we will discuss about executing a CDA.

*Please complete this template below and enlarge each section as needed.* *Include published references to support the proposal*.

1. **AZ compounds and quantities (dry weight, in milligrams) requested (include any alternate names and NSC#): ­­­­­­­­­­­­­­­­­­­­­­­­­­­**

*(Typical amounts for in vitro studies are 10 – 20 mg. Amounts for in vivo studies are based on recommended dose and schedule (compound-specific); this information can be provided by AstraZeneca. Please note that for large quantities, AstraZeneca may supply compound in smaller batches over the duration of the study based on periodic review of ongoing data).*

1. **Full Name and Title of Investigator(s):**
2. **Laboratory and Institution where the work will be performed:**

* *Laboratory Name*
* *Address*
* *Institution Name*
* *Email Address*

1. **Preclinical Research Proposal Title:** *Brief**Descriptive Title*
2. **Hypothesis:** *Statement of the hypothesis for the compound and biological target in human disease. Brief evidence why this biological pathway may be important in the disease area under investigation.*
3. **Outline of Research Plan**

* *Specific aims including scientific rationale*
* *Overview of the experimental plans including rationale for choice of in vitro cell/tissue assay and/or animal model with a clear study design and details of endpoints being measured. For in vitro cell assays, provide details on any cell lines that will be used. For in vivo studies justify choice of species, animal numbers and group size (e.g. using statistics/power analysis for primary endpoints). For studies using transgenic mouse, tissue or cells include details of the genetic background with appropriate published references.*
* *Include approximate dates for* 
  + *Start of project:*
  + *Completion of project:*
  + *Completion of final study report/draft publication:*
* *Anticipated outcome of results and describe the impact of the results (e.g. progressing this compound as a therapy or increasing understanding of mechanisms in disease).*

1. **Operational feasibility:** *What has/has not been done before by you or members of your team?*

*(Note: Innovative, novel approaches are welcome).*

1. **References:** *List of key publications used in your proposal.*
2. **Project Decision Tree or Scheme of Work Flow Plan:** *Including estimated timelines.*
3. **Human Tissue Use:** *Please complete if your research proposal includes the use of primary human tissue. Type “Yes” or “No” after the question.*

* Can your institute assure AstraZeneca that any *in vitro* studies using human tissue, conducted under this proposal, will be performed in a manner consistent with the principles of AstraZeneca's Bioethics policy?

(<https://www.astrazeneca.com/sustainability/resources.html#global-policies-and-positions-0>)

* If human-origin materials collected according to 45 CFR Part 46, please list Assurance Number:

1. **Animal Use Risk Assessment:** *Please complete if your research proposal includes the use of animals. Put a check (X) in each category that most accurately represents the animal model in the proposal.*

**Species**

**­­** Invertebrates, fish, birds, fetal/larval forms, reptiles

Mice, rats, hamsters

Guinea pigs, rabbits, ferrets, mini pigs, genetically altered animals, other species

Farm animals, equines, dogs, cats, harmful mutants, surgically prepared animals (any species)

Non-human primates (NHPs)

**Sensitivity**

Ex vivo studies, terminal studies, or studies on conscious animals with appropriate mitigation of pain/distress, but not involving any of the criteria in sensitivity selections below

Studies use not humanely established or unconventional methods of euthanasia

Models involve major surgery and/or repeated surgery, prolonged restraint, juvenile or neonatal animals

Models of public concern, smoking, brain surgery/instrumentation, drug dependency in NHPs, unalleviated pain, or with death required as an endpoint

**Potential for pain and distress**

Ex vivo or terminal studies

Studies involve no more than minor or transient discomfort or stress (routine dosing/sampling) or have the potential to cause prolonged pain or distress but the use of anesthetics/analgesics provides appropriate mitigation

Studies involve some pain or distress but with appropriate mitigation (most toxicity tests, surgery) or the potential to cause high degrees of pain or distress but procedures are terminated before pain or distress occurs

Studies involve potential for significant pain or distress which cannot be alleviated but are scientifically justified (acute tox studies with significant morbidity or death as an endpoint, pain models)

**Past engagement with AstraZeneca**

AZ and the external facility have had previous agreements over the last 5 years

AZ and the external facility have had no previous agreements in the last 5 years

**Name and Location\* of external facility:**

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**Reputation of facility**

Facility has external regulatory oversight, AAALAC accreditation or equivalent, and no history of security/media issues in last 3 years

Facility has no external regulatory oversight, AAALAC accreditation, and no history of security/media issues in last 3 years

Facility has no external regulatory oversight, no AAALAC accreditation, and no history of security/media issues in last 3 years

Facility has no external regulatory oversight, no AAALAC accreditation and/or has a history of security/media issues in last 3 years

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**For proposals involving animals, please answer the below questions:**

* Can your institute assure AstraZeneca that any *in vivo* studies using animals, conducted under this proposal, will be performed in a manner consistent with the principles of AstraZeneca's Bioethics policy? (<https://www.astrazeneca.com/sustainability/resources.html#global-policies-and-positions-0>)
* Please list species, estimated numbers, and length of study.
* Please give details of the specific procedure the animals will undergo.
* Please indicate if this is a terminal procedure under anesthetic, and if so, the anesthetic used.
* Please indicate if recovery anesthesia will be used as part of any procedures, if so, please provide details of the anesthetic regime.
* If surgery is involved, please include details of the procedure.
* Will the animals be imaged as part of the procedure? Please indicate frequency and length of each procedure. How will the animal be monitored?
* What endpoint criteria will be used to ensure that animals under study do not suffer unduly?
* Does your institute have an ethical welfare body e.g. IACUC/ERP? If so, please give brief details on remit, membership and meeting frequency.

1. **Please list all combinations, if any, that are being explored in the proposal. Include all non-AZ compounds as well and the source of these non-AZ compounds:**
2. **Contact details for compound shipments:**

* *Name*
* *Shipping Address*
* *Telephone number (Please provide a readily accessible number. Couriers may not authorize shipment of compounds in some countries without first being in direct contact with the recipient).*
* *Email Address*
* *FedEx (or similar) Account#*

1. **Contact details for Technology Transfer Office (NOTE: for Formulary requests, NCI negotiate the MTA with requestor’s TTO):**

* *Name*
* *Email Address*

1. **If a Third Party is providing funds to do the research, please describe how this proposal will be funded, specifying the source of funding:**
2. **Have any cell-lines/animal models, or other material, that will be used in the research been provided to your institution under an agreement (e.g. MTA) with an outside entity?**