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**USC Norris CCDD Submission Form**

**Project Scope:**

* Early-stage oncology therapeutic concepts/projects
* Stage-Target validation to candidate selection/preclinical development
* Modality agnostic

Out of Scope:

* + Indications outside oncology
  + Clinical trials
  + Technologies already licensed to startups or other companies
  + Drug delivery platforms (unless coupled to a therapeutics program)

**Eligibility:**

* Project lead must be USC faculty and have the obligation to assign IP to USC
* Individuals need to have a track record of conducting cancer research
* Concepts from USC Norris members may be prioritized.

Please complete form and return to the Melissa Rodgers at [**rodgersm@usc.edu**](mailto:rodgersm@usc.edu)

If you have any questions or would like to discuss your concept before sending the submission form, please contact [**Melissa Rodgers**](mailto:rodgersm@usc.edu) from the MESH Strategic Partnership team.

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| --- | --- | --- |
| **Name:** |  | |
| **Title:** |  | |
| **Department:** |  | |
| **School:** |  | |
| **Email address:** |  | |
| **Phone:** |  | |
|  |  | |
| **Are you a member of USC Norris?** | | Yes  No |

**Please answer all applicable questions with descriptive and detailed answers**

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| --- | --- | --- |
| 1. Biological Target/Pathway overview | | |
|  | * 1. Name of biological target or pathway: | |
|  |  | |
|  | * 1. Brief description of the target or pathway: | |
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|  | * 1. Is this a novel drug target or pathway? (i.e. a biological molecule or pathway that has not been previously targeted or explored for therapeutic intervention) | |
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| 1. Therapeutic Modality | | |
|  | * 1. Which therapeutic modality is being considered or developed? (ex. small molecule, cell therapy, monoclonal antibody) | |
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|  | * 1. What is the rationale for choosing this modality? | |
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| 1. Indication and Patient Population | | |
|  | * 1. What is the primary therapeutic indication in oncology (ex. melanoma, breast cancer, SCLC, AML): | |
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|  | * 1. Incidence and prevalence of cancer type: | |
|  |  | |
|  | * 1. Is there a specific patient population within the indication that would be targeted? (ex. refractory to first-line treatment, stage of disease, genetic signature, etc.) | |
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|  | * 1. Is there If a subset, how easy are those patients to identify? Are there appropriate diagnostic tests available? | |
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| 1. Standard of Care and Unmet need | | |
|  | * 1. What is the current standard of care? (i.e. Treatment that is accepted by medical experts as a proper treatment for specific disease) | |
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|  | * 1. Please describe the unmet need or problem with the current standard of care that you are trying to address. | |
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|  | * 1. How does your therapeutic approach address this problem? | |
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|  | * 1. What are the advantages of your approach over current treatment options/therapies? | |
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| 1. Disease Relevance | | |
|  | * 1. Please explain how this target/pathway is relevant to cancer: | |
|  |  | |
|  | * 1. Is there any human genetic or clinical evidence for role of the target/pathway in the proposed indication? If so, please explain: | |
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| 1. Competitive Landscape and Differentiation | | |
|  | * 1. Are other drugs currently available or under development for this target or pathway? If so, please describe and explain how your approach differs. | |
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|  | * 1. What is the competitive advantage of your proposed therapeutic approach compared to other drugs or treatments? | |
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| 1. Stage of development | | |
|  | * 1. What is the stage of the project? (Choose one) | |
|  | Target identification  Target validation  Hit identification  Hit-to-lead  Lead optimization  Candidate selection/Preclinical development  Clinical trial | |
|  | * 1. Brief description of stage of the project: | |
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|  | | |
| 1. Target Validation | | |
|  | * 1. Target validation status – (**For the following questions, please clearly distinguish between your own work and supporting data from others in the field)** | |
|  |  | * + 1. Briefly summarize any relevant **in vitr*o*** data that supports your target of interest (ex. loss of function/gain of function, pharmacological assays, etc.) |
|  |  |  |
|  |  | * + 1. Briefly summarize any relevant **in vivo** data that supports your target of interest (ex. loss of function/gain of function, pharmacological assays, etc.) |
|  |  |  |
|  |  | * + 1. Briefly summarize any relevant supporting evidence in **humans** (ex. patients and/or patient samples) |
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|  | * 1. Are disease relevant in vitro and/or in vivo models available? If yes, please describe: | |
|  |  | |
|  | * 1. Are tool compounds (antibodies, small molecules, etc.) available to? If yes, please describe: | |
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| 1. Candidate Therapeutic (**If you do not have a candidate therapeutic at this time please skip to section 10**) | | |
|  | * 1. Modality (ex. small molecule, antibody, cell therapy, etc.): | |
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|  | * 1. Is this a new chemical entity (NCE) or a repurposed drug? | |
|  |  | |
|  | * 1. If this is a repurposed drug, please provide the drug name: | |
|  |  | |
|  | * 1. Describe the stage of development of your candidate therapeutic. Please provide specific information about your progress so far including developmental milestones, key experiments and results: | |
|  |  | |
|  | * 1. Is the mechanism of action (MOA) known? If so, please describe: | |
|  |  | |
|  | * 1. Would the candidate therapeutic be a monotherapy, a component of a combination therapy or both? Please provide brief explanation: | |
|  |  | |
|  | * 1. Was the candidate therapeutic discovered and developed at USC? If not, where did it originate from? | |
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| 1. IP Status: | | |
|  | * 1. Has an Invention Disclosure been submitted to USC Stevens? | |
|  | Yes  No | |
|  | * 1. If an invention disclosure was submitted, what is the status? (ex. decision not to file, waiting for more information, filed patent application) Please explain: | |
|  |  | |
|  | * 1. Is any of the IP currently optioned or licensed to a company/start-up? If yes, please explain: | |
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|  | | |
| 1. If the target and/or candidate therapeutic are part of an academic or industry collaboration, please list the name(s) and affiliation(s) of any collaborators (USC and external) and describe their role(s) in the project? | | |
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|  | | |
| 1. Please list the sources of funding that have supported the work to date: | | |
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| 1. Please list key publications **you have authored** that support the target/pathway, its discovery, and the therapeutic candidate if applicable: | | |
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| 1. Project Goals | | |
|  | * 1. What is the immediate next milestone for this project? | |
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|  | * 1. Briefly describe the next critical set of experiments needed to reach this milestone: | |
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|  | * 1. What resources and/or expertise are needed? | |
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**Please attach your NIH biosketch and that of your collaborators.**