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**USC Norris CCDD Intake Form**

**Purpose:** This form is the first step in the CCDD review process

**Review Process:** Faculty will be paired with a MESH representative, your primary point of contact during the entire process. MESH will work with you to:

* Understand Scientific and Technical Rationale
* Discuss unmet needs and business considerations
* Create a path to clinic showing critical inflection points
* Incorporate information into presentation for EAC review

**Eligibility:** Individuals with a track record of conducting cancer research. Concepts from USC Norris members may be prioritized.

Please return the completed form to the MESH BDIR team at mesh.academy@usc.edu to begin the CCDD review process

If you have any questions or would like to discuss your target/therapeutic before submitting the intake form please contact the MESH BDIR team at mesh.academy@usc.edu

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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. Target Information (A drug target is a molecule in the body, usually a protein, that is intrinsically associated with a particular disease process and that could be modulated by a drug to produce a desired therapeutic effect):
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|  | * 1. Name of target (include full name in addition to any acronyms):
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|  | * 1. Target class (ex. transporter, GPCR, enzyme, cytokine, RNA, etc.):
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|  | * 1. Brief description of the target:
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|  | * 1. Is this a novel drug target (i.e. not known to be modulated by an approved drug)?
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| 1. Disease relevance of target/pathway for oncology:
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|  | * 1. Briefly summarize any relevant genetic, biochemical, pharmacological or clinical data/evidence:
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|  | * 1. Potential therapeutic indication(s) in oncology (therapeutic indication specifies which disease/condition the medication would treat, ex. melanoma, breast cancer, SCLC, AML):
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| 1. Unmet medical need:
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|  | * 1. Size of patient population for the specific indication:
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|  | * 1. Level of morbidity and mortality in patient population:
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|  | * 1. What are the current treatment options/therapies?
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|  | * 1. Please describe the unmet need or problem you are trying to address:
	2. How does your therapeutic approach address this problem?
	3. What are the are the advantages of your approach over current treatment options/therapies?
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| 1. Stage of development:
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|  | * 1. What is the stage? (Target ID, Target validation, Hit identification, Hit-to-lead, Lead optimization, Candidate selection/Preclinical development, Clinical trial):
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|  | * 1. Brief description of stage of the project:
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| 1. Target Validation:
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|  | * 1. Target validation status
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|  |  | * + 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.)
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|  |  |  |
|  |  | * + 1. Briefly summarize any relevant **in vivo** data that supports your target of interest (ex. loss of function/gain of function, pharmacological assays, etc.
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|  |  | * + 1. Briefly summarize any relevant supporting evidence in **humans** (ex. patients and/or patient samples)
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|  | * 1. Are there any potential target-related biomarkers? If yes, please describe?
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|  | * 1. Are disease relevant in vitro and/or in vivo models available? If yes, please describe?
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|  | * 1. Are tool compounds available? If yes, please describe?
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|  | * 1. Is a 3D structure available for the target?
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|  | * 1. Is a screening assay available? If yes, please describe?
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| 1. Candidate Therapeutic (If you do not have a candidate therapeutic please skip to section 7):
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|  | * 1. Modality (ex. small molecule, large molecule, antibody, cell therapy, and vaccines):
	2. Is this a new chemical entity (NCE) or a repurposed drug?
	3. If this is a repurposed drug, please provide the drug name:
	4. Drug properties (ex. structural, physicochemical, biochemical, pharmacological, pharmacokinetic (PK), toxicity characteristics, route of administration):
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|  | * 1. Describe the stage of development of your candidate therapeutic. Please provide specific information about your progress so far including key experiments and results:
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|  | * 1. Is the mechanism of action (MOA) known? If so, please describe.
	2. Would the candidate therapeutic be a monotherapy, a component of a combination therapy or both? Please provide brief explanation.
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|  | * 1. Was the candidate therapeutic discovered and developed at USC? If not, where did it originate from?
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| 1. Competitive landscape:
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|  | * 1. Are other drugs being developed for this target?
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|  | * 1. If so, please describe the other therapeutics or approaches currently under development and how yours differs.
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|  | * 1. What is the advantage of your proposed therapeutic approach compared to others under development?
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| 1. IP Status:
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|  | * 1. Has an Invention Disclosure been submitted to USC Stevens - yes/no?
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|  | * 1. If an invention disclosure was submitted, what is the status? (ex. decision not to file, waiting for more information, filed patent application)
	2. If a patent application(s) was filed or a patent(s) was granted, please list the applicable patent and/or application number(s):
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|  | * 1. Is any of the IP currently optioned or licensed to a company? If yes, please explain.
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| 1. If the target and/or candidate therapeutic are part of a 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. Who are the key academic competitors or experts in the field?
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|  |
| 1. Please list key publications you have authored that support the target, its discovery, and the therapeutic candidate if applicable:
2. Project Goals:
	1. What is the immediate goal for this project?
	2. Briefly describe the next critical set of experiments needed to reach this goal:
	3. What resources and/or expertise are needed?
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**Please attach your NIH biosketch and that of your collaborators.**