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PROGRAM OVERVIEW:

CBC-HITES is a funding and analytics resource for academic researchers from [nine Chicagoland institutions](#) built on the [processes and infrastructure](#) created by the [Chicago Biomedical Consortium](#) and is housed in Northwestern Medicine's [Comprehensive Transplant Center](#). Funded by the NIH through their [REACH award program](#), CBC-HITES offers **funding** and **industry-grade analytics and support** that will help improve applicants' projects.

Funding: Opportunities include “early” awards (**up to \$75K**) for projects that need an enabling experiment. Faculty from any one of the nine partnering institutions can apply for an “early” award. “Late” awards (**up to \$250K**) are for more progressed projects and require at least one Principal Investigator (PI) from UChicago, UIC, or Northwestern.

Support: CBC-HITES also provides support in the form of market, competitive, clinical, manufacturing, and feasibility analysis; experimental review and project management; connection to experts and venture; and many other resources needed to move inventions into the commercial sphere.

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REVIEW PROCESS GOALS:

The goal of the review process is to make sure that CBC-HITES works with applicants to evaluate and develop their ideas to move them along the path to commercialization. The support and analysis offered during the grant-making process will be as helpful to the applicant team as the funding itself. While a CBC-HITES application starts with a **two-page Letter of Intent (LOI)** submitted by the applicant team, the rest of the process is very different from traditional grant-making. After submission, CBC-HITES collaborates with the applicant team dynamically and interactively such that the CBC-HITES team develops the proposal with input from the team.

While funding is certainly one of the goals of the application, CBC-HITES's tailored analysis and strategic approach will be as impactful as the funding. CBC-HITES staff and our Entrepreneurial Fellows (EFs) form dedicated teams that work closely with the applying teams and each institution's [technology transfer office](#) to help Chicagoland academic scientists navigate and accelerate the translation of their innovative discoveries into impactful healthcare solutions.

We demystify the commercialization process by providing support at every stage:

- **Pre-funding guidance**
 - Evaluate ideas with industry-grade tools and analysis, including Key Opinion Leader feedback
 - Identify appropriate scientific pathways to meet business needs
 - Develop business requirements necessary for project translation (e.g., logistics, regulations, in-depth market analysis)
 - Solicit and share feedback from venture capitalists and industry experts as well as federal-

level feedback and guidance on regulatory issues

- **Post-funding support**
 - Integrate insights from relevant clinical trial results
 - Develop milestone-driven timeline for value creation
 - Manage project progress and troubleshoot
 - Network with industry experts and consultants
 - Guide to additional funding sources
- **Beyond funding**
 - Access cumulative knowledge of expert advisory boards from the private sector
 - Provide support across development and commercial lifecycle

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REVIEW PROCESS OVERVIEW:

A key element of success within this process is the role of the [Entrepreneurial Fellows \(EFs\)](#) – PhD level trainees who are dedicated full-time to helping shape the application. EFs and CBC-HITES staff will form a dedicated team that works with applicants to develop a triage analysis of the Letter of Intent (LOI). The research and conclusions from this triage analysis are presented to an external **Scientific Review Board (SRB)** made up of faculty and industry professionals selected based on their extensive subject-matter expertise. If the LOI is recommended by the SRB, the dedicated CBC-HITES team will work closely with the applicants to develop a comprehensive diligence analysis to be presented to the Venture Board (VB). The VB is composed of venture capital and pharma venture professionals who donate their time to assess the most promising applications and deliver funding recommendations.

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REVIEW PROCESS STEPS: There are 7 steps

Step	Action	Description	Timing
1) Pre-submission discussion with CBC-HITES	PI contacts CBC-HITES regarding a potential application	Interested PIs can reach out to CBC-HITES for an introductory conversation and guidance on crafting a compelling Letter of Intent (LOI)	Anytime
2) LOI Submission	PI submits LOI	PI submits a two-page overview of the translational research project	Accepted on a rolling basis
3) Triage analysis	CBC-HITES reviews LOIs	LOI is analyzed by the dedicated CBC-HITES team who review and analyze commercial, clinical, and technical potential in consultation with PI	Typically, up to 3 months after submission

4) Scientific Review Board (SRB)	CBC-HITES presents triage analysis to SRB for decision	<p>Triage analysis is discussed and SRB recommends whether to proceed for diligence or return the application with explanations of gaps that need to be addressed</p> <p>Applications selected by the SRB to move forward will complete the REACH Common Application. The CBC-HITES team will leverage the triage analysis and assist with the Common Application.</p> <p>Applications that are determined not to proceed are returned to the applicant with information about weaknesses that can be addressed prior to applying again in the future.</p>	Feedback given rapidly following SRB discussion
5) Diligence	CBC-HITES conducts diligence and develops materials used in next steps	<p>Applications that move forward undergo extensive diligence and business case development including interviews with external experts in preparation for review by industry experts (described below)</p> <p>The CBC-HITES team develops an extensive slide deck that documents the diligence and recommendations.</p>	Typically takes up to 4 months after SRB
6) Technology Guidance Committee (TGC)	NIH REACH TGC provides feedback on qualified applications	Applicable "late" award LOIs may be reviewed by NIH TGC, composed of federal experts assembled by NIH from the FDA and the Centers for Medicare and Medicaid Services. TGC provides feedback and guidance on relevant scientific, intellectual property, regulatory, and reimbursement issues. Feedback is provided to applicants to support their learning journey and technology development.	TBD

		Recommendations from this review will be used for the presentation to the Venture Board	
7) Venture Board (VB)	CBC-HITES & PI present to VB for funding recommendation	Diligence analysis and TGC feedback presented to and discussed with VB who then recommends whether to proceed to funding or return application with explanations of the gaps that need to be addressed	Feedback provided shortly following VB discussion

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INDIVIDUAL REVIEW STEPS DESCRIPTION:

Steps 1. and 2. Letter of Intent (LOI) Pre-Submission Discussion & Submission

Letters of Intent (LOIs) associated with a translational research project will be accepted **on a rolling basis**. CBC-HITES **strongly recommends** that the submitting PI contact CBC-HITES team for a pre-submission discussion to ensure alignment of the project with the funding criteria. The discussion can also inform whether the LOI will be considered for an “early” award (up to \$75K) or a “late” award (up to \$250K).

See [LOI Preparation](#) for instructions on how to submit the two-page LOI application

Steps 3. Triage analysis

Using a rubric that encompasses five main areas of inquiry, the applicant’s LOI is triaged to recommend further diligence. The triage is conducted according to five main criteria that cover:

- (1) Transformative Potential
- (2) Scientific Evidence
- (3) Development Feasibility
- (4) Commercial Potential
- (5) Near Term Execution

The CBC-HITES team will develop a three-slide triage summary and a recommendation based on the analysis. Recommendations designations are:

- “Now” and “soon” mean the application passed triage and will be assigned to a CBC-HITES team for diligence as capacity allows. Timing will be discussed with the applicant to ensure clear communication and transparency
- “Declined at this time” means there are limitations in the initial application. In some cases, this may be because the LOI is at an early stage and/or some elements need to be further elaborated by the submitting PI before it can be resubmitted for triage review. After the triage review with the SRB, CBC-HITES will discuss with the applicant how to convert a “declined at this time” into a “soon” or “now”, if this is possible

Step 4. Scientific Review Board (SRB)

The CBC-HITES team presents the triage analysis to an SRB, a committee made up of faculty and industry professionals selected based on their extensive subject-matter expertise. The triage analysis is presented, discussed, and the committee validates the CBC-HITES recommendation to either proceed for further diligence or return the application with explanations of the gaps that need to be filled.

Teams selected to go forward will complete the REACH Common Application in collaboration with the CBC-HITES team.

Step 5. Diligence

Once the application is designated as “now”, the assigned EF team will meet with the PI to further fact find on the LOIs basic idea as well as understand the supporting data that bolster’s the potential biomedical application. The EF team will determine five main criteria:

- (1) Size and timing of the ask
- (2) The clinical problem that is being solved
- (3) The competitive positioning of the proposed application across all competing inventions
- (4) The potential for follow on funding – both private and public
- (5) The key experiments that should be proposed as well as how these experiments may fit into the path to a regulatory milestone

Full diligence includes analysis and project planning from the CBC-HITES team. This research is meant to develop an “Investment Thesis” which includes all the aspects of the project that prospective investors and industry stakeholders would evaluate. The Investment Thesis is developed by CBC-HITES in collaboration with the PI applicant, removing a large burden on the applying PI.

Step 6. Technology Guidance Committee (TGC) Review

Under some circumstances, qualified Investment Theses will be reviewed by the Technology Guidance Committee (TGC) composed of Federal experts assembled by NIH which include NIH Entrepreneurs-in-Residence, experts from the FDA, and experts from the Centers for Medicare and Medicaid Services for additional input.

Step 7. Venture Board (VB) Presentation

After the diligence phase, the CBC-HITES team and the PI will present the Investment Thesis and, if available, recommendations from the TGC to the convened Venture Board (VB), a committee composed of venture capital and pharma venture professionals who donate their time to assess the most promising applications and deliver funding recommendations. This presentation will be led by the CBC-HITES team with support from the PI. The assembled VB will ask questions of the PI and CBC-HITES team. They will then submit their recommendation for funding based on their opinion of how fundable the potential project would be after the CBC-HITES investment as well as the projected time to reach seed funding.

The final funding decision will be made by CBC-HITES based on feedback from the VB and, when available, the TGC.

- “Early” awards will be up to **\$75,000 for one year of funding**
- “Late” awards will be up to \$250,000 for two years of funding
 - **Up to \$100,000 for the first year of funding**
 - “Late” award projects that have met proposed milestones during the first year **may be invited to apply for up to \$150,000 to support one more year of research**

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CBC-HITES AWARD DETAILS AND ELIGIBILITY:

- Applicants must have their own designated laboratory space. Faculty representing any of the nine partnering institutions may apply for up to \$75,000 in direct funding for one year of research. Applications that include a PI representing UChicago, Northwestern, or UIC with a biopharma/or biomarker-based diagnostic may be awarded up to \$250,000 for two years of research (see above). The CBC-HITES team will help the applicants develop a detailed budget during the application process.
- Although collaborative proposals are encouraged there is **no specific requirement for cross-institutional collaboration.**
- Applicants **may have created a company** to pursue translation of their innovation, but there is no expectation or requirement for so doing. CBC-HITES encourages applications before or without company formation.
- Multiple applications can be submitted from each institution.
- A PI is limited to one active CBC-HITES application at a time.
- There is no expectation that awards will be distributed evenly among the CBC-HITES institutions.
- The project should be focused on the development of **a therapeutic or associated diagnostic or biomarker, or a medical device** built around a compelling hypothesis and focus on gathering **data that advances the hypothesis and discharges key translational risks.**
- Research teams should not already be funded for the same (or closely related) specific aims and/or milestones.

- Research projects described in Letters of Intent (LOIs) applications cannot be under review at other funding institutions/agencies to support the same (or closely related) specific aims and/or milestones.
- LOIs should discuss **both innovation and scientific advances**.

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LOI PREPARATION:

All LOIs **MUST** be prepared according to the guidelines listed below. **All pages and documents listed below should be assembled into a SINGLE PDF document in the order listed. Portfolios will NOT BE ACCEPTED.**

To submit your application, please follow the below steps:

Step 1: Fill out the online form [HERE](#). All fields marked by asterisks (*) are required.

Step 2: Attach your LOI in PDF format. The LOI must conform to the following guidelines:

- Name the PDF file with "HITES_LOI_" followed by the last name of the PI designated as contact person (e.g., HITES_LOI_smith.pdf).
- The body of the LOI is limited to 3 pages; Include the following sections with the indicated titles and in the indicated order. Use at least size 11 font, 0.5-inch margins, and standard letter paper size (8.5" x 11").
 - One-paragraph lay-language summary of the project (*max. 150 words*)
 - A separate, two-page overview of the translational potential of the project, describing the following (please answer to the best of your ability, the goal is for the CBC-HITES team to fully develop these answers with applying team):
 - The basic research findings that are the basis of the hypothesis and project, including:
 - Its significance concerning the basic science
 - The compelling data that suggests clinical/translational potential
 - The diagnostic, biomarker, medical device or therapeutic you have in mind and its significance.
 - Proposed patient population that will benefit from your discovery
 - Potential clinical or therapeutic need.
 - Positioning: how the proposed diagnostic, biomarker, medical device, or therapeutic differs from existing ones and/or benefits patients in a new way.
 - The experiments you intend to do over the first year and how they will address key translational risks.
 - The translational goal(s) for your CBC-HITES project and proposed milestones (ensure that these are adequately quantitative for demonstrating progress).
 - Describe interactions with your Technology Transfer Office and the status of your intellectual property for this project. Has a company been formed?

- Has this project received any funding for translational work? If yes, please elaborate and indicate the relationship of this proposal to otherwise funded work.
- Relevant Cited Scientific References (*not to exceed one page; please follow the NIH format*)

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LOI SUBMISSION:

Completed LOIs **MUST** be submitted online. Clearly designate the contact person on the LOI. The contact person listed will be responsible for interacting with the CBC-HITES team and EFs.

Please designate the lead PI on the LOI as the administrative contact person and submit on the link below:

▶ [Submit your CBC HITES Award LOI here](#)

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