Form Approved Through 11/30/2010 OMB No. 1545-2175

Qualifying Therapeutic Discovery Project Program
Project Information Memorandum

Do not exceed word count restrictions indicated.

I. APPLICANT ORGANIZATION INFORMATION

1. NAME OF APPLICANT ORGANIZATION	2. TAXPAYER IDENTIFICATION NUMBER (TIN)	
3. ADDRESS NUMBER AND STREET	4. ROOM/SUITE	
5. CITY, TOWN, OR POST OFFICE	6. STATE	7. ZIP CODE
8. URL ADDRESS FOR APPLICANT'S WEB SITE		

II. CONTACT PERSON INFORMATION

9. FIRST NAME	10. MIDDLE NAME	11. LAST NAME	12. SUFFIX
13. ADDRESS NUMBER AND STREET		14. ROOM/SUITE	
15. CITY, TOWN, OR POST OFFICE	16.STATE	17. ZIP CODE	18. E-MAIL ADDRESS

TELEPHONE *(Area code, number and extension)* AND FAX NUMBER

19. TEL:		20. FAX:	

21. TITLE OF APPLICANT'S PROJECT

22. Signature of Authorized Representative Keep a copy of this form for your records.	Under penalties of perjury, I declare that I have examined this submission, including the accompanying documents, and, to the best of my knowledge and belief, all of the facts contained herein are true, correct, and complete.		
	Signature of Applicant	7LWOH	' DWH

Company Name

A. OVERVIEW: Provide an overview of the project for which you are seeking a credit or grant, including a description of the product, process or technology under development. **The description may not exceed 250 words.** If the project involves a new therapy, the description must include an explanation of why that therapy is novel**.**

Do not exceed 250 words.

B. Check each applicable box in the following and provide a short **(not more than 50 words)** statement supporting each positive assertion (i.e., where "Yes" is checked). Check all that apply, but you need check only one Yes for answers 1 through 4 for initial qualification.

1.	**Qualifying Therapeutic Discovery Project definition** Is the project • designed to develop a product to treat or prevent a disease or condition; • by conducting pre-clinical activities, clinical trials, or clinical studies, or by carrying out research protocols; and • for the purpose of securing approval of a product under section 505(b) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act?	☐ Yes ☐ No

If you checked the "Yes" box, then you must explain in 50 words or less. If you checked the "No" box, do not provide a narrative.

2.	Is the project designed to diagnose a disease or condition?	☐ Yes ☐ No

If you checked the "Yes" box, then you must explain in 50 words or less. If you checked the "No" box, do not provide a narrative.

3.	Is the project designed to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions?	☐ Yes ☐ No

If you checked the "Yes" box, then you must explain in 50 words or less. If you checked the "No" box, do not provide a narrative.

4.	Is the project designed to develop a product, process, or technology to further the delivery or administration of therapeutics?	☐ Yes ☐ No

If you checked the "Yes" box, then you must explain in 50 words or less. If you checked the "No" box, do not provide a narrative.

Selection Criteria

5.	Is this project likely to result in one or more new therapies?	☐ Yes ☐ No

If you checked the "Yes" box, then you must explain in 50 words or less. If you checked the "No" box, do not provide a narrative.

6.	If the answer to question 5 is Yes, will the new therapy(ies): a. treat areas of unmet medical need?	☐ Yes ☐ No

If you checked the "Yes" box, then you must explain in 50 words or less. If you checked the "No" box, do not provide a narrative.

	If the answer to question 5 is Yes, will the new therapy(ies): b. prevent, detect, or treat chronic or acute diseases or conditions?	☐ Yes ☐ No

If you checked the "Yes" box, then you must explain in 50 words or less. If you checked the "No" box, do not provide a narrative.

7.	Is the project likely to reduce long-term health care costs in the United States?	☐ Yes ☐ No

If you checked the "Yes" box, then you must explain in 50 words or less. If you checked the "No" box, do not provide a narrative.

8.	Is the project likely to significantly advance the goal of curing cancer within the next 30 years?	☐ Yes ☐ No

If you checked the “Yes” box, then you must explain in 50 words or less. If you checked the "No" box, do not provide a narrative.

For each of questions 9, 10, and 11, provide a short statement, not to exceed a total of 250 words, including responses to bulleted items. For question 9, applicants may also submit up to five literature citations in the specified format that will not be counted against the 250-word limit.	
9.	Explain the scientific rationale, based on prior conceptual and empirical work, which supports the belief that the proposed project will lead to the outcome the applicant has identified above. Explain the research and development plan that will lead to the outcome identified above. Describe the scientific evidence relied on by the applicant, including a description of any peer review of the project and a list of no more than five literature citations using the format provided below. **(DO NOT EXCEED 250 WORDS)**

Provide a short statement, not to exceed a total of 250 words.

Literature Citations: Include a list of no more than five (5) literature citations in reference to question 9, using the following format**:**

- Include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication.
- When citing articles that were authored or co-authored by the applicant and arose from NIH support, if available, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the Pubmed Central (PMC) reference number (e.g., PMCID234567) for each citation.
- Citations for which an NIH Manuscript Submission reference number is not available but are publicly available in a free, online format should include URLs or PMCID numbers along with the full reference. The references should be limited to relevant and current literature.

Literature citations are excluded from the 250-word limitation.

10.	Describe the stage of development of the project, including a description of pre-clinical and clinical trial results that are relevant to the proposal. Include in your description: • If the project involves the development of a product that is regulated by the Food and Drug Administration, an explanation of whether an investigational new drug application or an investigational device exemption has been filed with the Food and Drug Administration, and whether an application for approval, license, or clearance has been filed, and, if so, the status of that application as of the date of application as of the date this project information memorandum is submitted. • If the project does not involve the development of a product that is regulated by the Food and Drug Administration, information about any regulatory reviews or approvals that have occurred. • If the project involves preclinical testing, a description of the testing completed and/or contemplated. • If the project involves testing in humans, information about the phase(s) of the testing that has been completed and the number of subjects tested in each phase and information about trials for which the applicant is actively recruiting subjects. Summarize the results of the trails, noting any failed trials or successful trials. • The planned research and development strategy for the test or treatment being researched and a summary schedule for development of the project, including timelines and milestones planned and completed. **(DO NOT EXCEED 250 WORDS)**

Provide a short statement, not to exceed a total of 250 words, including responses to bulleted items.

11.	Describe the resources, management experience and organizational capacity of the applicant and explain how applicant believes that such resources, experience and capacity will support successful completion of the project. Include in this description: • A statement of the revenue levels and sources for this project over the past three years. • A statement of the revenue levels and sources for the proposed research and development plan delineated in response to question 10. • A description of any significant public or private investment, such as by venture capitalists, in the development or commercialization of the project. • A description of any strategic partnerships for the development or commercialization of the project. • A statement of whether the applicant has suspended operations for the project and, if so, whether the suspension is temporary or permanent. If the project has been suspended, terminated, or is otherwise inactive, explain why, including whether the cause is a lack of financial resources or other reasons. **(DO NOT EXCEED 250 WORDS)**

Provide a short statement, not to exceed a total of 250 words, including responses to bulleted items.

Company Name

Instructions for Completing Project Information Memorandum

Note: Font sizes and margins on some QTDP_PIM form pages may vary due to field or space limitations. The QTDP_PIM Microsoft Word (MS Word) and Portable Document File (PDF) Form Pages as provided are acceptable to NIH.

I. APPLICANT ORGANIZATION INFORMATION

This information is for the Applicant Organization, not a specific individual.

Field Name	Instructions
1. Name of Applicant Organization	Enter the legal name of the applicant organization. This field is required.
2. Taxpayer Identification Number (TIN)	Enter the TIN as assigned by the Internal Revenue Service. This field is required.
3. Address Number and Street	Enter the street number and street address for the applicant. This field is required.
4. Room/Suite	Enter the room or suite number for the applicant.
5. City, Town, or Post Office	Enter the city, town, or post office for address of applicant. This field is required.
6. State	Enter the State where the applicant is located. This field is required.
7. ZIP Code	Enter the nine-digit Postal Code (e.g., ZIP code) of applicant. This field is required.
8. URL Address for Applicant Organization's Web Site	Enter the Web site URL address for the applicant organization (e.g., http://www.companywebsiteurladdress.com/).

II. CONTACT PERSON INFORMATION

Person to be contacted on matters involving this application:

This information is for the Administrative or Business Official of the Applicant Organization. This person is the individual to be notified if additional information is needed.

Field Name	Instructions
9. First Name	Enter the first (given) name of the person to contact on matters related to this application. This field is required.
10. Middle Name	Enter the middle name of the person to contact on matters related to this application.
11. Last Name	Enter the last (family) name of the person to contact on matters related to this application. This field is required.
12. Suffix	Enter the suffix (e.g., Jr., Sr., Ph.D.) for the person to contact on matters related to this application.

Field Name	Instructions
13. Address Number and Street	Enter the street number and street address for the applicant. This field is required.
14. Room/Suite	Enter the room or suite number for the applicant.
15. City, Town, or Post Office	Enter the city, town, or post office for address of applicant. This field is required.
16. State	Enter the State where the applicant is located. This field is required.
17. ZIP Code	Enter the nine-digit Postal Code (e.g., ZIP code) of applicant. This field is required.
18. Email	Enter the email address for the person to contact on matters related to this application.
19. Phone Number	Enter the daytime phone number for the person to contact on matters related to this application. This field is required.
20. Fax Number	Enter the fax number for the person to contact on matters related to this application.
21. Title of Applicant's Project	Enter a brief descriptive title of the project. This field is required. Note: If a company is submitting multiple projects, a separate application and Project Information Memorandum must be completed for each project.
22. Signature of Authorized Representative	It is the organization's responsibility to assure that only properly authorized individuals sign in this capacity and/or submit the application.

Complete the remainder of the Project Information Memorandum (for Items A and B (including questions 1-11) in accordance with the instructions provided in the IRS Notice 2010-45 (http://www.irs.gov/pub/irs-drop/n-10-45.pdf). Note that all applications must correspond to the word limits specified. Exceptions will not be granted to exceed the word limits specified for the Overview and Questions 1-11. A Continuation Page is provided for those rare instances in which the text will not fit in the allocated space. However, note that text beyond the word limits will not be considered. Note: Font sizes and margins on some QTDP_PIM form pages may vary due to field or space limitations. The QTDP_PIM Microsoft Word (MS Word) and Portable Document File (PDF) Form Pages **as provided are acceptable to NIH**.