



**Detailed Application Instructions for
Technology Transfer/Commercialization Partnership (TTCP) Grant
for Tobacco-Related Diseases
August 10, 2009 – January 29, 2010**

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OVERVIEW

This document contains detailed instructions for completing the James & Esther King Biomedical Research Program Technology Transfer/Commercialization Partnership (TTCP) Grant application. Use this document along with the *Open Call for Grant Applications: Technology Transfer/Commercialization Partnership (TTCP) Grant for Tobacco-Related Diseases, August 10, 2009 – January 29, 2010* (hereafter referred to as “the Call”) to complete the application.

Important: All submitted materials are subject to the provisions of Art. 1, Sec. 24, Florida Constitution and Chapter 119, F.S., Florida’s public records law. These laws grant a right to inspect any public record. Refer to Chapter 14 B of the Call for instructions on how to properly identify confidential information.

Direct all questions about the online application process and related issues (e.g. username and password problems, other technical issues) to:

Technical Support
Lytmos Group
(816) 347-9449 (phone)
techsupport@floridabiomed.com (e-mail)

Awards will be made as applications are received until all funds set aside for TTCP grants have been allocated. The Department recommends that applications be submitted as soon as possible.

SECTION A. GENERAL PROJECT INFORMATION

Project Information

1. **Title of Project:** Enter the project title. Note: This exact project name must also appear on all submissions of regulatory approvals such as local IRB approval.
2. **Amount of Grant Funds Requested.**
 - a. **Total Amount of Grant Funds Requested (all eligible years):** Enter the amount of funds (direct and indirect) requested for the life of the grant. This number should be the same as “Amount of Grant Funds Requested in Year 1.”
 - b. **Amount of Grant Funds Requested in Year 1:** Enter the amount of funds (direct and indirect) requested for the initial 12-month period of the grant.

3. **Type of Project:** Select the type of grant mechanism for which you are applying (TTCP Grant).
4. **Previous James & Esther King Applicant:** If you have been a previous grant applicant to the James & Esther King Biomedical Research Program, check “Yes,” otherwise check “No.” If you answered “Yes,” indicate the date of the most recent submission.
5. **Research Site:** Indicate the site(s) where the work described in the Research/Project Plan will be conducted, including institution name, city, and state. If there is more than one site, list all the sites and provide an explanation in the Resources section of the application. The first site listed should be the site where most of the work will be conducted.
6. **Human Subjects:** If activities involving human subjects **are not planned at any time** during the proposed project period, check “No.” If activities involving human subjects, whether or not exempt from Federal regulations for the protection of human subjects, **are planned at any time** during the proposed project period, either at the applicant organization, or at any other site or collaborating organization, check “Yes.” If the answer to this question is “Yes,” an additional section in the Online Application will appear called “Human Subjects Used.”
7. **Vertebrate Animals:** If activities involving vertebrate animals **are not planned at any time** during the proposed project period, check “No.” If activities involving vertebrate animals **are planned at any time** during the proposed project period, either at the applicant organization or at any other site or collaborating organization check “Yes.” If the answer to this question is “Yes,” an additional section in the Online Application will appear called “Vertebrate Animals Used.”
8. **Recombinant DNA Molecules:** If research/project activities involving recombinant DNA molecules **are planned at any time** during the proposed project period, check “Yes,” otherwise check “No.” All research involving recombinant DNA techniques must meet the requirements of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*, including submission of the project for approval, if necessary.
9. **Excluded Peer Reviewers:** List individuals that you wish to exclude from peer reviewing your application. The Program already excludes peer reviewers from the state of Florida so please don’t include Florida scientists in your list. List the name and institution or city/state for each individual. Separate each individual with a semicolon. *Entry is limited to 200 characters.*
10. **Stem Cell Research:** If activities involving stem cells are not planned **at any time** during the proposed project period, check “No.” You do not need to complete the next question. If activities involving stem cells, whether or not exempt from Federal regulations for the protection of human subjects, **are planned at any time** during the proposed project period, either at the applicant organization, or at any other site or collaborating organization, check the type of stem cell – “Adult,” “Embryonic,” or “Animal”. If the project involves stem cells, please identify the source(s) of stem cells being used and include a very brief description of the relevant research activity. *Entry is limited to 1200 characters.*

Research Classification

In order to receive funding, an application must include a compelling case for its relationship to the prevention, treatment, diagnosis, or cure of tobacco-related diseases; however, many types of research/projects may qualify. Please select the research categories that best fit the work described in the application.

Principal Investigator Information

- 1. Name of Principal Investigator:** The Principal Investigator (PI) is the individual designated by the applicant organization to direct the grant project. The Principal Investigator is responsible and accountable to the applicant organization officials for the project's scientific and technical direction as well as the proper conduct of the project. Name the **one** person responsible to the applicant organization for the scientific and technical direction of this project.
- 2. Suffix:** Indicate the Principal Investigator's degree(s) or credential(s) (e.g., Ph.D., M.D., R.N.). The PI will be addressed using this suffix (example: Jane Doe, Ph.D, R.N.).
- 3. Position Title:** Provide the academic or professional title of the Principal Investigator. If more than one title, indicate the one most relevant to the proposed project, such as Professor of Biochemistry, Chief of Surgical Service, et cetera.
- 4. Department or Office, Service, Laboratory, or Equivalent:** Indicate the organizational affiliation of the Principal Investigator, such as Department of Medicine, Materials Research Laboratory, or Social Sciences Institute.
- 5. Institution/Organization:** Name the applicant eligible institution or small business that will be legally and financially responsible for this grant.
- 6. Mailing Address:** Provide complete and exact information, as it should appear on the mailing label, for postal delivery to the Principal Investigator. Most written communications to the Principal Investigator will use this address. Note: Providing precise mailing information is critical to resolving any problems with your application that might otherwise result in disqualification, and for making timely award notification.
- 7. Courier Address:** Provide complete and exact information, including room number, building identifier and street address, necessary for courier delivery. This address will be used for certain written communication, such as delivery of award notification and Award Terms and Conditions. Do not indicate a post office box.
- 8. Telephone Number:** Provide a daytime telephone number (including extension, if applicable) for the Principal Investigator.
- 9. Fax Number:** Provide a fax number (including area code) for the Principal Investigator.
- 10. E-mail Address:** Enter the appropriate electronic mail address for the Principal Investigator.

- 11. U.S. Citizenship:** If you are a U.S. Citizen check “Yes,” otherwise check “No.” If you are a lawful permanent resident (as demonstrated with evidence of a green card, I-151 or I-155 paperwork) check “Yes” and provide the expiration date from your green card. This information is being collected from all applicants for purposes of statistical analysis and will not be used in award determinations.
- 12. PI or Co-PI on a National Grant:** Check either “Yes” or “No,” depending on whether the Principal Investigator has previously served as the Principal Investigator or Co-Principal Investigator on a non-mentored, peer-reviewed, national research grant with a budget of \$100,000 per year in direct costs. This information is being collected from all applicants for purposes of statistical analysis.

Applicant Organization Information

- 1. Organization Federal ID Number:** Enter the nine-digit federal identification number assigned to the applicant organization by the Internal Revenue Service.
- 2. Applicant Organization Type:** Select the one description from the drop down box that best describes the applicant organization.
- 3. Financial Conflict of Interest:** Does the applicant organization have a Financial Conflict of Interest policy and procedure that is consistent with NIH requirements? Check either “Yes” or “No.”

Institution PI Qualifications

This section will only appear within the online application if the applicant organization is an eligible institution (not a small business). Entry in this section is required if the applicant is an eligible Institution.

- 1. Full Time Faculty or Equivalent at Florida Institution:** If you (PI) are a full-time faculty member at an eligible institution (or a postdoctoral fellow in his/her final fellowship year, by the time the application is submitted) check “Yes.” (See full time faculty, full-time equivalent, and eligible institution definitions in Chapter 15 of the Call.) If you do not meet the definition of full-time faculty (or equivalent) or are not a final year postdoctoral fellow check “No.”
- 2. First Full Time Faculty Appointment:** This information is being collected for purposes of statistical analysis.
 - a. Date:** Specify the date of your first full-time appointment as a university faculty member or an equivalent position at a research institution.
 - b. Institution:** Identify the university or research institution where you first became a full-time faculty member or held an equivalent position. (See full-time faculty and full-time equivalent definitions in Chapter 15 of the Call.)
 - c. Title:** Identify the title or position held in your first full-time faculty or equivalent position. (See full-time faculty and full-time equivalent definitions in Chapter 15 of the Call.)

Small Business PI Qualifications

This section will only appear within the online application if the applicant organization is a small business. Entry in this section is required if the applicant is a small business.

- 1. Employment Status at Florida Small Business:** If the PI is employed at least 50% effort with the small business check “Yes,” otherwise check “No.”
- 2. Other PI Employment:** If the PI has less than 100% effort at the small business, please explain where the additional effort is being expended. Include the name, location, percent effort, and responsibilities for each other employment. Entry is limited to 1800 characters.

Official Signing for Applicant Organization

Provide the name and title of the official authorized to sign on behalf of the applicant organization to certify all statements as true and authorize all commitments contained within, including matching funds if applicable. Provide complete and exact information as it should appear on a mailing label for postal delivery. Following these fields, also enter complete and exact information necessary for courier delivery, including building identifier, room number, and street address. Do not include a Post Office box number. Enter the telephone number (and extension, if applicable), fax number, and E-mail address.

Administrative Official Information

Whether or not this is the same person previously described, provide the name and title of the administrative official to be notified if an award is made. This official would sign the Terms and Conditions (contract) issued by the Program if an award is made. Provide complete and exact information as it should appear on a mailing label for postal delivery. Following these fields, also enter complete and exact information necessary for courier delivery, including building identifier, room number, and street address. Do not include a Post Office box number. Enter the telephone number (and extension, if applicable), fax number, and E-mail address.

SECTION B. GENERAL AUDIENCE ABSTRACT

State the project's broad, long-term objectives and specific aims, making specific reference to the project's relevance to prevention, diagnosis, treatment, and/or cure of tobacco-related disease(s). Provide an overview of the research design and methods for achieving these goals. Avoid summaries of previous accomplishments and the use of the first person. This description is meant to serve as a brief description of the project when separated from the application. **If the application is funded, this description will be used to compile reports and provide information to the Governor, Legislature, and the general public**, so ensure this summary is suitable for a general audience as opposed to the scientific community. Do not exceed the space provided. Some scientific notations and formatting may not show in the online application sections. Use only conventional alphanumeric letters and numbers with no drawings or symbols for on-line abstracts, project descriptions, or project titles. Do NOT include information in this section considered proprietary unless you think it is essential for proper evaluation of the application. *Entry is limited to 1500 characters.*

SECTION C. SCIENTIFIC ABSTRACT

Provide a scientific abstract for the project. This abstract will be used as the primary resource for assigning applications to individual peer reviewers. If the application is awarded, this description will be used to provide project information to the scientific community. Use only conventional alphanumeric letters and numbers with no drawings or symbols. *Entry is limited to 2000 characters.*

SECTION D. KEY PERSONNEL

Key personnel are those persons whose expertise in the subject area(s) are central to the project and to convincing the peer reviewers that the project is feasible. This list of key personnel must at least include the Principal Investigator and the project leader from the partnering entity, and may include one or a few additional individuals, as appropriate. For each individual, provide the name, organization, and role on the project. Under role on the project, indicate how the individual will function with regard to the proposed project, for example, Principal Investigator, Investigator, consultant, etc. "TBA" (to be announced/appointed) cannot be key personnel. Biographical sketches of any identified key personnel are required with the application. It is not necessary that all individuals or positions paid under the grant be listed as key personnel, nor is it necessary that key personnel be compensated with funds from the grant.

SECTION E. TOBACCO-RELATEDNESS

Provide a clear and concise explanation of how the proposed project is related to tobacco-use prevention or the diagnosis, treatment, and cure of tobacco-related diseases such as cancer, cardiovascular disease, stroke, and pulmonary disease. **Applicants must demonstrate the relatedness of the proposed project to tobacco use.** *Entry is limited to 3000 characters.*

SECTION F. SMALL BUSINESS INFORMATION

Refer to Chapter 5 in the Call for small business eligibility requirements and Chapter 15 for definitions before answering these questions. Answer the yes/no questions regarding the status and size of the small business entity. Indicate the percent effort to be performed by the eligible institution and the percent effort to be performed by the eligible small business. In the sections below, additional documentation regarding the small business and eligible institution are required, including *Partner Letters of Support* and a small business Certificate of Status.

MAIN APPLICATION BODY

This part of the application includes Sections identified as the main application body as indicated in Table 1 of the Call.

Use the link provided to download the main application form. When you have completed the form, convert the document to PDF format, and upload it into the online application by clicking on the *James & Esther King Application Form* button.

Section G. Table of Contents

Provide the page numbers for each application section listed on the *Table of Contents*. Number pages consecutively, at the bottom of each page throughout the application. Do not include unnumbered pages and do not use suffixes, such as 3a, 3b. This form also serves as a checklist to ensure all application components are included.

Section H. Alternative Funding Challenges

It is not the intent of the Program to replicate or replace funding from other traditional sources such as the National Institutes of Health, but rather to provide funding to fill gaps left by those traditional sources. Provide a clear explanation of why funding from other sources is not available for the proposed project. Include specific challenges and obstacles.

Section I. Resources

Specify the facilities, laboratories, clinics, animals, computers, offices, major equipment, or other resources to be used for the proposed project. Indicate the sites and describe capabilities, relative proximity, and extent of availability for the project. Also, identify support services such as machine shops, electronics shops, etc., and specify the extent to which they will be available to the project.

Section J. Research/Project Plan

The Research/Project Plan should include information sufficient to evaluate the project properly, independent of any other document. Be specific and informative, and avoid redundancies.

Within this section, answer the following four questions: (1) What do you intend to do? (2) Why is the work important? (3) What has already been done? (4) How are you going to do the work?

Do not exceed the page limitations for the Research/Project Plan as indicated in Table 1 of the Call. The Program recommends the format and page distribution as shown below. All tables, graphs, figures, diagrams, charts, and scanned photographs of material must be included within the page limit.

1. Introduction to Resubmitted Application:

All resubmitted TTCP applications must begin with an Introduction that summarizes the substantial additions, deletions, or changes. The Introduction must also include responses to the criticisms and issues raised in the Program Evaluation Report (Peer Review Report). Identify all changes in the Research/Project Design and Methods section clearly by bracketing, indenting, or changing the font, unless the changes are so extensive as to include most of the text. This exception should be explained in the Introduction. Do not underline or shade changes.

If this is the first time you have submitted this TTCP proposal to the Program, indicate “not applicable” in this section.

Do not exceed one page for this section.

2. Specific Aims:

State the specific objectives of the project, including the technical questions you will try to answer to determine the feasibility of the proposed approach.

State concisely and realistically what the proposed research/project is intended to accomplish in terms of its potential for technological innovation and commercial application. Define the final proposed product, process, or service to be developed in the long-term.

One page is recommended.

3. Background and Significance:

Provide a clear statement of the specific technical problem or opportunity. Describe significant research or research and development efforts that are directly related to the proposal, including any conducted by the eligible small business. Describe how it relates to the proposed effort, and any planned coordination with outside sources.

Briefly sketch the background to the present proposal, critically evaluating existing knowledge and alternative approaches, and specifically identify the gaps that the project is intending to fill.

Two to three pages are recommended.

4. Commercial Potential:

Describe the potential marketability and/or commercial viability of the research/project. Who will eventually be willing to pay for the resulting product, process, or service? What solutions are they using now, and why would they prefer your potential solution to all other alternatives? Explain the importance of the proposed project in advancing the concept toward commercialization, and briefly explain your anticipated next steps if this project is successful.

One to two pages are recommended.

5. Preliminary Studies:

Preliminary data are not required. However, such results may assist reviewers assess the likelihood of success of the proposed project and if available, should be included in this section. If no preliminary data is available, indicate “not applicable.”

For resubmissions, the Preliminary Studies section should incorporate any work done since the prior version was submitted.

One to two pages are recommended if applicable.

6. Research/Project Design and Methods:

Discuss in detail the experimental design, procedures and protocols, to be used to achieve each objective or task, and the means by which the data will be analyzed and interpreted. Describe any new methodology and its advantage over existing methodologies. Describe any novel concepts, approaches, tools, or technologies for the proposed studies. Discuss the potential difficulties and limitations of using the proposed procedures and alternative approaches to achieve the aims. Discuss the criteria that will be used to determine that feasibility has been demonstrated. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised. Include how the data will be collected, analyzed, and interpreted as well as the data-sharing plan as appropriate.

Although no specific number of pages is recommended for the Research/Project Design and Methods section, be succinct as possible. There is no requirement that all pages allotted for items 1 – 6 be used.

Section K. Partnership Information

1. Eligible Institution Qualifications:

Identify the related experiences and capabilities of the eligible institution to support its role in the proposed project. Identify any unique qualifications.

2. Eligible Small Business Qualifications:

Identify the related experiences and capabilities of the eligible small business to support its respective role in the proposed project. Identify any unique qualifications.

3. Partnership Agreement:

Describe any relevant formal agreement(s) that currently exists between the partners, such as a teaming agreement, memorandum of understanding, or licensing agreement. If none exists, how do you plan to formalize agreements between the partners related to this project, especially as it pertains to ownership of any resulting intellectual property? Include a scanned copy of any subcontract agreement(s) in this section of the form.

Section L. Literature Cited

List key references only. The section may include, but may not replace, the list of publications required in the Preliminary Studies section (of the Research/Project Plan section, above.) for applications for already existing projects. Each reference must include the title, names of all authors, book or journal, volume number, page numbers, and year of publication. The reference should be limited to relevant and current literature. Observe page limitations specified in Table 1 of the Call. It is important to be concise and to select only those literature references pertinent to the proposed project.

Section M. Human Subjects

If the proposed project does NOT involve human subjects at any time during the project, write "N/A" in this section.

Even if a grant application is exempt from these regulations, you must address the issues of gender/race/ethnic composition of the subject population, as explained below. (Please note, if an award is made, the Principal Investigator may additionally be responsible for obtaining Department of Health IRB approval.)

If human subjects are involved in this project proposal, address the following six points. In addition, when research involving human subjects will take place at collaborating site(s) or other site(s), provide this information before discussing the six points. **Although no specific page limit applies to this section of the application, be concise.**

1. Provide a detailed description of the proposed involvement of human subjects in the work previously outlined in the Research/Project Plan. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable.
2. Identify the sources of research/project material obtained from individually identifiable **living** human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for project purposes or whether use will be made of existing specimens, records, or data.
3. Describe plans for the recruitment of subjects and the consent procedures to be followed. Include how consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. State if the Institutional Review Board (IRB) has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent. The informed consent form, which must have IRB approval, should be submitted to the Program only if requested.
4. Describe potential risks to the subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

5. Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety and privacy of subjects.
6. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result. If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of applicant certification to the Food and Drug Administration and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the Food and Drug Administration.

Gender and Minority Inclusion for Research Involving Human Subjects:

Women and members of minority groups and their subpopulations should be included in all Program-supported biomedical research projects involving human subjects, unless a clear and compelling rationale shows that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion, except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This applies to research subjects of all ages.

Address the inclusion of women and members of minority groups and their subpopulations in developing a research design appropriate to the scientific objectives of the study. Describe the composition of the proposed study population in terms of gender and racial/ethnic group, and provide a rationale for selection of such subjects. Provide the proposed enrollment beginning and end dates. Include a description of proposed outreach programs for recruiting women and minorities as participants. Provide compelling rationale and justification for requesting any exclusion noted above. When proposing Phase III clinical trials, show whether clinically important gender or race/ethnicity differences are to be expected, and how the trial is designed to accommodate any differences.

Section N. Vertebrate Animals

If the proposed project does NOT involve vertebrate animals at any time during the project, write "N/A" in this section.

If the proposed project involves vertebrate animals at any time during the project, address the five points shown below. In addition, when research involving vertebrate animals will take place at collaborating site(s) or other site(s), provide this information before discussing the five points.

Although no specific page limit applies to this section of the application, be concise.

1. Provide a detailed description of the proposed use of animals in the work outlined in the Research/Project Plan section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.

3. Provide information on the veterinary care of the animals involved.
4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.
5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.

Section O. Consultants

Include scanned letters from all individuals confirming their roles in the project. For consultants, letters should include the rate/charge for consulting services. If this information is not applicable to the grant proposal, so indicate by writing "N/A" in this section.

Section P. Publications (Optional)

Include scanned copies of the publications (including accepted or submitted manuscripts) in this section of the form. It is important that section and total page limits are observed. See Table 1 in the Call for section and maximum total page limits.

Section Q. Survey Instruments (Optional)

Include scanned copies of the survey instruments in this section of the form.

OTHER DOCUMENTS

This part of the application includes Sections identified as "Other Documents" as indicated in Table 1 of the Call.

Section R. Partner Letters of Support

All TTCP projects must include two *Letters of Support*, one from the eligible institution and one from the collaborating eligible small business.

The eligible institution letter must contain:

- A statement of intent to collaborate with the eligible small business
- A brief description of the responsibilities, roles, and contributions that will be provided by the institution
- A statement of the percent of work/effort that will be performed by the institution

The eligible small business letter must contain:

- A statement of intent to collaborate with the eligible institution
- A brief description of the responsibilities, roles, and contributions that will be provided by the small business
- A statement of the percent of work/effort that will be performed by the small business
- A description of its type of business entity, as defined in section 606.03(1); *F.S.*, Federal Entity Identification Number (FEIN) or in place of that, a Dun and Bradstreet (DUNS) number
- An attestation that the small business meets the criteria for eligibility at the time of application.

Convert (or scan) all Partner Letters of Support into a single PDF file and upload the file where indicated.

Section S. Miscellaneous Letters of Support (Optional)

Miscellaneous letters of support are optional and can be uploaded in this section. Letters of interest from potential commercial partners or investors and letters of commitment of funds or other resources that will enhance the likelihood of commercialization should be included.

Convert (or scan) all miscellaneous letters of support into a single PDF file, and upload the file where indicated.

Section T. Certificate of Status or Authorization from Division of Corporations

All TTCP applications must include a copy of the eligible small business's Certificate of Status or Authorization from the Division of Corporations, Florida Secretary of State; or any other certifications from the Secretary of State resulting from the requirements of Chapter XXXVI, Business Organizations, *F.S.*; or in place of either of those above, a county business license.

To complete this section, convert the Certificate of Status or Authorization to a single PDF file, and upload the PDF file where indicated.

Section U. Biographical Sketches

This section must contain the biographical sketches of the Principal Investigator, the project leader of the partnering entity, and any other key personnel. Each biographical sketch must use the National Institutes of Health biographical sketch template, available for download at <http://grants1.nih.gov/grants/funding/phs398/phs398.html#forms>. Up to 4 pages per key person may be included.

To complete this section, assemble and convert all biographical sketches into a single PDF file, and upload it into the online application where indicated.

Section V. Budget

Use the button provided online to download the Budget Form. Complete all required information and obtain the signature of the designated Administrative Official. It is NOT necessary to obtain a signature from the Department of Health at this time. Convert the signed document to PDF format and upload it into the online application by clicking on the *Budget Form* button.

The contents of the Budget Form will be used to establish the official budget for the grant, if awarded.

When preparing your proposed budget, consider the following Program guidelines as well as those shown in Chapter 6 of the Call.

Allowed Direct Costs

Allowed direct cost expenses must be directly related to the project and may include:

- salaries
- fringe benefits
- supplies
- equipment
- domestic travel
- consultant costs
- patient-care costs
- Department of Health IRB fees (if applicable)
- consortium or contractual costs

Administrative costs *may* be included in direct cost categories, but only under two conditions:

- the services, functions, or activities are directly necessary for this grant,
AND
- these administrative costs have not been included in the calculation of the indirect costs.

Allowed Indirect Costs

Indirect costs (also referred to as IDC, F&A, or administrative costs) are limited to 10% of the direct costs requested.

Disallowed Costs

The following items shall NOT be purchased with grant funds:

- Construction, renovation, or remodeling
- International travel
- Vehicles
- Entertainment
- Employment subsidies
- Dues/Membership fees
- Meals/Food (other than as part of travel costs)
- Malpractice insurance premiums

Instructions for TTCP application budget:

The first page of the Budget Form breaks down the total amount of project costs by budget category. Each entry **must be directly related** to the project. You may find it easier to complete the Budget Narrative/Justification (Page 2) first.

Budget Form - Page 1

Personnel: Describe personnel information as indicated on the application form.

Name: Starting with the Principal Investigator, list the names of all applicant organization employees who will be involved on the project during the entire funding period, regardless of whether salary is requested. Include all collaborating investigators, individuals in training, and support staff. Do not include consultants in this detail. Use "TBA" (to be announced) for any necessary positions, other than key personnel, for which an appointment has not yet been made.

Role on Project: Identify the role of each individual listed on the project.

Type Appointment (months): Indicate whether the base salary is a 9-month salary or a 12-month salary.

Percent Effort on Project: For each individual or position, list the percent of time to be spent by each person on this project even if no salary is requested. *Percent effort must be greater than or equal to the percent of salary requested.*

Percent Salary on Project: For each individual or position, list the percent of base salary requested for this project. *Percent salary requested cannot exceed percent effort on the project.*

Institution Base Salary: List the annual base salary (without fringe benefits) for each position. The **maximum annual base salary** used in calculating these payments must not exceed the Executive Level 1 annual salary rate of the Federal Executive Pay Scale that is in effect as of September 18, 2009. See Chapter 15, Definitions, for more information about the Federal Executive Pay Scale. This salary cap excludes fringe benefits, facilities, and administrative (F&A) expenses, and also excludes any income that an individual may be permitted to earn outside of the duties to the applicant institution. This provision is consistent with the NIH salary limitations on grants, cooperative agreements, and contracts.

Salary Requested: List the total salary (without fringe benefits and for the total funding period) for each position. The percent FTE (Full Time Equivalent) salary support requested cannot exceed the actual percent of effort.

Fringe Benefits: State the percent used to calculate fringe benefits.

Total Amount Requested: List the totals (total salary with fringe benefits for the total funding period) for each position (cannot exceed percent effort).

In the next section of Page 1, provide the budget amount requested for each category listed. If project income is anticipated, indicate the amount. This budget amounts should match the corresponding *budget narrative* section information on page 2 of the Budget Form.

Budget Form – Page 2

On the second page, provide a narrative justification for each budget category by describing how it is related to the project. Where appropriate, include details that show how the estimated cost was calculated. Use additional sheets as necessary.

Personnel: Provide the names of all personnel and their roles on the project. Describe their responsibilities on the project. Further explain salary and effort figures from the Personnel Table on page 1 if clarification is needed. In cases where an individual's appointment is divided into academic and summer segments, please explain and provide calculations.

Consultant Costs: Provide the names of any consultants, their roles on the project, and the total amount requested. Whether or not costs are involved, provide the names and organizational affiliations of all consultants, other than those involved in consortium/contractual arrangements. Include consultant physicians in connection with patient care and persons who serve on external monitoring boards or advisory committees to the project. Describe the services to be performed. Include the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs.

Consortium/Contractual Costs: List each consortium and/or contractual arrangement, the total dollar amount, and provide justification. Each participating consortium/contractual organization may be required to submit a separate detailed budget for the budget period.

Any consortium arrangements may involve personnel costs, supplies, and other allowable costs, including indirect costs. Contractual costs for support services, such as laboratory testing of biological materials, clinical services, or data processing, are occasionally sufficiently high to warrant a similar categorical breakdown of costs.

Equipment: List each item separately, with dollar amount, and justify each purchase. Property and equipment are defined as non-expendable, tangible property having a useful life of more than one year.

Supplies: Itemize supplies (with costs) in separate categories, such as glassware, chemicals, radioisotopes, etc. Categories in amounts less than \$1,000 do not have to be itemized. If animals will be purchased, state the species and the number to be used. (Note: animal maintenance cost should be included in the Other Expenses category, not supplies).

Travel: Itemize domestic travel requests and provide justification. Provide the purpose and destination of each trip and the number of individuals for whom funds are requested. Travel of a reasonable amount (\$1,500 per year for one traveler) may be proposed to attend conferences and similar meetings in the scientific field(s) of endeavor. TTCP Grants are usually limited to two travelers per year. International travel is not allowed.

Patient Care Costs: If inpatient and/or outpatient costs are requested, list them and provide the names of any hospitals and/or clinics and the amounts requested for each. State whether each hospital or clinic has a currently effective DHHS-negotiated research patient care rate agreement, and if not, what basis is used for calculating costs. If an applicant does not have a DHHS-negotiated rate, a provisional rate can be approved. Indicate, in detail, the basis for estimating costs in this category, including the number of patient days, estimated cost per day, and cost per test or treatment. If both inpatient and outpatient costs are requested, provide information for each separately. If multiple sites will be used, provide detailed information by site.

Include information regarding projected patient accrual for the project/budget periods and relate this information to the budget request for patient care costs. If patient accrual will be lower at the start or during the course of the project, plan budget(s) accordingly.

Provide specific information regarding anticipated sources of other support for patient-care costs, e.g., third-party recovery or pharmaceutical companies. Include any potential or expected utilization of General Clinical Research Centers.

Other Expenses: Itemize any other expenses by category and unit cost. These might include animal maintenance (unit care costs and number of care days), patient travel, donor fees, publication costs, computer charges, rentals and leases, equipment maintenance, service contracts, tuition remission, and Department of Health (DOH) IRB fees (if applicable). Provide justification of these costs. All items listed in this category must meet the definition of direct costs.

Project Income: If project income is anticipated, provide detailed information and justification. If the application is funded, the award document(s) will provide specific instructions regarding the use of such income.

Section W. Research Milestone Chart

All grant applications require a Research/Project Milestone Chart that provides a high-level overview of the anticipated project schedule with references to the major aims, tasks, and experiments planned for the research/project. The online application contains a link to an example of a completed Milestone Chart. Instructions are included in the Milestone Chart form.

To complete this section, download the Milestone Chart form by following the online instructions, complete it in Microsoft Excel, convert it to PDF format, and upload it into the online application.

Section X. Other Support

Completion of the Other Support section consists of downloading the appropriate form, completing it, converting it to a single PDF file, and uploading it into the online application. On the Other Support Form, include all additional current and pending support for the Principal Investigator and the project leader at the partnering entity.

Other Support information assists peer reviewers and Program staff in the identification and resolution of potential overlap of support. **Overlap, whether scientific, financial, or commitment of an individual's effort greater than 100 percent, is not permitted.** The goals in identifying and eliminating overlap are to ensure that sufficient and appropriate levels of effort are committed to the project; that there is no duplication of funding for scientific aims, specific budgetary items, or an individual's level of effort; and that funds not otherwise necessary for the approved project are not included in the award.

The following definitions may guide you in determining the appropriate information to report on the Other Support form.

Financial overlap occurs when duplicate or equivalent budget items (e.g., equipment, salary) are requested in an application and are already funded by another source.

Commitment overlap occurs when any project personnel has time commitments exceeding 100 percent. This is the case whether or not the grant includes salary support for the effort. While information on other support is only requested for the Principal Investigator and project leader at the partnering entity, **no personnel on the project may have combined commitments of more than 100 percent.**

Scientific Overlap occurs when: (1) substantially the same research is proposed in more than one application or is submitted to two or more different funding sources for review and funding consideration, or (2) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more applications or awards, regardless of the funding source.

Instructions for Other Support Report form fields:

Principal Investigator: The Principal Investigator is the individual designated by the applicant organization to direct the project to be supported by the grant.

Project Title: Indicate the title of the project being entered for consideration.

Institution: Indicate the university or institution.

Date: Enter the current date.

PI Percent Effort on Non-Research Activities (teaching, mentoring, etc.) at the Institution: Indicate the PI's percent effort on non-research activities such as teaching, clinical work, mentoring, or administrative responsibilities at the institution or small business.

The rest of the form consists of as many Section A's as are required to completely report the instances of Other Support for the Principal Investigator and the project leader at the partnering entity. A sample completed Section A is included in the body of the report.

Name of Key Person: Name of the key individual associated with the other support being described.

Role in the James & Esther King Project: Indicate the role of this person on the TTCP Grant.

Grant Number: Enter the code or identifier for the project assigned by the funding organization. If this is a pending proposal, enter N/A.

Dates of Grant: Indicate the inclusive dates of the project as approved/proposed. For example, in the case of NIH support, provide the dates of the approved/proposed grant.

Source: Identify the agency, institute, foundation, or other organization that is providing the support.

Total Annual Costs: In the case of an active project, provide the current year's total budget amount (sum of direct and indirect costs). For a pending project, provide the proposed total budget amount (sum of direct and indirect costs) for the initial budget period.

Grant Status: Indicate the status of the award, such as applied for, pending, or active.

Total Annual Direct Costs: Provide the current year's direct costs. For a pending project, provide the proposed direct cost amount for the initial budget period.

Percent Effort: For an active project, provide the level of effort (even if unsalaried) as approved for the current budget period. For a pending project, indicate the level of effort as proposed for the initial budget period. In cases where an individual's appointment is divided into academic and summer segments, indicate the proportion of each devoted to the project.

This Project PI: Identify the principal investigator for the other support project being reported.

Percent Salary: For an active project, provide the percent of salary paid for the current budget period. For a pending project, indicate the percent of salary as proposed for the initial budget period. In cases where an individual's appointment is divided into academic and summer segments, indicate the proportion of each devoted to the project.

Title of Project: Provide the exact title of the funded or proposed "other" project.

Major Project Goals: Provide a brief statement of the overall objectives of the project, subproject, or subcontract.

Overlap Status: Summarize any potential scientific, financial, or time commitment overlap with active or pending projects and the James & Esther King application. If there is no overlap, state this. Any necessary resolution of overlap due to this application being funded will be arranged with the applicant prior to award.

When you have completed the Other Support Report Form, convert the document to PDF format and upload it into the online application.

Section Y. IRB and IACUC Approvals

IRB Assurance Information (Human Subjects Used)

This section only applies if the research involves the use of human subjects.

- 1. Exemption Number:** If human subjects are to be used in your research but an approval exemption applies, enter the exemption number provided by your local IRB, if it is available.
- 2. Review Status:** If approval has already been received for the proposed research from your institutional IRB, indicate whether the approval was granted by a full IRB review or an expedited review.
- 3. IRB Approval Date:** Enter the date the IRB was approved, if available.
- 4. Effective and End Dates:** Enter the dates the IRB approval became effective, as well as the date of its expiration, if available.
- 5. Assurance of Compliance:** Identify the compliance number associated with the IRB Assurance, if available.

IRB approvals are not required at the time of application, however, if available please upload the approvals. Convert the document(s) to PDF format and upload into the online application where indicated. The IRB approval must have the same project title as the application project title and must be signed by the IRB chairperson.

IACUC Assurance Information (Vertebrate Animals Used)

This section only applies if the research involves the use of animal subjects.

- 1. Review Status:** Check the appropriate status box for the IACUC approval.
- 2. IACUC Approval Date:** Enter the date that Animal Welfare Assurance approval was received, if available.
- 3. Assurance of Compliance:** Enter the Animal Welfare Assurance number associated with the IACUC Assurance, if available.
- 4. Effective and End Dates:** Enter the dates the IACUC approval became effective, as well as the date of its expiration, if available.

IACUC approvals are not required at the time of application, however, if available please upload the approvals. Convert the document(s) to PDF format and upload into the online application. The IACUC approval(s) must have the same project title as the application project title and must be signed by the IACUC chairperson.

Section Z. Cover/Certification – Signed Page 1

Click on the *Print Forms* link on the upper right side of this screen to generate and print a PDF document displaying the information you entered online, as well as copies of all the files you uploaded. Review this information carefully. If you want to make modifications, change your entries within the online form or upload replacement files and reprint the appropriate sections of your application.

The Principal Investigator and designated Organization Official must sign the first page of the printed application to show agreement with the listed certifications. **It is important to read them carefully. These certifications apply to all information contained on ALL required sections of the application.** Signatures must be in an ink color other than black (preferably blue) so the original is easily recognized. “Per” or “For” signatures are not acceptable.

After obtaining the appropriate signatures, scan this first signed page ONLY into a PDF formatted document and return to this screen to upload it into your application.

The original signed cover page must be delivered to the Florida Department of Health by the date and time listed in Chapter 9 of the Call. The delivery address may be found in Chapter 14 C of the Call as well as in the *Final Instructions for James & Esther King Biomedical Research Program* section of the online application.