



**Call for Grant Applications:
Research Project Grant (RPG):
Special Emphasis on Translational
and/or Health Disparities Research
for Cancer
Fiscal Year 2010-2011**

**Florida Department of Health
Office of Public Health Research
Tallahassee, Florida**



Issued: December 4, 2009

TABLE OF CONTENTS

**Bankhead-Coley Cancer Research Program
Call for Grant Applications: RPG, FY 2010-2011**

1. Introduction	4
2. Highlights	6
3. Cancer Relatedness	6
4. RPG Mechanism Information	6
A. Research Emphasis	6
B. Award Amount and Duration	8
5. Eligibility Requirements	8
A. Open Innovation and Sharing of Publication-Related Materials, Data, and Software	8
B. Eligible Applicants	9
C. Additional Application Requirements and Limits	10
6. Allowed and Disallowed Costs	11
A. Allowed Direct Costs	11
B. Allowed Indirect Costs	12
C. Disallowed Costs	12
7. Online Application Registration	12
8. Required RPG Application Components	13
Table 1. RPG Application Components and Page Limits	13
9. Schedule of Important Dates	16
Table 2. Schedule of Important Dates	16
10. Inquiries and Contacts	17
A. Programmatic Questions About This Call	17
B. Technical Questions About the Online Application	18
11. Evaluation of Applications	18
A. Administrative Review	18
B. Peer Review	19
C. Programmatic Review	20
D. Evaluation Reports	20
12. Notification of Funding Decision	20
13. Requests for ReConsideration	21
14. Instructions for Application Submission	21
A. Technical Assistance	21
B. Confidentiality of Submitted Materials	22
C. Online Application Submission	22
D. General Guidelines	23
E. Reducing File Sizes	24
15. Definitions	25
16. Frequently Asked Questions	28
Appendix A – General Research Information Instructions	32
Section A – General Project Information	32
Section B – General Audience Abstract	36
Section C – Scientific Abstract	36
Section D – Cancer Relatedness	36
Section E – Key Personnel	36
Section F – Disparate Groups	37

Appendix B – Main Application Body Form	38
Appendix C – Main Application Body Instructions	40
Section G – Table of Contents	40
Section H – Resources	40
Section I – Research Plan.....	40
Section J – Literature Cited	41
Section K – Human Subjects	41
Section L – Vertebrate Animals.....	43
Section M – Consortium/Contractual Agreements	43
Section N – Consultants.....	44
Section O – Survey Instruments (Optional).....	44
Appendix D – Budget Form	45
Appendix E – Budget Form Instructions.....	48
Budget Summary.....	48
Year One Budget.....	48
Year One Budget Narrative/Justification.....	49
Appendix F – Other Documents Instructions	52
Section Q – Biographical Sketches.....	52
Section R – Research Milestone Chart	52
Section S – Other Support.....	52
Section T – Miscellaneous Letters of Support (Optional).....	54
Section U – Cover/Certification – Signed Page 1.....	54
Section V – IRB and IACUC Approvals	55
Appendix G – Research Milestone Chart Form	56
Appendix H – Other Support Form.....	58

Closed

1. INTRODUCTION

The William B. “Bill” Bankhead, Jr., and David Coley Cancer Research Program (hereafter referred to as “the Program”) was established in section 381.922, *Florida Statutes* (s. 381.922, *F.S.*) in 2006. The purpose of the Program is to “advance progress towards cures for cancer through grants awarded through a peer-reviewed, competitive process.” The legislative intent of the Program is to significantly impact Florida’s high cancer burden, reducing both cancer incidence and mortality, while advancing scientific endeavors in the state and making Florida a world-class leader in cancer research and treatment.

Between 2006 and 2009, \$6 to \$9 million was allocated to the Program annually. Beginning in fiscal year (FY) 2009-2010, the Program will receive 2.5%, not to exceed \$25 million, of the revenue deposited into the Health Care Trust Fund from the increased cigarette user fee imposed by s. 210.02, *F.S.*

The Florida Department of Health, through the Office of Public Health Research (hereafter referred to as “the Department”) administers the Program with the support of a contracting partner, the Lytmos Group, Inc. The Program also solicits recommendations and suggestions on policy alternatives from the Biomedical Research Advisory Council consistent with s. 20.435 and s. 381.922, *F.S.*

The Program has three long-term goals:

1. Significantly expand cancer research capacity in the State.
2. Improve both research and treatment through greater participation in clinical trials networks.
3. Reduce the impact of cancer on disparate groups.

In pursuit of these goals, **the Program is soliciting Research Project Grant (hereafter referred to as “RPG”) applications** from eligible institutions to fund initiatives addressing the prevention, diagnosis, treatment, and/or cure of cancer.

Through separate calls for grant applications, the Program is also soliciting grant applications for four other grant mechanisms:

1. Post-Doctoral Research Fellowship (PRF)
2. New Investigator Research (NIR) Grant
3. Team Science Program (TSP) Grant
4. Technology Transfer/Commercialization Partnership (TTCP) Grant

This Call for Grant Applications applies only to RPG applications. To access the PRF, NIR, TSP, and TTCP Calls for Grant Applications, visit the Program website at www.floridabiomed.com.

The Program has historically operated in general accord with the policies and procedures for extramural funding employed by the National Institutes of Health (NIH) and looks to the NIH as a source of standard practices. To protect the credibility of the Program and to ensure public trust, this general accord includes but is not limited to similar expectations of adequate institutional control and oversight to guard against financial conflict of interest, scientific misconduct, scientific and financial overlap and the mismanagement of funds, the protection of human and vertebrate animals, and compliance with applicable state and federal laws or regulations.

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 to anyone upon request. Refer to Chapter 14 B for instructions on how to properly identify confidential information.

All awards in response to this Call are subject to the availability of funds and spending authority provided by the Florida Legislature. By submitting a grant application pursuant to this Call, all applicants acknowledge and consent to this condition.

After awards are made, each grantee must sign a contract, called the "Terms and Conditions," agreeing to certain legal requirements of the award. An example of the "Terms and Conditions" is located on the Program website and can be accessed by clicking on the following link: [Terms and Conditions \(www.floridabiomed.com/bc_call\)](http://www.floridabiomed.com/bc_call). The "Terms and Conditions" are non-negotiable and acceptance is required as part of the grant award process. The Program reserves the right to change or modify the "Terms and Conditions" as needed. By submitting a grant application pursuant to this Call, all applicants acknowledge this requirement. The "Terms and Conditions" also include the post-award schedule of deliverables.

2. HIGHLIGHTS

- Each grant mechanism has its own Call for Grant Applications document.
- This mechanism is very similar to the New Investigator Grant; however, it is open to investigators at any experience level.
- This grant requires a focus on translational or health disparities research. See Chapter 4.
- Indirect cost allocation has increased to 15%. See Chapter 6.
- All instructions for filling out the application are now included in this Call for Grant Applications, either in the main body or the appendices.
- All uploaded files must be less than or equal to 3 MB each. File sizes larger than 3 MB will not be permitted.
- Definitions of key terms used throughout this document are located in Chapter 15.

3. CANCER RELATEDNESS

All applicants must clearly demonstrate how the proposed project is relevant to cancer. Grant requests must support the work of **biomedical and biotechnological research** addressing the etiology, pathogenesis, prevention, diagnosis, treatment, and/or cure of cancer. **Social scientific and behavioral** proposals must address the development, implementation, and/or evaluation of existing or novel approaches to cancer prevention, diagnosis, or treatment. Proposed projects that do not or cannot demonstrate a close relationship with advancing progress toward cures for cancer or endeavor to dramatically improve cancer morbidity and mortality will not be funded.

4. RPG MECHANISM INFORMATION

A. Research Emphasis

The intent of this grant mechanism is to encourage research in two specific areas of cancer: **translational research** and **health disparities research**.

RPGs are for the conduct of research projects that are hypothesis driven. Research projects must be fully developed, scientifically rigorous, and include sound background information, hypotheses, and promising preliminary studies or supporting data.

Projects must be highly relevant to cancer and this relevance will be taken into account when making award recommendations.

A grant recipient must commit to and show proof of applying for a follow-on national grant such as an R21, R33, or R01.

1) Translational Research

For purposes of this initiative, translational research:

- a) applies basic discoveries generated during research in the laboratory through pre-clinical research involving human derived tissue
- b) involves clinical trials, including efforts that improve access to or enrollment in clinical trials
- c) enhances the adoption of best practices in the community

Translational research projects would most likely address outcomes that focus on:

- Drug development
- Biomarker development for gauging disease progression and treatment efficacy
- Diagnostics
- Cellular therapies
- Behavioral therapies
- Target identification through any clinical trials phase
- Measures or mechanisms to improve access to clinical trial information for patients and/or physicians
- Interventions to increase patient participation in clinical trials that move research from laboratory to clinical application

2) Health Disparities Research

Health disparities apply to individuals who have limited access to resources and privileges that impact their health. This area of research includes a focus on ethnic and racial minority populations as well as low literacy, rural and low-income populations, those geographically isolated, the hearing and visually impaired, individuals with physical or mental disabilities, immigrant and refugee families, and language minority populations.

Examples of eligible health disparities research projects include:

- Studies of genetic, physiological, social, psychological, economic and demographic, environmental, and cultural factors believed to influence health disparities
- Culturally and developmentally appropriate interventions designed to reduce risk factors and exposures that lead to development of one or more poor health outcomes
- Community interventions that reduce health disparities

- Studies that test and evaluate the cost and/or health effectiveness of health interventions conducted in nontraditional settings
- Interventions that include technology in biomedical imaging and bioengineering that reduce health disparities, such as low-cost diagnostic imaging and point-of-care technologies
- Factors (genetic, behavioral, etc.) increasing the risk of adverse long-term or late effects among ethno-culturally diverse or medically underserved populations

B. Award Amount and Duration

1. The maximum award for RPGs is \$300,000 for the first year, not to exceed \$1,500,000 over five years (including direct and indirect costs).
2. Awards are for a period of 60 months.
3. Grants will begin on or about July 1, 2010.
4. Subsequent year grant funding is dependent on project performance and subject to the availability of funds. Grantees must submit a request for continuation and an annual progress report at least 60 days before the end of years one, two, three, and four. Subsequent annual support shall comply with the same "Terms and Conditions" as the initial award, including any amendments thereof. Initial awards are for three years with the expectation that after the submission and review of a comprehensive progress report and a request for renewal, projects may be extended for up to two more years, for a maximum of five years of support.

5. ELIGIBILITY REQUIREMENTS

A. Open Innovation and Sharing of Publication-Related Materials, Data, and Software

Publishing a scientific paper is a transaction whereby the author(s) receive credit and status in exchange for sharing their scientific findings. Authors have a responsibility to make available materials, databases, and software integral to their findings so that others may validate or refute the results and/or extend them in new directions. Grantees funded through this Program are encouraged to use materials transfer agreements to make materials, data and databases, and software that result from this funding and which is integral to their research findings, freely and promptly available upon request for research use by other scientists.

In accord with the National Institutes of Health notice NOT-OD-08-033, Grantees shall submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication, in a manner consistent with copyright law. This applies to all publications resulting from Program funded projects/research. For more information on the NIH Open Access Policy visit <http://publicaccess.nih.gov/>.

B. Eligible Applicants

The applicant must be an eligible institution (see the definitions provided in Chapter 15). According to s. 215.5602(5)(a) and s. 381.922(3)(a), *F.S.*, applications for biomedical research funding may be submitted from any university or established research institute in the state. For the purposes of this program, **eligible institutions** shall include:

- State universities - A state university is defined in s. 1001.60, *F.S.*, except as otherwise specifically provided, as the 11 named public, postsecondary institutions and any branch campuses, centers, or other affiliates of the institution. For purposes of the Program, the named university or college and any branch campus, centers or affiliates, unless it can be legally shown otherwise, are considered one and the same, and where the number of applications is limited, the university and its branch campuses, centers or other affiliates must coordinate submission(s) in order to comply with the limitation. Public institutions must be accredited by a nationally recognized organization.
- Nonpublic institutions - For the purposes of the Program, nonpublic institutions operating under Chapter 1005, *F.S.* are also eligible. Any branch campuses, centers or other affiliates of a nonpublic institution are considered one in the same with that institution, and where the number of applications is limited, the institution and its branch campuses, centers or other affiliates must coordinate submission(s) in order to comply with the limitation. Nonpublic institutions must be accredited by a nationally recognized organization.
- Established research institutes - An established research institute is defined as any Florida nonprofit or foreign nonprofit covered under Chapter 617, *F.S.*, with a physical location in Florida, whose stated purpose and power is scientific, biomedical or biotechnological research and/or development and is legally registered with the Florida Department of State, Division of Corporations. This includes federal government and non-profit medical and surgical hospitals including Veteran's Administration hospitals.

The applicant organization, in accordance with its own policies and procedures, should designate the Principal Investigator. The Principal Investigator must supervise the project directly and in person. Grant applications from Principal Investigators failing to meet all applicable eligibility requirements will be rejected. The Principal Investigator 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.

To be eligible as a **Principal Investigator at an eligible institution**, the individual must be a full-time faculty member, or a postdoctoral fellow in his/her final fellowship year, by the time the application is submitted. Postdoctoral applicants must be a Full-time Faculty member or equivalent by the grant start date. Temporary faculty members, even though full-time, are not eligible to apply. See Full-time Faculty and Full-time Equivalent definitions in Chapter 15.

General information regarding the project and specific information about the Principal Investigator and the applicant organization will be collected in the *General Project Information* section of the application. See [Appendix A](#) for instructions on completing this section of the application.

C. Additional Application Requirements and Limits

Investigator Requirements:

The RPG is open to investigators at eligible institutions with no limits placed upon experience or past funding track record. Previous King or Bankhead-Coley grantees are eligible to apply.

Duplicate Applications and Overlap Limits:

Applicants may not submit duplicate projects or projects with significant scientific or financial overlap to different mechanisms within the Bankhead-Coley Cancer Research Program for the same Call for Applications. The same project/research cannot be submitted to the Bankhead-Coley Program by more than one investigator regardless of the grant mechanism. Applicants may not submit duplicate projects or projects with significant scientific or financial overlap to both the James and Esther King Biomedical Research Program and the Bankhead-Coley Cancer Research Program during the same competition year. The Principal Investigator may submit two or more completely different projects at the same time.

Applicants must ensure that their proposed project does not duplicate or significantly **overlap**, scientifically or financially, with other projects in which they or any key personnel are involved. Overlap, whether scientific or financial is not permitted. Commitment of a project member's effort greater than 100% is also prohibited.

Grantee Reporting Requirements:

If the applicant's proposal is funded, the Grantee must submit one follow-on national grant application such as an R21, R33, or R01, before the end of the grant.

If the applicant's proposal is funded, the Grantee must respond to Program requests for information for a period of five (5) years after the end of the grant period, including any no cost extensions. The requested information may include long-term outcomes based on the funded project, including the value of additional grant awards for cancer-related research, a list of cancer-related presentations, a list of cancer-related publications in peer-reviewed journals, commercialization results and any invention disclosures, patent filings, patents received, et cetera.

Refer to the Program website at www.floridabiomed.com/bc_call to review the "Terms and Conditions" that includes the full post-award deliverable schedule.

6. ALLOWED AND DISALLOWED COSTS

The following information explains direct and indirect costs allowed by the Program, as well as disallowed costs. The Budget Form, shown in [Appendix D](#), will be used to establish the official budget for the grant, if awarded. Instructions are located in [Appendix E](#) and the Budget Form is provided online for download as a Microsoft Word™ document.

A. 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.

The Program does not prohibit administrative costs as part of direct costs, but to be allowable, they must meet both of the above conditions. All direct costs must be specifically and directly related to the project, necessary for the project's completion, and adequately justified. Pay particular attention to these criteria with costs such as copying charges, telephone and Internet charges, maintenance contracts, etc.

Maximum Annual Base Salary Calculations:

The Program will pay a proportional percentage of the base salary (based on effort) of any personnel named on the application for this grant. 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 February 12, 2010. 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.

Work Must Occur in Florida:

It is the intent of the Program that activities funded through the Program, including data analysis, occur in Florida. Ninety percent of work (effort) must occur and 90% of funds must be spent in Florida at the eligible institution and any collaborating entities. Funding for any out-of-state personnel or consulting expenses cannot exceed 10% of the total requested direct costs. This does not include lab services, supplies, or equipment.

B. Allowed Indirect Costs

Indirect costs (also referred to as IDC, F&A, or administrative costs) are limited to 15% of the direct costs requested. Indirect costs are those costs that are incurred for the joint or common benefit of several separate organizational or financial components (cost centers) of an organization, which specifically or readily cannot be identified to a particular cost center, project, or program.

C. Disallowed Costs

All direct costs must be specifically and directly related to the project, necessary for the project's completion, and adequately justified. Any other costs are disallowed. Additionally, 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

7. ONLINE APPLICATION REGISTRATION

Only applications received through the GrantEase™ online application system will be accepted. Applicants must register online at www.floridabiomed.com/login.html to be able to submit an application. Data collected during registration includes basic contact information, proposal subject, brief proposal description, and the grant mechanism of interest. Registered applicants will receive a username and password that will allow access to the online application system.

See Chapter 14 for application submission instructions and the appendices for specific field-level and form instructions.

8. REQUIRED RPG APPLICATION COMPONENTS

A complete RPG application package **must** contain all required items listed in Table 1.

TOTAL MAXIMUM PAGE LIMIT: 75 printed pages

MAXIMUM UPLOADED SINGLE FILE SIZE: 3 MB

The total maximum page limit includes cover/certification page and all required and optional sections. Proposals exceeding the page limits where specified are subject to truncation to the page limit or may be disqualified without review. Proposals exceeding the total maximum page limits may be disqualified without review. All required application forms are available for download within the online application in GrantEase™. **File sizes greater the 3 MB will not be allowed to be uploaded.** For information on how to reduce file sizes, see Chapter 14 E, or contact technical support via email at techsupport@floridabiomed.com.

Table 1. RPG Application Components and Page Limits			
Section	Category	Page Limit	Comment
General Research Information*:			
See Appendix A for detailed instructions for these sections of the application.			
A	General Project Information	2	Required. Identifies general project information, the applicant organization and the Principal Investigator.
B	General Audience Abstract	1500 characters	Required. Explains the proposed project in layman's terms, including its relationship to the goals of the Program.
C	Scientific Abstract	2000 characters	Required. This is the scientific description of the project.
D	Cancer-Relatedness	3000 characters	Required. Provides a clear explanation of how the project is related to cancer.
E	Key Personnel	1	Required. Identifies all key personnel.
F	Disparate Groups	1	Required. This is a yes/no question asking if the proposed research reduces the impact of cancer on disparate group(s) and if so, how.

Table 1. RPG Application Components and Page Limits			
Section	Category	Page Limit	Comment
Main Application Body**:			
See Appendix B for an example of the form and Appendix C for detailed instructions for these sections of the application.			
G	Table of Contents	1	Required.
H	Resources	2	Required.
I	Research Plan	20	Required.
J	Literature Cited	6	Required.
K	Human Subjects	No limit	Required if applicable.
L	Vertebrate Animals	No limit	Required if applicable.
M	Consortium/Contractual Agreements	1	Required if applicable.
N	Consultants	3	Required if applicable.
O	Survey Instruments	No limit	Optional.
Budget:			
See Appendix D for an example of the form and Appendix E for detailed instructions for this section of the application.			
P	Budget	4	Required. The budget must explain the planned spending.
Other Documents:			
See Appendix F for detailed instructions for these sections of the application and Appendices G , and H for examples of the forms.			
Q	Biographical Sketches	4 per person	Required for the Principal Investigator and any other key personnel.
R	Research Milestone Chart	2	Required. See Appendix G for an example. Provides a high-level overview of the project schedule.

Table 1. RPG Application Components and Page Limits			
Section	Category	Page Limit	Comment
S	Other Support	No Limit	Required. See Appendix H for an example. All other active and pending awards for the Principal Investigator.
T	Miscellaneous Letters of Support	No Limit	Optional.
U	Cover/Certification Page – Signed	1	Required. A signed PDF copy must be uploaded.
V	IRB and/or IACUC Approvals	No limit	You may submit an application without necessary IRB or IACUC approvals. Project work may not begin until all approvals are provided.
TOTAL MAXIMUM PAGE LIMIT: 75 printed pages MAXIMUM UPLOADED SINGLE FILE SIZE: 3 MB			
<p>* (Sections A-F) Submitted materials are subject to the provisions of Art. I, Sec. 24, <i>Florida Constitution</i> and Chapter 119, <i>F.S.</i>, Florida’s public records laws. These laws grant a right to inspect any public record. There are some documents and information that are exempt from the public records laws. <u>Applicants are discouraged from submitting information considered proprietary unless it is deemed by the applicant to be essential for proper evaluation of the application. If this is the case, DO NOT place such information in the General Research Information sections of the application. These sections are subject to publication and wide dissemination in the event you are awarded a grant.</u></p> <p>** (Sections G-O) If the application contains information that the applicant believes constitutes trade secrets or proprietary information or is protected by a specific statutory exemption, it should be limited to the Main Application Body. The applicant must CLEARLY identify the information with [brackets] and a footnote that specifies the law, which makes the document or information exempt from the public records laws. If a public record request is made involving documents with declarations of confidentiality, the Department will notify the applicant so that he/she may defend the claim in circuit court. The Department of Health will not provide legal representation to assert a confidentiality claim when a public record request is made.</p>			

9. SCHEDULE OF IMPORTANT DATES

The following schedule applies to all applications submitted in response to this Call for Grant Applications.

Table 2. Schedule of Important Dates		
ACTIVITY	DATES	IMPORTANT INFORMATION
Competition opens for online applications	December 4, 2009	Visit www.floridabiomed.com and register for access to an online application.
Written questions accepted	QUESTIONS MAY BE SUBMITTED AT ANY TIME AFTER THE CALL IS PUBLISHED AND MUST BE RECEIVED BEFORE 5:00 PM EST FEBRUARY 3, 2010	E-mail questions to: bcquestions@floridabiomed.com
Answers posted to written questions	Updates will be made frequently to the website while the Call is open. Final updates will be posted on or around FEBRUARY 9, 2010	Find questions and answers at http://floridabiomed.com/bc_ga.html
Online applications due	APPLICATIONS MUST BE SUBMITTED BEFORE 5:00 PM EST FEBRUARY 12, 2010	Online applications must be submitted through www.floridabiomed.com
Proposal evaluation summaries available to applicants online	On or around May 26, 2010	For all eligible and qualified applications, the evaluation report will be available to the applicant by logging in at www.floridabiomed.com .
Awards announced	On or around June 1, 2010	Award letters will be mailed to the Administrative Official. The Principal Investigator will receive notification by e-mail.

Table 2. Schedule of Important Dates

ACTIVITY	DATES	IMPORTANT INFORMATION
Regulatory Approvals Due (if applicable)	Immediately after award notification, grantees should submit all necessary applications to regulatory authorities including, but not limited to, the IACUC, local or institutional IRB, and if necessary the DOH IRB. Project work may not begin until all approvals are provided.	Send scanned signed approvals to: programsupport@floridabiomed.com Note: The project name on the approvals must match the application project name. Refer to Chapter 15 for the DOH IRB definition to determine if approval is required for your project. Visit www.flpublichealthethics.net for DOH IRB instructions and forms.
Grants begin	July 1, 2010	Contingent on verification of all eligibility requirements and regulatory approvals.

Changes will be posted to the Program website at www.floridabiomed.com. Applicants should monitor the website for changes and announcements.

10. INQUIRIES AND CONTACTS

A. Programmatic Questions About This Call

This Call for Grant Applications is issued by the Program on behalf of the State of Florida, Department of Health. To ensure that no applicant receives an advantage over any other applicant, employees of the Department of Health and members of the Biomedical Research Advisory Council will not respond to questions regarding this Call for Applications until after all awards are announced. The Lytmos Group, Inc., the Department's contracted agent for managing the Calls for Applications, acceptance of applications, and peer review, is responsible for answering all applicant questions. Applicants and persons acting on their behalf may contact the Lytmos Group in writing via e-mail as indicated below regarding programmatic issues. Applicants who attempt to contact Department of Health and/or Biomedical Research Advisory Council members regarding this Call for Applications may have their applications disqualified.

To ensure equal access by all applicants to questions and answers, all programmatic questions must be submitted in writing via e-mail to bcquestions@floridabiomed.com.

Answers to questions will be available on the Program website, www.floridabiomed.com. Answers will be posted to the website frequently as questions are received. Applicants are responsible for checking this website regularly throughout the application, peer review, and award processes for Program announcements.

B. Technical Questions About the Online Application

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

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

If you experience technical difficulties during the final hours of the competition, please contact technical support immediately for assistance. The Department recommends that applications be submitted early and that you do not wait until the last day.

11. EVALUATION OF APPLICATIONS

The Program will use a multi-step evaluation process before making award determinations for all applications submitted in response to this Call for Grant Applications. The Program will consider the outcome of each of these evaluation steps in making final funding recommendations to the Florida State Surgeon General.

A. Administrative Review

Application materials not received according to the dates, times, and locations specified in Chapter 9 will be disqualified.

Each application submitted by the deadline indicated in Chapter 9 will receive an administrative review verifying mandatory eligibility requirements and the completeness of the application. The administrative review does not include review of the overall impact.

Any application failing to meet all administrative requirements may be ruled ineligible for funding in response to this Call for Applications and not entitled to further consideration. However, the Program may send ineligible proposals for peer review in order to provide feedback to the applicant, which may be useful in competing for future funding opportunities.

At the Department's discretion, minor irregularities can be waived if doing so does not give the applicant an advantage over other applicants.

B. Peer Review

Program peer reviewers will assess the overall impact of all qualified/eligible applications, and at the discretion of the Program may assess some ineligible/disqualified applications. Peer review panels will be comprised of reviewers with expertise in the substance and methodology of the proposed project. Individual reviewers will review and rate applications, including assessing cancer-relatedness, examining budget requests, and recommending the level of support necessary to complete the work. Reviewers will be nationally prominent individuals drawn from various sectors in the life sciences including universities, government agencies, and industry. Reviewers will be located outside of Florida and will not be associated with any Florida-based public or private entity working in the life sciences. Before being granted access to proposals, every reviewer will be required to accept the terms of a Confidential Nondisclosure Agreement and will receive instructions on the avoidance of conflict-of-interest. Reviewers will receive honoraria for their participation and are expected to set a high standard for scientific excellence. The number and composition of peer review panels will be determined by the number and scientific range of applications received.

Overall Impact Score:

Similar to the National Institutes of Health, peer reviewers will use a standard rating format: (1) exceptional, (2) outstanding, (3) excellent, (4) very good, (5) good, (6) satisfactory, (7) fair, (8) marginal, and (9) poor. Qualified/eligible applications will be assigned to five independent peer reviewers. Each reviewer will submit their independent ratings and comments online to the Lytmos Group. During the evaluation process, reviewers will not be able to see critiques by the other reviewers assigned to the same application, and will not be able to see applications or critiques assigned to other reviewers. For each application, the high and low overall impact scores will be dropped and the remaining scores will be averaged to determine the overall score. All peer reviews will be complete by the date and time shown in Chapter 9, after which time the reviewers will be able to see only the final evaluation reports for the applications they evaluated.

Peer reviewers will rate all RPG proposals for overall merit based on the following criteria:

- Significance: the importance of the topic being addressed
- Investigators: the qualifications of the key personnel contributing to the project
- Innovation: the potential for the project to shift current paradigms
- Approach: the appropriateness of the planned strategy, methodology, and analyses
- Environment: the suitability of institutional support, equipment, and physical resources
- Research emphasis: the fit between the proposed project and the targeted research topics of translational research and/or health disparities

Other Review Considerations:

In addition, reviewer concerns regarding protection for human and/or animal subjects will be factored into the overall impact score.

Separately from the overall impact score, peer reviewers will rate the relationship of the project to the advancement toward prevention, diagnosis, treatment, and/or cure of cancer and identify any concerns regarding the proposed budget or apparent scientific or budgetary overlap with active or pending support. The cancer-relatedness ratings of all reviewers will be averaged to determine the overall score for cancer-relatedness.

Peer reviewers only have access to the online application and do not receive applications in paper format.

Questions that will be used by the peer reviewers are available on the Program website at www.floridabiomed.com/bc_call.

C. Programmatic Review

The Florida Biomedical Research Advisory Council will consider the Program peer review overall impact and scores regarding cancer-relatedness in a manner that is blind to investigator and institutional identities. In addition, Council members may take into account other programmatic interests, such as the balance of support among grant mechanisms, the availability of funds, and Program goals and preferences, in forming a set of funding recommendations to the State Surgeon General.

Applications with a high overall impact score may be excluded from the list of recommended projects for programmatic reasons including the relevance of the research to cancer. (See Chapter 3 for Cancer-relatedness description.)

D. Evaluation Reports

For all eligible and qualified applications, the evaluation report will be available online to the applicant on or around the date indicated in Table 2. To access the evaluation report, the applicant must log in at www.floridabiomed.com using the same username and log in used for the application process.

12. NOTIFICATION OF FUNDING DECISION

Institutions and Principal Investigators will receive written notification of funding decisions. Applications deemed fundable but not awarded due to funding limitations will remain active for one year from the date of submission. The Program may fund these applications if funding becomes available. Prior to making an award decision, the Department may ask applicants to update and verify their application. This additional information shall in no way alter or extend the one-year criterion.

13. REQUESTS FOR RECONSIDERATION

All funding decisions of the State Surgeon General are final. After receiving the peer review scores and comments, the applicant may request a reconsideration by submitting a written statement outlining the substantive concern(s) and basis for the request. This written statement must be submitted by e-mail to bcprogramsupport@floridabiomed.com no later than five business days after notification of the availability of the evaluation report.

A subcommittee of the Florida Biomedical Research Advisory Council (with the exception of recused members from the applicant's institution) will consider the merits of the complaint, and when warranted by apparent deficiencies in the peer evaluation, may order a reconsideration. The Program will provide a written response to the Principal Investigator containing the outcome of this process.

If the application is granted a reconsideration, the new peer review scores will be used to reposition it in the rank-ordered list of all unfunded applications. Based on the new peer review scores and availability of funds, the application will be classified either as funded, fundable but unfunded, or unfundable. Note that while a reconsideration may lead to funding, it could also result in a lower ranking. Reconsideration results are final.

14. INSTRUCTIONS FOR APPLICATION SUBMISSION

All applications must be prepared and submitted online through the online application system accessible from the Program's website, www.floridabiomed.com. Paper applications will not be accepted. **Application materials not submitted in the specified manner and in the specified format will be disqualified from competition.**

The Program reserves the right to disqualify any and all applications or to waive minor irregularities when doing so would be in the best interest of the State of Florida. A minor irregularity is defined as a variation from the specifications of this Call for Grant Applications that **does not** give any applicant an advantage or benefit not enjoyed by other applicants, does not affect the cost of the application, nor adversely affects the interests of the State. At its option, the Program may correct minor irregularities, but is under no obligation to do so.

Required signature pages such as budgets, and letters of support, must be scanned and included in the appropriate section of the application as indicated in the online instructions. Online applications without these pages will be disqualified.

Other documentation and materials such as biosketches and other support must be converted to electronic format and placed in the appropriate section of the online application. Peer reviewers only have access to the online application and do not receive applications in paper format.

A. Technical Assistance

For technical assistance completing an application, visit the Program website at www.floridabiomed.com and use the Live Help feature or contact the Lytmos Group via e-mail at bcprogramsupport@floridabiomed.com or by phone at (816) 347-9449.

B. Confidentiality of Submitted Materials

Submitted materials are subject to the provisions of Art. I, Sec. 24, Florida Constitution and Chapter 119, *F.S.*, Florida's public records law. These laws grant the right to any person to inspect any public record. There are some documents and information that are exempt from the public records laws. Applicants are strongly discouraged from submitting information considered proprietary unless it is deemed by the applicant to be essential for proper evaluation of the application. However, if proprietary information is included, DO NOT put such information in the General Research Information sections of the application. These sections are subject to publication and wide dissemination if the applicant is awarded a grant. If the application contains information that the applicant believes constitutes trade secrets or proprietary information or is protected by a specific statutory exemption, it should be limited to the Main Application Body. The applicant must CLEARLY identify the information with [brackets] and a footnote that specifies the law that makes the document or information exempt from the public records laws. If a public records request is made involving documents with declarations of confidentiality, the Department will notify the applicant so that he/she may defend the claim in circuit court. The Department of Health will not provide legal representation to assert a confidentiality claim when a public record request is made.

C. Online Application Submission

To complete the online application process:

1. Register as an applicant on <http://www.floridabiomed.com/login.html> and complete the brief project profile. Registration will be acknowledged with an e-mail message containing application instructions and a username and temporary password.
2. Log in at <http://www.floridabiomed.com/login.html> and change the assigned temporary password.
3. Complete the online application form for the appropriate grant mechanism. Field level instructions are available in the appendices of this document. **Certain sections of the application include downloadable Microsoft Word™ or Excel™ forms to simplify preparation and submission. All forms can be found in the online application by clicking on the Application Form Templates link. Do not alter the forms.** Deviations may be grounds for the Program to reject the entire application. Special formatting, scientific notation, pictures, and objects may be included in these documents. However, within the online application form fields such as the Project Title, General Audience Abstract and the Scientific Abstract, use only conventional alphanumeric letters and numbers (i.e., ASCII text) with no drawings, special characters or symbols.

4. When the Word and Excel forms are completed, convert each file to Adobe Acrobat™ (PDF) format. The conversion to PDF will require access to the full Adobe Acrobat™ software product. This is a separately licensed software product from Adobe, not to be confused with the free Adobe Acrobat Reader™ that is used only to view PDF-formatted documents. Specifications and ordering information for either the full Adobe Acrobat™ software package or an online conversion subscription service can be found at Adobe's website, www.adobe.com/products/acrobat/main.html. It is the sole responsibility of the applicant to make sure that this conversion to PDF format is completed successfully. The maximum uploaded file size is shown in Table 1. See Chapter 14 E for tips on how to reduce PDF file sizes.
5. Return to the website to work on the application at any time prior to submission. All required fields and sections must be completed before an application may be submitted. **Once submitted, applications cannot be returned. If an application is accidentally submitted, contact technical support (see Chapter 14 A) for assistance.**

D. General Guidelines

1. An application should be self-contained and written with the care and thoroughness given to manuscripts for publication. Review the application carefully to ensure that information necessary for evaluation is included. The scientific and technical merit of the proposed project is the primary concern for peer evaluation.
2. Read and follow all instructions carefully to avoid delays and misunderstandings. Address each section of the application clearly and precisely.
3. Applications must be legible and in English.
4. The entire text of all documents uploaded into the online application must be single spaced in an easily readable font. Use standard 11-point type for the text, and no less than 10-point type for table figures and legends. Place the Principal Investigator's name (last, first) in the designated space (upper right-hand corner) on each page of every uploaded document. All four margins should be at least one inch (excluding required headers and footers). Do not use photo reduction for scanned items. Use black type for all text, graphs, diagrams, tables, and charts. The application must contain only materials that, when scanned or converted to PDF format, are clear, sharp, and easy to read.
5. **Observe the character and page number limitations or the application may be disqualified without review.** A summary of these limitations is given in Table 1. Character limits include spaces. Applicants are encouraged to confirm compliance with this requirement by printing the full application before submission.
6. **File sizes greater the 3 MB will not be allowed to be uploaded.**

7. Before it can be submitted, the application must contain all of the required sections identified in Table 1. Use Table 1 and the Table of Contents in the Main Application Body to ensure that a complete application is submitted. Uploaded files should be titled by the categories listed in Table 1 and page numbered within the form. **Appended material may not be used to circumvent the page limits for individual sections of the application.**

E. Reducing File Sizes

Below are some tips on reducing file sizes to meet Program application file size limitations.

- a. Compress images in the original Microsoft Word™ file before converting to PDF.

Embedded high-resolution images often lead to very large file sizes when a document is converted to PDF. To reduce file sizes prior to conversion, while in Microsoft Word™:

- Right click on the image and select “Format Picture.”
- Select the “Compress” button.
- Select “Apply to > All pictures in document” and “Change resolution > Web/Screen.” Click “OK.”

Check key images to make sure they are still clear enough for reviewers to interpret as they read your proposal. If not, Choose “Undo Compress Pictures” or selectively reinsert images at the lowest possible clear resolution, and use one or more of the next options for managing the overall size of your file.

- b. Compress a PDF file with Reduce File Size

Reduce the PDF file size with the “Reduce Files Size” feature in Adobe Acrobat™. After completing this step make sure the file is still readable and includes everything intended.

- In Adobe Acrobat™, go to “File > Reduce Files Size.”

Note: This function may be under a different menu option depending on the version of Adobe Acrobat™.

- c. Reduce PDF file size with ‘Save As’ rather than ‘Save’

Saving PDF files adds incremental updates to the original document, meaning any changes that you make to a document are appended to the end of the file without doing a complete rewrite. This is why the Save feature is much faster than a Save As, and also why PDF files saved this way can become very large. The Save As feature will rewrite the entire file and provide you with a smaller file size.

- In Adobe Acrobat™, go to “File > Save As.”

d. Re-create the PDF to reduce PDF file size

A method of reducing PDF file size is to re-create the PDF by removing many unwanted objects, removing tags, and further compressing images. Any tool that supports 'print to PDF' functionality will allow this. Once again, check the clarity of key images to make sure they still add value to the proposal.

e. Remove unwanted objects

For the greatest control of objects that are removed in the conversion process, such as bookmarks, links, annotations, form fields, JavaScript, Named Destinations, and embedded fonts, use optimizing features within the PDF software.

- In Adobe Acrobat, go to "Advanced > PDF Optimizer," choose the objects to remove, and click "OK."

15. DEFINITIONS

Collaborator: An individual involved with the Principal Investigator in the scientific development or execution of the project. These individuals typically devote a specific percent of effort to the project and are identified as key personnel. The collaborator may be employed by, or affiliated with, either the Grantee institution or an institution participating in the project under a consortium or contractual agreement.

Commercialization: The process of developing markets and producing and delivering products or services for sale (whether by the originating party or by others). As used by the Program, commercialization includes both government and non-government markets.

Consortium or Contractual Agreement: An agreement whereby a project is carried out by the Grantee and one or more other institutions that are separate legal entities. In this arrangement, the Grantee contracts for the performance of a substantial and/or a significant portion of the activities to be conducted under the grant. These agreements typically involve a specific percent of effort from the consortium institution's Principal Investigator and a breakdown of costs by category, such as personnel, supplies, and other allowable expenses, including indirect costs.

Consultant: An individual hired to give professional advice or services for a fee, normally not as an employee of the hiring entity. Consultants may also include firms that provide paid professional advice or services.

Cooperative Agreement: A support mechanism that will have substantial scientific and/or programmatic involvement. Substantial programmatic involvement means that after award, scientific or project staff will assist, guide, coordinate, or participate in programmatic activities beyond the normal stewardship responsibility in the administration of grants. Proposed cooperative agreements will be published as policy announcements, program announcements, or requests for applications.

Development: The systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

DOH IRB: DOH IRB refers to the Institutional Review Board operated by the Florida Department of Health Office of Public Health Research. It is independent from any IRB that may have jurisdiction over research performed at the Grantee institution. Per the “Department of Health, Institutional Review Board, Activities Subject to IRB Jurisdiction” policy DOHP 400-1.2, studies funded by the James and Esther King Biomedical Research Program and the Bankhead-Coley Cancer Research Program do NOT require review by the DOH IRB unless the research involves Department of Health clients, personnel, facilities, or data. Note: an application for DOH IRB approval (if applicable) is not required to be submitted until after a project has been awarded. Visit www.flpublichealthethics.net for DOH IRB instructions and forms.

Eligible Institution: Any public university, non-public institution, or established research institute (see specific definitions of each).

Established Research Institute: An established research institute eligible for Program funding is an organization that is any Florida nonprofit or foreign nonprofit covered under Chapter 617, *F.S.*, with a physical location in Florida, whose stated purpose and powers are scientific, biomedical or biotechnological research and/or development and is legally registered with the Florida Department of State, Division of Corporations. This includes federal government and non-profit medical and surgical hospitals including Veteran’s Administration hospitals.

Feasibility: The practical extent to which a project is capable of being successfully performed within the requested time and for the awarded money.

Federal Executive Pay Scale, Executive Level 1: The U.S. Office of Personnel Management establishes executive pay schedules each year normally around the first month of the calendar year. To view the current Executive Level 1 pay scale, visit the website of the U.S. Office of Personnel Management at <http://www.opm.gov/oca/> and search for executive schedule.

Full-time Equivalent (FTE): The definition of a Full-time Equivalent must be in accordance with the institution’s policy, used consistently by the institution regardless of the source of support, and may be different in terms of actual months per year or days per week at the applicant institution.

Full-time Faculty: Full-time Faculty positions are defined as teaching, clinical, and research appointments carrying classroom teaching, laboratory teaching, clinical teaching or service, or research assignments equal to at least 75% of the contracted services for the fiscal year. This includes tenured, tenure-track, and non-tenure track appointments.

Health Disparities: Health disparities apply to individuals who have limited access to resources and privileges that impact their health. This area of research includes a focus on ethnic and racial minority populations as well as low literacy, rural and low-income populations, those geographically isolated, the hearing and visually impaired, individuals with physical or mental disabilities, immigrant and refugee families, and language minority populations. See examples in Chapter 4.

Institutional Base Salary: The annual compensation that the applicant institution pays for an employee's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of duties to the applicant institution. Base salary may not be increased as a result of replacing institutional salary funds with grant funds.

Key Personnel: Key personnel are defined as, and should be limited to, individuals who contribute to the scientific development or execution of the project in a substantive way, whether or not salaries are requested. For RPG applications, the Principal Investigator must be identified as key personnel.

Nonpublic Institutions: For the purposes of the Program, nonpublic institutions operating under Chapter 1005, *F.S.* are eligible. Any branch campuses, centers, or other affiliates of a nonpublic institution are considered one and the same with that institution. Where the number of applications is limited, the institution and its branch campuses, centers, or other affiliates must coordinate submission(s) in order to comply with the limitation.

Overlap, Commitment: Commitment overlap occurs when any project staff has time commitments exceeding 100%. 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 of the partnering entity, no individual on the project may have combined commitments in excess of 100%.

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

Overlap, Scientific: 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.

Principal Investigator: The one individual designated by the applicant organization to direct the project to be supported by the grant. The Principal Investigator is responsible and accountable to applicant organization officials for the proper conduct of the project. The Principal Investigator must supervise the project directly and in person.

Public University: A public (state) university is defined in s. 1001.60, *F.S.*, except as otherwise specifically provided; as the 11 named public, postsecondary institutions and any branch campuses, centers, or other affiliates of the institution. For purposes of the Program, the named university or college and any branch campus, center, or affiliate, unless it can be legally shown otherwise, are considered one and the same. Where the number of applications is limited, the university and any branch campuses, centers, or other affiliates must coordinate submission(s) in order to comply with the limitation.

Translational Research: For purposes of this initiative, translational research i) applies basic discoveries generated during research in the laboratory through pre-clinical research involving human derived tissue, ii) involves clinical trials, including efforts that improve access to or enrollment in clinical trials, or iii) enhances the adoption of best practices in the community.

16. FREQUENTLY ASKED QUESTIONS

1. What is needed before the application deadline? Is there a short letter of intent that is due earlier?

No document or correspondence is required before to the Application and signed cover/certification page deadline. A letter of intent is not required. To obtain the application, you must complete the online registration as described in Chapter 7.

2. Is U.S. citizenship or a green card required before being awarded a grant?

No, United States citizenship or a green card is not a requirement.

3. Can faculty members at the same university but within different departments submit proposals?

Yes, all eligible investigators may submit an application regardless of the department; however, two investigators may not submit the same proposal.

4. What is the budget limit for equipment and supplies?

There is no specific dollar limit for purchasing equipment or supplies. You should identify and justify equipment and supplies in the budget. Excessive equipment and supplies budgets will be scrutinized.

5. Regarding the budget form, what is the difference between percent effort and percent salary?

The percent effort on a project is the amount of an individual's time (some percentage between 1 and 100) that is spent on this project. Percent salary is the percent of the person's salary that is funded by this project. For example, an individual could work 50% of his/her time on a project but only request funds for 40% of his/her salary. Most often these two numbers are the same.

6. Regarding "all financial resources" in Other Support – does this include institutional support funds received in the recruitment package for the Principal Investigator?

Yes, recruitment packages are reportable as "other support."

7. Are consortiums restricted to charging 15% in indirect costs?

If Program funds will be used to pay the consortium, the consortium's indirect costs are limited to 15% of the direct costs requested.

8. When calculating indirect costs in a grant that contains a consortium contract (where the consortium charges also indirect costs included in the total cost of the contract that then shows up as an expenditure as direct costs for the primary institution): are the indirect costs for the primary institution calculated on the total of the consortium contract (direct plus indirect), or only on a portion of the consortium contract. If it is the latter, what amount?

As specified in Chapter 6, "Indirect costs are limited to 15% of the direct costs requested." Subcontracts including consortium contracts are also limited to 15% indirect costs. If your consortium contract includes the maximum permissible indirect cost, you must deduct the full value of the consortium contract from the primary institution's direct costs in calculating its indirect costs in order to avoid double billing.

For example:

Case 1 – Consortium contract includes indirect costs:

Budget items:

<i>Personnel</i>	<i>\$50,000</i>
<i>Supplies</i>	<i>\$20,000</i>
<i>Consortium Contract</i>	<i>\$11,500 (\$10,000 direct + \$1,500 indirect)</i>
<i>Direct Costs</i>	<i>\$81,500</i>

Then the applicant institution's indirect cost is limited to 15% of \$70,000 (\$50,000 + \$20,000) or \$10,500.

Total Direct and Indirect Costs - \$92,000

Case 2 – Consortium contract excludes indirect costs:

Budget items:

<i>Personnel</i>	<i>\$50,000</i>
<i>Supplies</i>	<i>\$20,000</i>
<i>Consortium Contract</i>	<i>\$10,000 (all direct costs to the consortium)</i>
<i>Direct Costs</i>	<i>\$80,000</i>

Then the applicant institution's indirect cost is limited to 15% of \$80,000 (\$50,000 + \$20,000 + \$10,000) or \$12,000.

Total Direct and Indirect Costs - \$92,000

9. Can a Principal Investigator submit the same project to both the Bankhead-Coley Program and the James and Esther King Program?

No, applicants may not submit duplicate applications or applications for projects with significant scientific, commitment, or financial overlap to both the Bankhead-Coley Cancer Research Program and the James and Esther King Biomedical Research Program. The Principal Investigator may submit completely different applications to the two programs. The Principal Investigator must decide which program is a better fit for his/her project.

10. Can a Principal Investigator submit two different projects to the Bankhead-Coley Program and the James and Esther King Program?

The Principal Investigator may submit different applications to Bankhead-Coley Cancer Research Program and the James and Esther King Biomedical Research Program, as long as there is no scientific, commitment, or financial overlap between the projects. The PI can receive funding from both programs for completely different projects.

11. Does the Program solely fund biomedical research or does it also fund projects pertaining to motivational and behavior problems relevant to cancer without any biomedical component?

Refer to Chapter 3 Cancer Relatedness, which addresses behavioral research proposals. Motivational and behavioral research proposals related to cancer are appropriate and encouraged.

12. Normally, in my experience with electronic submissions, the agencies require that the authorized official and the institution register in order to be notified when a proposal is ready for approval (if required by the agency). As the authorized official that signs grants and contracts for the [institution], do I need to register myself and/or [my institution] for these grant programs?

No, only one registration is required for each application; this is normally the Principal Investigator. Certain sections of the application require the Principal Investigator to download and complete forms that must be signed by the Authorizing and/or Administrative Official(s) before being uploaded into the online application. Examples include the cover/certification page and the budget form.

13. I am an investigator planning to submit to the RPG mechanism. I have also been invited to join a Team Science Program team. Can I submit to both mechanisms without hurting the chances for either, assuming the aims are scientifically distinct? In addition, would the same reviewers review both grants?

You can apply as the Principal Investigator for a RPG and as a participant, Project Director or Principal Investigator on a TSP proposal as long as there is no scientific, commitment, or financial overlap between the projects. An individual's effort on all projects and responsibilities at the university cannot exceed 100%. The grants may or may not be reviewed by the same reviewers.

14. Can a Principal Investigator submit two separate applications for the Research Project Grant mechanism?

Yes, as long as there is no scientific, commitment, or financial overlap between the projects. An individual's effort on all projects and responsibilities at the university cannot exceed 100%.

15. Are IRB or IACUC approvals needed before the application deadline, or can I submit them later?

The IRB approval is not required before the application deadline. You may submit an application without the necessary IRB or IACUC approvals. Immediately after award notification, grantees must submit all necessary applications to regulatory authorities including, but not limited to, the IACUC, local or institutional IRB, and if necessary the DOH IRB. Project work may not begin until all approvals are obtained. To determine if you will need to obtain the DOH IRB approval, please review the definition of DOH IRB in Chapter 15, Definitions.

16. What are the numbers of awards that will be made? How many of each type of award were given in past years?

There is no predetermined number of grants. The quality of the proposals, cancer-relatedness, and the amount of available funding are considerations used in making award decisions.

Closed

APPENDIX A – GENERAL RESEARCH INFORMATION INSTRUCTIONS

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.
 - 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 grant mechanisms for which you are applying (RPG).
4. **Previous Bankhead-Coley Applicant:** If you have previously been an applicant to the Bankhead-Coley 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 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 pursuit of cures for cancer; however, many types of research may qualify. Please select the research categories and research emphasis that best fit the project work.

Principal Investigator Information

1. **Name of Principal Investigator:** 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 Principal Investigator 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:** Select the eligible applicant institution that will be legally and financially responsible for this grant. If the institution is not included in the drop down list, select "other" and enter the institution name.
6. **Organization Federal ID Number:** Enter the nine-digit federal identification number assigned to the applicant organization by the Internal Revenue Service.
7. **Applicant Organization Type:** Select the one description from the drop down list that best describes the applicant organization.

- 8. Financial Conflict of Interest:** Does your institution have a Financial Conflict of Interest policy and procedure that is consistent with NIH requirements? Check either “Yes” or “No.”
- 9. 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.
- 10. Courier Address:** Provide complete and exact information, including room number, building identifier and street address, necessary for courier delivery (Ex: Fed Ex). 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.
- 11. Telephone Number:** Provide a daytime telephone number (including extension, if applicable) for the Principal Investigator.
- 12. Fax Number:** Provide a fax number (including area code) for the Principal Investigator.
- 13. E-mail Address:** Enter the appropriate electronic mail address for the Principal Investigator.
- 14. U.S. Citizenship:** If the Principal Investigator is 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.
- 15. Full-time Faculty or Equivalent or a Final Year Postdoc Fellow at Florida Institution:** If the Principal Investigator is a full-time faculty member (or full-time equivalent) or a postdoctoral fellow in his/her final year by the application due date (indicated in Table 2 of Chapter 9) at an eligible institution check “Yes,” otherwise check “No.” (See full-time faculty, full-time equivalent, and eligible institution definitions in Chapter 15.)
- 16. First Full-time Faculty Appointment:** This information is being collected from all applicants for purposes of statistical analysis and will not be used in award determinations.
 - a. Date:** Specify the date of your first full-time appointment as a university faculty member or an equivalent position at any 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.)
 - 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.)

17. 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 (equally responsible independent investigator) on a non-mentored, nationally peer-reviewed grant, including career development grants, with a budget of \$100,000 or more per year in direct costs. Examples of national grants include those from the National Institutes of Health, the National Science Foundation, and components of the Department of Defense, as well as national programs offered by the American Cancer Society, the American Heart Association, and the American Lung Association. This information is being collected from all applicants for purposes of statistical analysis and will not be used in award determinations for this mechanism.

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 the application, 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 in the courier address. Enter the telephone number (and extension, if applicable), fax number, and E-mail address.

Administrative Official for Applicant Organization

Whether or not this is the same person as the signing official, 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 in the courier address. 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 cancer. Describe concisely 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 succinct and accurate description of the proposed work 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 make this summary for a general audience as opposed to the scientific community.** 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. Do NOT include information in this section considered proprietary/confidential. *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. Do NOT include information in this section considered proprietary/confidential unless you think it is essential for proper evaluation of the application. 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. *Entry is limited to 2000 characters.*

Section D – Cancer Relatedness

Applicants must demonstrate the relatedness of the proposed research to cancer. Also see Chapter 3. *Entry is limited to 3000 characters.*

Section E – Key Personnel

Key personnel are those persons whose expertise in the subject area(s) of the project is central to convincing the peer reviewers that the project is feasible. This list of key personnel must at least include the Principal Investigator and may include just 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 F – Disparate Groups

If the proposed research does not help reduce the impact of cancer on disparate groups, check “No;” otherwise check “Yes” and describe the disparate group(s) and how the research will help reduce the impact of cancer on that group(s). Disparate groups include the underserved, minority, elderly, and populations with low income and education levels. *Entry is limited to 1200 characters.*

Closed

APPENDIX B – MAIN APPLICATION BODY FORM

Principal Investigator: _____



**BANKHEAD-COLEY CANCER RESEARCH PROGRAM
RESEARCH PROJECT GRANT APPLICATION
SECTION G. TABLE OF CONTENTS**



Section	Page Number
Section G. Table of Contents	6
Section H. Resources	
Section I. Research Plan	
Section 11. Specific Aims	
Section 12. Background & Significance	
Section 13. Preliminary Studies	
Section 14. Research Design & Methods	
Section J. Literature Cited	
Section K. Human Subjects (if applicable)	
Section L. Vertebrate Animals (if applicable)	
Section M. Consortium/Contractual Agreements (if applicable)	
Section N. Consultants (if applicable)	
Section O. Survey Instruments (optional)	

NOTES

- ▼ Refer to the Call for Grant Applications for page limitations and instructions.
- ▼ Number pages consecutively at the bottom throughout the application. Do not use suffixes such as 3a, 3b.
- ▼ The name of the Principal Investigator must be on the top right-hand corner of each page.

Closed

Page _____

Principal Investigator: _____

SECTION H. RESOURCES

SECTION I. RESEARCH PLAN

SECTION J. LITERATURE CITED

SECTION K. HUMAN SUBJECTS

SECTION L. VERTEBRATE ANIMALS

SECTION M. CONSORTIUM/CONTRACTUAL AGREEMENTS

SECTION N. CONSULTANTS

SECTION O. SURVEY INSTRUMENTS

EXAMPLE
Closed

Page _____

APPENDIX C – MAIN APPLICATION BODY INSTRUCTIONS

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

Click on the link called *Application Form Templates* to download the main application form. When you have completed the form, convert the document into a single PDF file and upload it into the online application by clicking on the *Core Application Documents* link and clicking the upload button for Main Application.

Section G – Table of Contents

Provide the page numbers for each application section listed in 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. *One page limit.*

Section H – 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. *Limit is two pages.*

Section I – Research Plan

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

Organize this section to answer these 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 Plan as indicated in Tables 1. The Program recommends the format and page distribution as shown below. All tables, graphs, figures, diagrams, charts, scanned photographs of material must be included within the page limit. *Limit is 20 pages. Shorter is acceptable.*

1. Specific Aims:

List the broad, long-term objectives and what the specific research proposed in this application is intended to accomplish. State the hypotheses to be tested. *One to two pages are recommended.*

2. Background and Significance:

Briefly sketch the background leading to the present research proposal, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research by relating the specific aims to the broad, long-term objectives. *Two to three pages are recommended.*

3. Preliminary Studies:

Provide an account of the Principal Investigator's preliminary studies pertinent to the application that help to establish the experience and competence of the investigator to pursue the proposed project. The complete references to appropriate publications and manuscripts submitted or accepted for publication may be listed. *Four to six pages are recommended.*

4. Research Design and Methods:

Describe the research design and the procedures that will be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions that will be exercised.

Although no specific number of pages is recommended for the Research Design and Methods section, be succinct as possible. There is no minimum page requirement for items 1 – 4.

Section J – Literature Cited

List key references only. This section may include, but may not replace, the list of publications required in the Preliminary Studies (of the Research Plan section, above). 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. It is important to be concise and to select only those literature references pertinent to the proposed research. *Limit is six pages.*

Section K – 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, address the following seven 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 seven 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 outlined in the Research/Project Plan section. Describe the characteristics of the subject population, including their anticipated number, age range, gender, race, ethnicity, 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.
7. **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 L – 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 maintenance and 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 M – Consortium/Contractual Agreements

List all consortium or contractual arrangements. If this information is not applicable to the grant proposal, indicate by placing “N/A” in this section. *Limit is one page.*

Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the consortium investigator, should be the Grantee.

If awarded, the consortium investigator and the authorized official at the consortium institution(s) may be required to provide a signed statement or confirming letters that the

appropriate programmatic and administrative personnel of each organization involved in the application are aware of Program grant policy and are prepared to establish the necessary inter-institutional agreements consistent with that policy. The Grantee institution has the specific responsibility for ensuring that all required assurances are obtained from the consortium institution. If awarded, the Program may request detailed consortium and/or contractual budgets.

Section N – 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, indicate by writing “N/A” in this section. *Limit is three pages.*

Section O – Survey Instruments (Optional)

Include scanned copies of any survey instruments that will be used in this section of the form. *No page limit; be concise.*

Closed

APPENDIX D – BUDGET FORM



**Bankhead-Coley Cancer Research Program
Application Budget Form for Research Project Grants
Budget Summary**

PI Name: _____
 Institution: _____

	AMOUNT REQUESTED FOR INITIAL YEAR	TOTAL PROJECT BUDGET
Personnel		
Consultant Costs		
Conferences/Concessional Costs		
Equipment		
Supplies		
Travel		
Patient Care Costs	Inpatient	
	Outpatient	
Other Expenses:		
TOTAL DIRECT COSTS		
Indirect Costs (limited to 15% of direct costs)		
TOTAL AMOUNT REQUESTED		
Project Income		

DOI-1109

YEAR ONE BUDGET NARRATIVE JUSTIFICATION

PI Name: _____

Justify each entry 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

Consultant Costs

Consortium/Contractual Costs

Equipment

Supplies

Travel

Patient Care Costs

Other Expenses

Project Income

Closed

DOH 10/09

APPENDIX E – BUDGET FORM INSTRUCTIONS

Click on the online link called *Application Form Templates* 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. Specific instructions for completing the form are included below. Once completed, convert the signed document into a single PDF file and upload it into the online application by clicking on the *Core Application Documents* link and then clicking the upload button for Budget.

An example of the Budget Form is included in [Appendix D](#).

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

When preparing your proposed budget, consult the guidelines contained in Chapter 6.

Budget Summary

The Budget Summary breaks down the total amount of project costs by budget category. **Each entry must be directly related to the project.**

Amount Requested for Initial Year: Enter the amount of grant funds being requested for the initial 12-month funding period for each budget category.

Total Project Budget: Enter the total amount of funds needed to complete the project over the maximum allowable project time (five years for RPGs).

Indirect Costs: Indirect costs may be requested and are limited to 15% of total direct costs. The sum of direct and indirect costs must NOT exceed the maximum allowable amount outlined in the Call (\$1,500,000 for RPGs).

Project Income: If project income is anticipated, indicate the amount.

Currency: All amounts must be in U.S. dollars. List only the costs requested that are necessary to carry out the Research Plan.

Year One Budget

The first page of the Year One Budget breaks down the total amount of project costs for year one 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) of the Budget Form first.

Personnel: Describe personnel information as indicated.

Name: Starting with the Principal Investigator, list the names of all applicant organization employees who will be involved in the project during the first year of the grant, regardless of whether salary is requested. Include all collaborating investigators, individuals in training, and support staff. Do not include consultants in this description. Use "TBA" (to be announced) for any necessary positions, other than key personnel, for which an appointment has not yet been made. In cases where an individual's appointment is divided

into academic and summer segments, please explain and provide calculations in the narrative section.

Role on Project: Identify the role of each individual.

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 individual or position. The maximum annual institutional base salary used for calculations for project salary for any personnel named on the application for this grant must not exceed the Executive Level 1 annual salary rate of the Federal Executive Pay Scale that is in effect as of February 12, 2010. See Chapter 15, Definitions, for more information about the Federal Executive Pay Scale. This salary cap is exclusive of fringe benefits, facilities and administrative (F&A) expenses, and excludes any income that an individual may be permitted to earn outside of the duties to the applicant organization. This provision is consistent with NIH salary limitations on grants, cooperative agreements, and contracts.

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

Fringe Benefits: State the total fringe benefits for each position.

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

In the next section of this page, provide the budget amount requested for each category listed. If project income is anticipated, indicate the amount. The budget amounts should match the corresponding budget narrative/justification section.

Year One Budget Narrative/Justification

Provide a narrative justification for each budget category for year one (the first 12 months) costs by describing why it is needed and 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 in the Year One Budget 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, business location where services will be performed, 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, business location (city and state), and provide justification. If awarded, each participating consortium/contractual organization may be required to submit a separate detailed budget for the appropriate period at a later date.

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. Consortium indirect costs are limited to 15%. The institution and the consortium/contractor cannot both charge indirect cost on the consortium/contractor direct costs; one or the other may charge indirect costs. Funding for any out-of-state personnel or consulting expenses cannot exceed 10% of the total requested direct costs. This does not include lab services, supplies, or equipment.

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 (\$1,800 per year, per traveler) may be proposed to attend conferences and similar meetings in the scientific field(s) of endeavor. RPGs are limited to two travelers (trips) 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 the hospital or clinic 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.

Closed

APPENDIX F – OTHER DOCUMENTS INSTRUCTIONS

Section Q – Biographical Sketches

This section must contain the biographical sketches of all individuals identified as **key personnel** (including the Principal Investigator) in the application. Each biographical sketch must use the National Institutes of Health biographical sketch format at <http://grants1.nih.gov/grants/funding/phs398/phs398.html#forms>. Convert all biographical sketches into a single PDF file and upload it into the online application by clicking on the *Core Application Documents* link and then clicking the upload button for Biographical Sketches. *Limit is four pages per person.*

Section R – Research Milestone Chart

All applications require a Research Milestone Chart that provides a high-level overview of the anticipated project schedule with references to the major aims, tasks, major training, and experiments planned for the project. An example Research Milestone Chart form located in [Appendix G](#). An example completed form is also included in [Appendix G](#).

Click on the online link called *Application Form Templates* to download the Research Milestone Chart Form. Instructions are included in the Milestone Chart form. An example of a completed Milestone Chart is also available for download. Once completed, convert the Microsoft Excel™ document into a single PDF file and upload it into the online application by clicking on the *Core Application Documents* link and then clicking the upload button for Research Milestone Chart. *Limit is two pages.*

Section S – Other Support

Click on the online link called *Application Form Templates* to download the required Other Support Form. Include all additional current and pending support for the Principal Investigator. Once completed, convert the document into a single PDF file and upload it into the online application by clicking on the *Core Application Documents* link and then clicking the upload button for Other Support. *No page limit.*

See [Appendix H](#) to see an example of the Other Support Form.

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%, 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. See Chapter 15 for definitions of Financial Overlap, Commitment Overlap, and Scientific Overlap.

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 Principal Investigator's percent effort on non-research activities such as teaching, clinical work, mentoring, or administrative responsibilities at the institution.

Section A:

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. A sample completed Section A is included in the body of the form.

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

Role in the Bankhead-Coley Project: Indicate the role of this person on the RPG.

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.

Your Role on this Project: Identify the role of this person for the other support project being reported.

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 this 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.

Section T – Miscellaneous Letters of Support (Optional)

Upload scanned copies of the letters in a single PDF file in the online application where indicated. Convert all signed letter into a single PDF file and upload it into the online application by clicking on the *Core Application Documents* link and then clicking the upload button for Letters of Support. *No page Limit.*

Section U – Cover/Certification – Signed Page 1

Click on the *Print Forms* link on the upper right side of this screen in the online application 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 upload it into the online application by clicking on the *Core Application Documents* link and then clicking the upload button for Cover/Certification Page.

Section V – 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.
6. **Department of Health Clients, Employees or Facilities:** Does your project involve Florida Department of Health clients, employees or facilities? Check either “Yes” or “No.”

IRB approvals are not required at the time of application; however, if available please upload the approvals. Convert all IRB approval documents into a single PDF file and upload it into the online application by clicking on the *IRB Approval* upload button. 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 all IACUC approval documents into a single PDF file and upload it into the online application by clicking on the *IACUC Approval* button. The IACUC approval(s) must have the same project title as the application project title and must be signed by the IACUC chairperson.

Example of a Research Milestone Chart with data



 Bankhead-Coley Cancer Research Program
 Research Milestone Chart - Example

Project Title	Start Date	End Date																				
Project Title	1/1/2010	12/31/2010																				
<p>Form Purpose: The purpose of this form is to show a realistic progression of research milestones for a program supported by the Bankhead-Coley Cancer Research Program. It is intended to be used as a guide for the development of a research proposal. The milestones should be specific to the aims of the program. The milestones should be realistic and achievable. The milestones should be specific to the aims of the program. The milestones should be realistic and achievable. The milestones should be specific to the aims of the program. The milestones should be realistic and achievable.</p>																						
A	B	C	Year 1												Year 2				Year 3			
Research Objective	Estimated Duration (months)	Percent Complete	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4				
1. Develop a pre-clinical model of... 2. Assess the efficacy of... 3. Assess the efficacy of... 4. Assess the efficacy of... 5. Assess the efficacy of... 6. Assess the efficacy of... 7. Assess the efficacy of... 8. Assess the efficacy of... 9. Assess the efficacy of... 10. Assess the efficacy of...	6 months 6 months 6 months 6 months 6 months 6 months 6 months 6 months 6 months 6 months	100% 100% 100% 100% 100% 100% 100% 100% 100% 100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%				
Add additional rows as needed.																						
<p>Research Objectives:</p> <ul style="list-style-type: none"> 1. Develop a pre-clinical model of... 2. Assess the efficacy of... 3. Assess the efficacy of... 4. Assess the efficacy of... 5. Assess the efficacy of... 6. Assess the efficacy of... 7. Assess the efficacy of... 8. Assess the efficacy of... 9. Assess the efficacy of... 10. Assess the efficacy of... 																						
<p>Research Objectives:</p> <ul style="list-style-type: none"> 1. Develop a pre-clinical model of... 2. Assess the efficacy of... 3. Assess the efficacy of... 4. Assess the efficacy of... 5. Assess the efficacy of... 6. Assess the efficacy of... 7. Assess the efficacy of... 8. Assess the efficacy of... 9. Assess the efficacy of... 10. Assess the efficacy of... 																						
<p>Research Objectives:</p> <ul style="list-style-type: none"> 1. Develop a pre-clinical model of... 2. Assess the efficacy of... 3. Assess the efficacy of... 4. Assess the efficacy of... 5. Assess the efficacy of... 6. Assess the efficacy of... 7. Assess the efficacy of... 8. Assess the efficacy of... 9. Assess the efficacy of... 10. Assess the efficacy of... 																						

APPENDIX H – OTHER SUPPORT FORM

Bankhead-Coley Cancer Research Program		Other Support Update	
DOH Grant ID: <input type="text"/>		Date: <input type="text"/>	
Principal Investigator(s): <input type="text"/>			
Project Title: <input type="text"/>			
Institution: <input type="text"/>			
PI Percent Effort on Non-Research Activities (teaching, mentoring, etc.) at the Institution: <input type="text"/>			
<small>Provide the following information on all active or pending sources of support for research activities for the Principal Investigator, and Mentor/Sponsor (if applicable for grant), using the format indicated here. Repeat Section A for each person and other support. In the overlap status section, address potential financial overlap, scientific overlap and/or effort overlap. Add continuation pages as needed.</small>			
SAMPLE			
Section A			
Name Of J&E King Key Personnel:	Doe, Jane	Role in the J&E King Project:	PI
Grant Number:	RO1 HL 00213-10	Dates of Grant:	1/1/2007 – 6/30/2009
Source:	NIH/NHLBI	Total Annual Costs:	\$185,000
Grant Status:	Active	Total Annual Direct Costs:	\$150,000
Your Role on this Project:	PI	Percent Effort:	30%
This Project PI:	Doe, Jane	Percent Salary:	30%
Title of Project:	Chloride and Sodium Transport in Airway Epithelial Cells		
Major Project Goals:	The major goals of this project are to define the biochemistry of chloride and sodium transports in airway epithelial cells and close the genes involved in transport.		
Overlap Status:	There is scientific overlap between Aims 2 of James and Esther King application under consideration and aim 3 of this NIH grant.		
ENTRY FORM			
Section A			
Name Of J&E King Key Personnel:	<input type="text"/>	Role in The James & Esther King Project:	<input type="text"/>
Grant Number:	<input type="text"/>	Dates of Grant:	<input type="text"/>
Source:	<input type="text"/>	Total Annual Costs:	<input type="text"/>
Grant Status:	<input type="text"/>	Total Annual Direct Costs:	<input type="text"/>
Your Role on this Project:	<input type="text"/>	Percent Effort:	<input type="text"/>
This Project PI:	<input type="text"/>	Percent Salary:	<input type="text"/>
Title of Project:	<input type="text"/>		
Major Project Goals:	<input type="text"/>		
Overlap Status:	<input type="text"/>		
Section A			
Name Of J&E King Key Personnel:	<input type="text"/>	Role in The James & Esther King Project:	<input type="text"/>
Grant Number:	<input type="text"/>	Dates of Grant:	<input type="text"/>
Source:	<input type="text"/>	Total Annual Costs:	<input type="text"/>
Grant Status:	<input type="text"/>	Total Annual Direct Costs:	<input type="text"/>

J&E OSI 10/09

1