



WRCE Research Project Proposals
to be incorporated into the Research Program
for the RCE Competitive Renewal Application

INSTRUCTIONS TO APPLICANTS

Release Date: March 13, 2008

Application Receipt Dates(s): April 1, 2008 at 3pm CST

Peer Review Date(s): April 30, 2008

Anticipated Start Date: March 1, 2009

The Western Regional Center for Excellence for Biodefense and Emerging Infectious Diseases Research (WRCE) invites investigators in DHHS Region VI (which includes Texas, New Mexico, Louisiana, Oklahoma, and Arkansas) to submit proposals for *Research Project Awards*. Applications will be considered for inclusion in the RCE competitive renewal application that will be submitted to NIH before June 3, 2008.

Applications received after the deadline of 3pm CST on Tuesday, April 1, 2008 will not be accepted.

What's new from previous WRCE grant submissions?

1. PHS398 forms were updated on 11/07. Do not use old proposals and simply change the footers. You must use the WRCE-specific forms provided. If you do not have them, email us – kischuen@utmb.edu or rcobbs@utmb.edu. There are details on the forms for your convenience and as a reminder of specific information that is required.
2. A cover page, in addition to the Face Page, must be included.
3. Signatures are not required for the April 1, 2008 deadline. However, if your project is selected, a signed Face Page will be required before the application is submitted to NIH. These will be required before May 20, 2008. For those of you at UTMB, no routing forms are required.
4. "Third tier" subcontracts are not allowed by NIH. In other words, non-UTMB institutions cannot subcontract to other institutions. All subcontracts must flow through UTMB as the lead institution.
5. The old PHS398 sections A-D have been changed and are akin to the SF424 sections. There is an **8-page limit** for Sections 1-4, including charts, graphs, figures, and timetable/ milestone information.
6. You must include a resource sharing plan.
7. Please answer three questions regarding your core needs (Section 17).

Please **give these instructions to your grant support staff** to insure that all sections are included.

You must use the forms provided. Incomplete or wrong forms will be returned. Refer to PHS398 instructions when filling out the forms. The relevant sections that must be submitted include:

- Cover Page
- Form Page 1 (Face Page). The award date is for five years (3/1/2009-2/28/2014) or less. Signatures are not required.
- Form Page 2 (Summary, relevance, performance sites, key personnel, significant contributors, embryonic stem cells). Multiple PIs are not allowed on WRCE projects, but co-investigators are allowed.
- Form Page 3 (Table of Contents).
- Form Pages 4 and 5 (Detailed budget and budget justification). **DO NOT USE THE MODULAR BUDGET.** Applications for a WRCE Research Projects are not limited in dollars, but should reflect the actual needs of the proposed project. Include budget pages of collaborators after the Research Plan, if applicable. Actual salaries must be listed. Please verify these with your home institution. Do not use the NIH salary cap. In the justification, include a statement regarding the fringe rates. Do not use third tier subcontracts.
- Biographical Sketch Format Page for all key personnel that hold an advanced degree (including collaborators, if applicable).
- Resources Format Page. Include Resources pages for collaborators, if applicable.
- Checklist Form Page. F&A rates must be current. It would be helpful to include your institutional statement regarding your F&A (indirect cost) rate.
- Research Plan: Up to **8 pages for sections 1-4**, including tables, graphs, figures, charts, and milestones. The following sections must be included, even if they are not applicable to your submission:
 - 1. Specific Aims
 - 2. Background and Significance
 - 3. Preliminary Studies/ Progress Report
 - 4. Research Design and Methods.
 - 4a. Timetable and milestones for product development
 - 5. Bibliography & References Cited
 - 6. Protection of Human Subjects. **Any project that includes any human subjects work must also include a concept sheet using a standard format; contact Rosina Cobbs for these forms.** Human Subjects or Vertebrate Animal questions should be directed to Rosina Cobbs (rcobbs@utmb.edu, 409-747-0745).
 - 7. Inclusion of Women and Minorities
 - 8. Targeted/Planned Enrollment Table
 - 9. Inclusion of Children
 - 10. Vertebrate Animals
 - 11. Select Agent Research
 - 12. Multiple PI Plan (*does not apply for RCE grants*)
 - 13. Consortium/ Contractual Arrangements. The role of each participant must be clearly indicated in Section 4.
 - 14. Letters of Support
 - 15. Resource Sharing Plan(s)
 - 16. BSL3/4 Access
 - 16. Potential Core Needs (3 questions)

- Face Page (Form Page 1) of consortium/collaborators, if applicable.
- Budget Pages (Form Pages 4&5) of consortium/collaborators, if applicable.
- Checklist Form Page of consortium/collaborators, if applicable.
- Other Support Format Page for all key personnel. Other Support includes all financial resources, whether federal, non-federal, commercial, or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards.

Subcontracts with institutions outside the WRCE region are discouraged, unless the subcontract is absolutely required for the project and is highly justified.

- o You must use the electronic PHS398 forms tailored for the WRCE, available by emailing kischuen@utmb.edu. These forms have specific formatting, correct headers and footers, and section breaks, which should not be altered in any way.
- o Please note that the WRCE PI, David H. Walker, is the PI of the WRCE parent grant and his name must appear on the header (not the name of the PI of the application), as has been completed for you on the tailored forms. The name of the PI of the application goes on the cover page and face page only.
- o Use Arial or Helvetica 11 point font or larger.
- o Submit **18 copies**. Applicants are responsible for making all color copies.
- o Submit **one electronic file** (either DOC or RTF; PDFs and other formats will not be accepted) by either emailing to kischuen@utmb.edu or submitting on CD with hard copies. Files over 5MB should not be emailed and must be submitted on CD.
- o Appendices will not be accepted.

Example of timetable and milestone outline

The applicant must submit a detailed milestone chart (hard copy and electronic) that includes specific aims. An example is given below. Gantt charts, Excel spreadsheets, or Word tables are acceptable. Specific aims are considered too broad to be individual milestones. Product development activities should be included, as applicable.

Task #	Task Name	Start Date	End Date	Dependencies
1	Specific Aim #1: To develop an attenuated strain of virus X for vaccine purposes.	3/1/2008	2/28/2009	
2	Milestone #1: Complete genome sequencing of virus X.	3/1/2008	6/1/2008	
3	Milestone #2: Construction of virus clones with selected knockout mutations.	6/1/2008	9/1/2008	2

Task Name is the description of event to occur (e.g., clone gene into vector, sequence gene, analyze expression, purify protein, vaccinate animal, bleed day, etc.)

4	Milestone #3: Viability testing of knockout mutants in cell culture.	9/1/2008	11/1/2008	2,3
5	Milestone #4: <i>In vivo</i> challenge with viable mutants.	11/1/2008	1/1/2009	2,3,4
6	Milestone #5: Comprehensive analysis of pathogenesis and immune response to each mutant.	1/1/2009	2/28/2009	2,3,4,5
7	Milestone #6: Identification of corporate partners interested in vaccine for virus X.	8/1/08	2/28/09	2,3,4,(5)

Dependencies:
Which tasks must precede the current task

***Mailing address for WRCE application
(hard copies)***

Use this label or a facsimile

Applications should be sent to the following address:

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 = **Dr. Kimberly Schuenke** =
 = **Center for Biodefense and** =
 = **Emerging Infectious Diseases** =
 = **Dept. of Pathology** =
 = **The University of Texas Medical Branch** =
 = **301 University Blvd., Route 0609** =
 = **G.170 Keiller Building** =
 = **Galveston, TX 77555-0609** =
 = - - - - - =

The telephone number is 409-747-2464. C.O.D. applications will not be accepted.

Email address for WRCE application (electronic version)

Electronic applications smaller than 5MB can be emailed to Kimberly Schuenke at kischuen@utmb.edu. Applications larger than 5MB should be submitted on a CD with the hard copies.

Incomplete applications, including failure to submit the required number of copies or failure to submit one electronic file (not PDF), will not be reviewed and will be returned to the applicants. There will be no exceptions for late applications, so early submissions are encouraged.

Review and Approval

All proposals will be reviewed by the WRCE Steering Committee (formerly the Scientific Advisory Board), composed of established scientists with expertise in infectious disease research and/or product development. The Principal Investigator, Dr. David Walker, retains the ultimate responsibility and primary role for planning, directing, and executing the activities within the WRCE with substantial NIH scientific and/or programmatic involvement. Applications are judged on:

1. The appropriateness of the proposal for one of four research themes.
2. The potential impact of research on vaccine, diagnostic, and therapeutic development for Category A, B, and C agents and emerging infectious disease agents.
3. The scientific merit of the proposal, including a sound rationale and innovative research approach.
4. The environment in which the research will be conducted, including whether the applicant has the agent and the facilities available to conduct the work (as applicable)
5. Training and experience of the investigator.
6. Collaboration with other institutions.

PIs of approved applications will then be contacted by theme “leaders”, who will coordinate submission of the research plan into the overall application that will be submitted through UTMB to NIAID before June 3, 2008. Decisions on funding will be made by NIAID around January 2009.

Institutional approval for animal studies (IACUC) and approval for human studies (IRB) will be required before any work with animals or human subjects can begin in accordance with NIH guidelines.

Institutions outside of UTMB will be required to comply with the WRCE Intellectual Property Management Plan and Amendment and all applicable federal regulations before an award is made.

For domestic work with Select Agents, documentation of Registration status must be provided before funds are awarded.

Human Subjects and animal use questions should be directed to Rosina Cobbs (rcobbs@utmb.edu; 409-747-0745) or Douglas Watts (dowatts@utmb.edu; 409-772-2504).

Budget questions should be directed to Teri Kingsley (tkingsle@utmb.edu; 409-772-2862).

The following contact information is for questions regarding the application process and whether the concept you will be proposing fits within the scope of allowable activities:

Kimberly Schuenke, Ph.D.
WRCE Program Administrator
The University of Texas Medical Branch
301 University Blvd.
G.170 Keiller Bldg.
Galveston, TX 77555-0609
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All unfunded applications will be destroyed and/or returned to the applicants, including electronic copies.

Monitoring

All WRCE projects are carefully monitored throughout the year by the WRCE leadership and may include site visits, written progress reports, and presentations at regional and national RCE meetings. Periodic discussions with the WRCE leadership may also be required.