壹、創新研究計畫申請書撰寫說明

Guidelines for Innovative Research Grant Application

I. GENERAL INFORMATION

1. In preparing the application, **use English only** and avoid jargon. For terms not universally known, spell out the term the first time it is used followed by the appropriate abbreviation in parentheses; the abbreviation may be used thereafter.

2. Type the application single spaced, and stay within the margin limitations indicated on the form pages. The type must be clear, readily legible and font size is **12 point** (approximately 1/8 inch in height for capital letters). There must be no more than six lines of text within a vertical inch. **Do not reduce font size or line spacing to circumvent the page limitations**.

3. Use black type that can be copied. Provide clear figures, graphs, diagrams, charts, and tables, and include appropriate legends. All photographs or other illustrative materials must be presented in the body of the application in a clear and readable manner, the font size should not be smaller than 9 point, that can be photocopied. When it is essential to illustrate materials in their original forms (color or size), 5 hard copies of the original materials, which have been shown in the Research Plan Section, can be sent to the National Health Research Institutes (NHRI) as supporting documents.

4. If there is any sponsor, consultant or cooperation laboratory listed in this application, please provide the collaborative agreement or supporting letters.

5. **Stay within the page limitations, or the application will be returned without review.** A summary of the page limitations is given as follows:

FORM SECTION	PAGE LIMIT
1. Face Page	1
2. Personnel	
a. Key Professional Personnel	as needed
b. Supporting Staff	as needed

FORM SECTION	PAGE LIMIT
3. Abstracts	
a. in Chinese	1
b. in English	1
4. Progress Report	3
Response to Previous Review Comments	5
5. Research Plan	
A to E (Specific Aims to Anticipated Results)	13
F to K (Human Subjects to Reference)	as needed
6. Institutional Environment and Resources	1
7. Detailed Budget Requested for Initial Year	
a. Initial Year Budget for Personnel	as needed
b. Initial Year Budget for Other Categories	as needed
8. Equipment and Budget Requested for Entire Proposed Project Period	
a. Equipment Requested for Entire Proposed Project Period	as needed
b. Budget Requested for Entire Proposed Project Period	as needed
9. Other Support	as needed
10. Biographical Sketches	4 each
11. Certificate of Agreement for the Application	as needed
12. Checklist	1
13. Appendix (publications related：**no more than 10 materials)**	

7. Use continuation pages if necessary.

8. Edit page number consecutively at the right bottom for each section respectively.

II. SPECIFIC INSTRUCTIONS - FORMS

1. FORM SECTION 1 - Face Page

   A. Complete all items on the face page of the application. This is page 1 of the application.

   B. Title of Application: Choose a title that is descriptive and specific rather than general. Do not exceed 100 typewriter spaces, including the spaces between words and punctuation. ***Be aware of that this application fits in the research fields listed in the Chinese manual on page I-2~I-5.***

   C. Type of Application: Choose one type for this application; if this

application is being submitted to the NHRI for the first time, check "New"; if this application is revised to replace an unfunded version of a new application submitted previously to NHRI, check "Revision or Amendment"; if this application is to extend a current grant beyond its funded project period—including extending a current CDG to form an IRG, check "Renewal"; if this application is revised to replace an unfunded version of a renewal application submitted previously to NHRI, check "Revised Renewal".

A New application must have a different title from any other NHRI project with the same Principal Investigator. If the application is an Amendment, Renewal, or Revised Renewal, please also write down the title of the prior application and the year of its submission. If the specific aims of the project have changed significantly, use a new title.

D. Entire Proposed Project Period: Request 3-5 years of support for the entire proposed project period.

E. Budget requested for each year can not exceed NT$3,000,000.

F. Human Subjects: If the activities involving human subjects are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution, check "Yes". An official document of approval along with its original application contents*, including **Data and Safety Monitoring Plan**, for the proposed activities from the Institutional Review Board (IRB; e.g., The Committee on Clinical Research, etc.) should be submitted at the same time of this application. If the project is conducted in multiple hospitals or organizations, the IRB approved document is required from each one. If the certification of IRB is unavoidably delayed, the IRB pending sheet and IRB application contents should be submitted with the grant application. The IRB approved document should be presented by **June 25, 2014**. If the certification, the pending sheet, or the application contents of IRB could not be submitted before deadlines, it might affect the outcome of the review.

*Note: The Biographical Sketch of investigator is part of the proposal, thus the Biographical Sketch in the original application contents submitted to the Institutional Review Board should not be attached.

G. Gene Recombination: If the activities involving gene recombination are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating

institution, check "Yes". An official document of approval for the proposed activities by an institutional biosafety committee should be submitted along with the application. If the certification is unavoidably delayed, the pending sheet should be submitted with the application. The committee approved document should be presented by **June 25, 2014**. If the certification or the pending sheet could not be submitted before deadlines, it might affect the outcome of the review.

H. Microbes in Risk Group 2, 3, 4: If the activities involving microbes in risk group 2, 3, 4 are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution, check "Yes". An official document of approval for the proposed activities by an institutional biosafety committee should be submitted along with the application. If the certification is unavoidably delayed, the pending sheet should be submitted with the application. The approved document should be presented by **June 25, 2014**. If the above mentioned documents could not be submitted before deadlines, it might affect the outcome of the review.

I. Vertebrate Animals: If the activities involving vertebrate animals are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution, check "Yes". *The description of animal ethics 3Rs (Replace, Reduce and Refine) and* an official document of approval for the proposed activities by the Institutional Animal Care and Use Committee (IACUC) should be submitted along with the application. If the certification of IACUC is unavoidably delayed, the IACUC pending sheet should be submitted with the application. The IACUC approved document should be presented by **June 25, 2014**. If the certification or the pending sheet of IACUC could not be submitted before deadlines, it might affect the outcome of the review.

2. FORM SECTIONS 2a and 2b - Personnel

List all individuals who will participate in the scientific execution of the project, whether or not salaries are offered by this project.

FORM SECTION 2a- Key Professional Personnel

Key Professional Personnel shall be defined as, and also shall be limited as, individuals who contribute substantively to the scientific development, and

execution of the project. Typically, these individuals have the doctoral or other professional degree and act as the Principal Investigator (PI), Co-Principal Investigators (Co-PIs), and Investigators. Detailed qualifications of the PI, Co-PIs and Investigators are stated in the Chinese manual on page II-3.

FORM SECTION 2b- Supporting Staff

Supporting Staff is defined as individual(s) who will participate in the project execution, other than the Key Professional Personnel described above, i.e. postdoctoral fellows (for those who have been recruited, i.e. other than "to be hired", please fill out the Biographical Sketch), graduate students, undergraduate students, or research assistants.

For every individual listed in Form 2a and 2b, include the position title, the organization and the highest degree. Under the Role on Project describe their specific function.

Estimate the percent effort of all personnel on the project. It should be shown in percentage based on the **working hours for each individual.** For instance, "30 percent effort" means that this individual will devote 30% of his/her working hours on this project, "100 percent effort" means that this individual is full time working on this project. For those who working part time on this project, such as **part time research staff, PI or other key professional personnel, the percent effort should not be 100.**

3. FORM SECTIONS 3a and 3b - Abstracts in Chinese and in English

State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Describe concisely the research design and methods for achieving these goals.

4. FORM SECTION 4 - Progress Report and Response to Previous Review Comments

A. For "New" application that indicated in Section 1 – Face Page, if the PI never applied or received NHRI grants in the past 5 years, please upload the file indicating "N/A" in this section. If the PI has received NHRI grants in the past 5 years, it is essential to briefly describe the progress (within 3 pages) made during previous grant period in this section. Besides, it is necessary to upload the abstracts of progress

reports, abstracts of previous NHRI application, and previous review comments in the past 5 years as appendixes. If the PI has applied for NHRI grants but was not funded in the past 5 years, please upload the review comments in the past 5 years as appendixes.

B. For competing Renewal applications, a progress report of previous NHRI grant in the past 5 years is required. The "progress report" in this section should not exceed **3** pages. Progress report serves as a basis for continuing support of the proposal, which should describe in detail the progress made during previous NHRI grant period, and compare what was planned in the original application with what was accomplished. Summarize the previous application's specific aims and provide a succinct account of published and unpublished results indicating progress toward their achievement. Summarize the importance of the findings. Discuss any changes in the specific aims since the project was last reviewed competitively. List all of the patents, invention reports, publications and manuscripts submitted or accepted for publication supported by this grant.

Besides the statements mentioned above, please upload the abstract of the previous NHRI application, previous abstracts of progress reports from the grants funded by NHRI and previous review comments in the past 5 years in appendixes.

C. For the "Revision or Amendment" or "Revised Renewal" application, a concise description (within 5 pages) of responses to the previous review comments in the past 5 years should be provided. In this section, specify changes that have been made or justify why suggested changes were not made. Point out (Mark) any additions, deletions, or revision, and briefly explain any responses to criticism for this project. Upload the previous review comments in the past 5 years in appendix. For "Revised Renewal" application, the description of progress made during previous NHRI grant period (within 3 pages) is also required, and the abstract of the previous NHRI application and previous abstracts of progress reports from the grants funded by NHRI in the past 5 years should be uploaded in appendix as well.

For an amended or renewal application, this section is very important. Those who respond to each criticism or suggestion carefully and indicate how and where the application has been improved leave a favorable impression on the review committee. Disregarding the previous review comments or without progress report by submitting a "New" application may affect the results of the review.

5. FORM SECTION 5 - Research Plan

Include sufficient, but concise information to facilitate an effective review. Be specific and informative yet avoiding redundancies. The research plan should consist of in the order of all the following components: (A) specific aims, (B) background and significance, (C) previous and current studies, (D) research design and methods, (E) anticipated results, (F) human subjects, (G) gene recommendation, (H) microbes in risk group 2, 3, 4, (I) animal investigations, (J) potential hazards and (K) references. **The absolute maximum number of pages for part (A) to (E) is 13 pages, which will be strictly enforced.** Mark in bold type what was changed or improved based on the previous review comments or results of previous study for "Renewal", "Revision or Amendment" or "Revised Renewal" application.

A. Specific Aims (One page is recommended)

Outline the broad, long-term objectives; then, list and describe concisely and realistically what the specific research is intended to accomplish and any hypotheses to be tested. Avoid giving a long list of aims that are unachievable and over ambitious.

B. Background and Significance (Part B+C：do not exceed 6 pages)

Briefly sketch the background of the present proposal, critically evaluate existing knowledge, and specifically identify the gaps which the project is intended to fill. State concisely the importance of the research described in this application, especially in terms of health relevance, scientific contribution, uniqueness and originality.

C. Previous and Current Studies (Part B+C：do not exceed 6 pages)

A report of the Principal Investigator's previous studies and all current projects and sources of funding pertinent to the application is required. For a new application, the applicants' preliminary studies will help to demonstrate the experience and competence of the investigators. For a competing renewal application, preliminary studies may help establish the feasibility and importance of the renewal application. Appropriate publications and manuscripts submitted or accepted for publication may be listed.

D. Research Design and Methods

Describe the research design and the procedures to be used to accomplish the specific aims of the project. Include the means by which the data will be collected, analyzed, and interpreted. Provide information on statistical analysis whenever applicable. Describe any new methodology and its advantage over existing methodologies. This section however should NOT be just a compilation of protocol and methods. It should also present the logic strategy of the research plan. For instance, one may discuss the sensitivity, the specificity and logistics of an enzyme assay, not just the incubation conditions, the concentration of the buffers, etc. Provide a sequence or time-table for the proposed investigations. If expert consultants and collaborators are mentioned, make certain to include collaborative agreement or supporting letters in the Appendix.

E. Anticipated Results

Estimate the extent to which anticipated results would satisfy the original hypothesis and how those results would be important for planning the next steps in the research plan. Discuss the potential pitfalls, difficulties and limitations of the proposed procedures and provide alternative approaches if the original approaches do not work.

F. Human Subjects

Provide a detailed description of the proposed involvement of human subjects in the work outlined above in the Research Design and Method Section. Describe plans for the recruitment of subjects, the consented procedures to be followed and Data and Safety Monitoring. Describe any potential risk (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Describe the procedures for protecting against or minimizing any potential risks and assess their likely effectiveness. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may reasonably be expected to be gained from the study. Attach the IRB approved document along with its original application contents in Appendix. Assure the title and execution period on official document of approval are consistent with this application.

G. Gene Recombination

Provide a detailed description of the proposed involvement of gene recombination in the work outlined above in the Research Design and Methods Section. Describe any potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Describe the procedures for protecting against or minimizing any potential risks and assess their likely effectiveness. Attach an approved document from the institutional biosafety committee in Appendix. Assure the title and execution period on official document of approval are consistent with this application.

H. Microbes in Risk Group 2, 3, 4

Provide a detailed description of the proposed involvement of microbes in risk group 2, 3, 4 in the work outlined above in the Research Design and Methods Section. Describe any potential risks (pathogenicity, mode of transmission and host range…etc.) and assess their likelihood and seriousness. Describe the availability of effective preventive measures or treatment (e.g., vaccines; antibiotics; food and water hygiene; chemotherapeutic agents…etc.) or procedures for protecting against or minimizing any potential risks. Attach an approved document from the institutional biosafety committee in Appendix. Assure the title and execution period on official document of approval are consistent with this application.

I. Animal Investigations

If animals are involved, indicate what species are to be used, whether non-human primates are to be used and list the special justifications for their use. Indicate all details for the care, use, treatment, and disposal of all animals. Observe the law or regulation for animal protection during the project period. Attach the IACUC approved document *along with the description of animal ethics 3Rs (Replace, Reduce and Refine)* in Appendix. Assure the title and execution period on official document of approval are consistent with this application.

J. Potential Hazards

Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

K. References

Include a complete citation for each reference in the text. Each literature citation must include the names of all authors, title, source (book or journal), volume number, page numbers and year of publication. Make every attempt to be judicious in compiling a selected, relevant, and current list of literature citations.

6. FORM SECTION 6 - Institutional Environment and Resources

A. Briefly describe the features of the institutional environment that are relevant to the effective implementation of the research project.

B. Describe available resources such as clinical and laboratory facilities, participating and affiliated units; indicate their capabilities, relative proximity, and extent of availability to the project.

C. List the most important equipment items already available for this project, noting the pertinent capabilities of each.

7. FORM SECTIONS 7a and 7b - Detailed Budget Requested for Initial Year

FORM SECTION 7a - Initial Year Budget for Personnel

A. Salary supplement of NT10,000 per month could be listed for Principal Investigator. No payment is allowed for either Co-PIs or Investigators.

B. List the names of the personnel involved in the project during the initial year for whom salary or payment is requested.

C. Identify the role of each individual listed. Describe their specific functions under the Justifications section.

D. For the labor insurance premium and the health insurance premium, refer to the Chinese manual regarding budget limitation on page II-19 to II-21.

FORM SECTION 7b - Initial Year Budget for Other Categories

A. Travel: Indicate domestic or overseas travel. State under the Justifications section, the purpose of any travel, giving the number of

trips involved and the number of individuals for whom funds are requested.

B. Consumables: Itemize consumables in separate categories such as glassware, chemicals, radioisotopes, etc. For each item, give the unit price, amount purchased, and total cost requested under the Justifications section. Categories in amounts less than NT10,000 do not have to be itemized. Explain and justify the purchase of unusual consumable requests.

C. Equipment: List separately each item of equipment. Justify the purchase under the Justifications section.

D. Additionally, read the Chinese guidelines regarding the budget limitation for detailed information on page II-13 to II-21, and meet those regulations to conduct projects.

8. FORM SECTIONS 8a and 8b - Equipment and Budget Requested for Entire Proposed Project Period

FROM SECTION 8a - Equipment Requested for Entire Proposed Project Period

A. For equipment category, list all of the items and budget requested for the initial year and the additional years of support requested.

B. Under the Justifications section, explain and justify the purchase of major equipment in subsequent years following the initial year.

FORM SECTION 8b - Budget Requested for Entire Proposed Project Period

A. For each budget category, give the amount requested for the initial year and the additional years of support requested.

B. Under the Justifications section, identify and justify any significant increase or decrease over the initial project period.

9. FORM SECTION 9 - Other Support

A. Every individual listed on Form Section 2a is required to provide a list

of all governmental grants, contracts, fellowships, and other forms of support, in which the individual serves as a Principal Investigator or Responsible Investigator. For each individual, list all supports that were funded in the **past three years** (from 2011 until now) and all **current pending** applications. Upload all the abstracts of the funded grants in the past three years and of the current pending applications in appendix, not limited to the ones supported by NHRI. For individuals without other support, please indicate "None".

B. Note the extent of potential overlaps (financial and/or scientific) of other support with the proposed application. If there is no potential overlap, please indicate "None" in "Overlap with this Application" column. Failure to provide full and accurate information on such overlaps may result in disqualification of the application.

C. For a long-term project, fill in the **entire** project period (e.g. yyyy/mm/dd~ yyyy/mm/dd) in "Duration of support" column.

10. FORM SECTION 10 - Biographical Sketches

A. Give biographical information for key professional personnel (**4 pages for each person**) listed on FORM SECTION 2a, beginning with the Principal Investigator. If the biographical sketches cannot sufficiently provide key professional personnel's information, it may result in disqualification of the application.

B. Education

Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.

C. Statement of Qualifications for Innovative Research Grant **(For PI only)**

The Innovative Research Grant is dedicated to encouraging independent researchers in national health research fields. The PI's past or ongoing work must have resulted in or will result in significant improvement in medical and health research. State the PI's status of independence and scientific achievement.

D. Research and Professional Positions Held in Chronological Sequence

List in chronological order, previous employment, experience, and honors. Conclude with present position. Outline previous experience relevant to proposed research.

E. Record of Serving as Principal Investigator

Outline previous experience of serving as Principal Investigator in charge of some scientific projects. List the source of support, project number, title, duration and budget for entire project period, for each scientific project. (If there is no previous experience of serving as PI, please indicate “None”.)

F. Publications

Attach a publication list, in chronological order, of all authors, title, volume number, page numbers, and year of publication, for all relevant publications during the past three years, as well as representative earlier publications pertinent to this application. Mark the publications / manuscripts submitted or accepted for publication that have resulted from NHRI funded grant. Patents, invention reports, technology transfer or licensing can also be included. (If there is no publication, please indicate “None”.)

11. FORM SECTION 11 - Certificate of Agreement for the Application

A. Principal Investigator’s statement: To pursue this grant, the PI must meet the required qualification and guarantee that there is no falsification or misrepresentation in this application. Examine the statement of assurance and have it endorsed both by the PI and the head of applicant organization.

B. The key professional personnel listed on FORM SECTION 2a must sign the certificate of agreement to promise that they have provided full and accurate information and will provide the support during the entire proposed project period.

12. FORM SECTION 12 - Checklist

Use the checklist to check each item in detail before submitting the application. Make certain that the application meets the administrative criteria for IRG programs. If the application does not meet the

administration criteria, it will affect the results of the review or be returned without review.

13. Appendix

A. The Appendix is not to be used to circumvent the page limitation in the Research Plan.

B. The Appendix should include the official documents of approval by all the review boards involving human subjects, vertebrate animals, microbes in risk group 2, 3, 4, and gene recombination, previous review comments, abstract of the previous NHRI application, previous abstracts of progress reports from the grants funded by NHRI, the abstracts of the funded grants in the past three years and the abstracts of current pending applications, the collaborative agreement or supporting letters from the sponsor or cooperation laboratory, and quotations.

C. To submit any original color photographs of those shown in the Research Plan Section as supporting documents, 5 hard copies of them can be sent to NHRI.

D. Competing Renewal applications may submit no more than 10 publications, manuscripts submitted or accepted for publication, patents, invention reports, and other printed materials that have resulted from the project since it was last reviewed competitively. Such background material documenting preliminary studies may also be appended to New applications.