CTSI KL2 Scholars Career Development Program

2019 APPLICATION INSTRUCTIONS

CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE

UNIVERSITY OF MINNESOTA
Driven to Discover℠

Note to applicants, The KL2 application content is based on an NIH K individual mentored career development award (e.g. K23, etc.) to facilitate the submission to other NIH K applications.

A major difference between the KL2 and the individual K is that the KL2 has a length of 3 years and the individual K of 5 years. This will require some changes in the length of the research project and the career development plan.

There are some additional local KL2 application sections that include:

- Initial Start Up Plan
- Translation Plan
- Statistical Support Plan
- Mentor Team Form
- Mentor Mentee Compact with Primary Mentor (and Co-Primary Mentor, if applicable)
- Curriculum Vitae

Unless otherwise noted, please follow the NIH page limits found here.

If you have questions, please contact us at ctsieduc@umn.edu.

Introduction

|1| Introduction to Application (RESUBMISSION ONLY)

Who must complete the "Introduction to Application" attachment:

An "Introduction to Application" attachment is required only if the type of application is resubmission. An introduction is not allowed for new applications.

Format:

Not to exceed one page in length. Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Resubmission applications: See specific instructions on the content of the Introduction on the NIH's Resubmission Applications page.

Candidate Section

|2| Candidate Information and Goals for Career Development

Format:

Follow the page limits for Candidate Information and Goals for Career Development in the NIH Table of Page Limits.

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Organize your attachment into three sections, following the headings and specified order below, and discuss each of the points listed below. Start each section with the appropriate section heading - Candidate's Background, Career Goals and Objectives, and Candidate's Plan for Career Development/Training Activities During Award Period.

Candidate's Background:

- Describe your past scientific history, indicating how the award fits into past and future research career development.
- If there are consistent themes or issues that have guided previous work, these should be made clear. Alternatively, if your work has changed direction, indicate the reasons for the change.

Career Goals and Objectives:

- Describe your short-term and long-term career goals.
- Justify the need for the award by describing how the career development award will enable you to develop and/or expand your research career.
- You are encouraged to include a timeline, including plans to apply for subsequent grant support.

Candidate's Plan for Career Development/Training Activities During Award Period:

Describe a 3-year career development plan with a timeline and objectives that will advance your career goals. Present a systematic plan to obtain the necessary educational background, research experiences and skills, and mentoring necessary to launch an independent career in clinical/translational research. Describe your proposed research project.

- Describe how the educational plan you propose supplements your previous educational background and the new or enhanced research skills and knowledge you will acquire as a result of the proposed award.
- Describe any structured activities that are part of the developmental plan, such as coursework or workshops that will help you learn new techniques or develop needed professional skills. If coursework is included, provide course numbers (if available) and descriptive titles.
- Briefly discuss each of the activities, other than research, in which you expect to participate. For each activity, other than research, explain how it relates to the proposed research and to the career development plan. Include a percentage of time involvement for each activity by year, expressed in person months. For more information about calculating person months, see NIH's Frequently Asked Questions on Person Months.
- Give an outline of other projects or studies you plan to pursue over the three years of KL2 funding

- Describe why interdisciplinary approaches and mentorship are critical to your research area. Describe what you intend to learn from each proposed mentor as well as how the mentors will interact with you as a team (i.e. meeting schedule, format, etc…)

|3| NIH Format Biosketch and Curriculum Vitae

Format:

Attach this information as a PDF file. See NIH's Format Attachments page. Append biosketch and curriculum vitae and upload as a single PDF file.

Content:

Customize your NIH Biosketch to support this KL2 application.

Your curriculum vitae should be current as of date of application submission. Include manuscripts In Press and Submitted (no abstracts). Include all current, pending, and previous research funding. Include NIH Other Support form if that information is not listed in your CV.

Research Plan Section

The Research Plan is a major part of the overall career development goal. It is important to relate the proposed research to the candidate's scientific career goals. Describe how the research, coupled with other developmental activities, will provide the experience, knowledge, and skills necessary to achieve the objectives of the career development plan. Also describe how the research and other developmental activities will enable the candidate to launch and conduct an independent research career or enhance an established research career.

For most types of research, the Research Plan Section should include:

- a specific hypothesis,
- a list of the specific aims and objectives that will be used to examine the hypothesis,
- a description of the methods/approaches/techniques to be used in each aim,
- a discussion of possible problems and how they will be managed, and
- alternative approaches that might be tried if the initial approaches do not work.

A KL2 Research Plan is expected to be tailored to the experience level of the candidate and to allow him/her to develop the necessary skills needed for further career advancement. Reviewers will evaluate the plan accordingly. The plan should be achievable within the requested time period. Pilot or preliminary studies and routine data gathering are generally not appropriate as the sole part(s) of a KL2 Research Plan.

Although candidates for mentored career development awards are expected to write the Research Plan, the mentor should review a draft of the plan and discuss it in detail with the candidate. Review by other knowledgeable colleagues is also helpful.

|4| Specific Aims

Format:

Follow the page limits for the Specific Aims in the NIH Table of Page Limits.

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will have on the research field(s) involved.

List succinctly the specific objectives of the research proposed (e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology).

|5| Research Strategy

Format:

Follow the page limits for the Research Strategy in the NIH Table of Page Limits.

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Organize the Research Strategy in the specified order and use the instructions provided below. Start each section with the appropriate heading - Significance, Innovation, Approach.

Cite published experimental details in the Research Strategy section and provide the full reference in G.220 - R&R Other Project Information Form, Bibliography and References Cited.

Note: Explain the relationship between the candidate's research on the KL2 and the mentor's ongoing research program.

1. Significance

- Explain the importance of the problem or critical barrier to progress that the proposed project addresses.
- Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

2. Innovation

- Explain how the application challenges current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.

3. Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Unless addressed separately in the Resource Sharing Plan section, include how the data will be collected, analyzed, and interpreted, as well as any resource sharing plans as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
- Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex.
- Refer to NIH Guide Notice on Sex as a Biological Variable in NIH-funded Research for further consideration of NIH expectations about sex as a biological variable.
- If your study(s) involves human subjects, the sections on Inclusion of Women and Minorities and Inclusion of Children can be used to expand your discussion on inclusion and justify the proposed proportions of individuals (such as males and females) in the sample, but it must also be addressed here in the "Approach" section of the "Research Strategy" attachment.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of select agents should appear in the Select Agents section below.
- If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be chosen, provide a strong justification for why an appropriate cell line cannot be chosen from the registry at this time.

If you have multiple Specific Aims, you may address Significance, Innovation, and Approach either for each Specific Aim individually or for all of the Specific Aims collectively.

As applicable, also include the following information as part of the Research Strategy, keeping within the three sections (Significance, Innovation, and Approach) listed above.

Preliminary Studies:

Include information on preliminary studies. Discuss the PD/PI's preliminary studies, data, and or experience pertinent to this application.

|6| Initial Start-Up Plan

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Briefly describe (3-5 sentences) the specific steps you will take in the first three months of the award to operationalize your research project. Please include IRB submission plans.

|7| Translation Plan

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

A brief description of the translational, clinical or public health impact of your research. Clearly state how a disease or group of diseases will be better diagnosed, treated or prevented, or how the successful completion of your research will improve human health.

|8| Statistical Support Plan

Format:

Complete Statistical Support Plan form at the conclusion of this document. Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Using the Statistical Support Plan form, describe the level of biostatistics support required by the project and the amount, if any, needed to budget in the research proposal. Include name of faculty-level biostats mentor or consultant-recommended biostatistics mentor.* To be completed during consultation - handwritten is acceptable.

*Note: All applicants without a faculty-level biostats or informatics mentor are required to contact the CTSI Biostatistical Design and Analysis Center for an initial consult, at no charge, with a BDAC faculty biostatistician to review the statistical support needs of the proposal. At the consultation the applicant and a BDAC consultant will determine together the level of statistical support required by the project and the amount, if any, applicants need to budget in the proposal. Statistical Support Plan form should be completed during consultation – handwritten is acceptable.

BDAC Consultation Request Instructions

1. Go to the CTR Portal, z.umn.edu/ctsirequest, to request a BDAC consultation. You will be asked to log in with your x.500 username and password.
2. Click **New Request**
3. Enter the project title and the PI information. Select **No** for *'Do you need Scheduling System access?'* Click **Proceed to next step.**
4. Select **Yes I would** from the pop-up menu.
5. Select **Biostatistical and Data Management Support**
6. Answer the remaining questions as completely as you can. In response to the question, 'How will your research be funded?', please choose 'Other' and then **enter the name of the career development program** in the 'further details' text box.
7. Submit the form upon completion

BDAC meets to assign new requests every Monday. A biostatistician will contact you following that meeting.

For assistance setting up your consultation contact:

Melissa Hansen
Research Navigator
ctsi@umn.edu
(612) 626-2318

|9| Budget

Format:

Complete the budget template at the conclusion of this document. Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Use budget template for each year of the grant and provide a short justification narrative. Be sure to budget for required ACTS conference travel and include any costs for statistical support services. *Your salary and the primary mentor stipend should not be included in the budget.

|10| Training in the Responsible Conduct of Research

Format:

Follow the page limits for the Training in the Responsible Conduct of Research in the NIH Table of Page Limits . Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Attach a description of plans for obtaining or providing instruction in RCR. This section should document prior instruction or participation in RCR training during the applicant's current career stage (including the date instruction was last completed). This section should also propose plans to either receive instruction or provide instruction (e.g., to participate as a course lecturer) to meet the frequency requirement of RCR training (see the "For more information section" below).

The plan must address the five required instructional components outlined in the NIH Policy on Instruction in the Responsible Conduct of Research (RCR), as more fully described in the Supplemental Instructions. Part III, Section 1.16: Policy on Instruction in the Responsible Conduct of Research:

1. **Format:** Describe the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable);
2. **Subject Matter:** Describe the breadth of subject matter (e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics);
3. **Faculty Participation:** Describe the role of the mentor(s) and other faculty involvement in the instruction;
4. **Duration of Instruction:** Describe the number of contact hours of instruction, taking into consideration the duration of the program; and

5. **Frequency of Instruction:** Instruction must occur during each career stage and at least once every four years. Document any prior instruction during the applicant's current career stage, including the inclusive dates instruction was last completed.

The plan may include career stage-appropriate individualized instruction or independent scholarly activities. Instruction and activities should enhance the applicant's understanding of ethical issues related to their specific research activities and the societal impact of that research. The role of the mentor in RCR instruction must be described.

For more information:

See Supplemental Instructions, Part III, Section 1.16: Policy on Instruction in the Responsible Conduct of Research for information on the NIH Policy on Training in RCR.

See the NIH Guide Notices on the Availability of Resources for Instruction in the Responsible Conduct of Research and on the Requirement for Instruction in the Responsible Conduct of Research.

Mentor, Co-Mentor, Consultant, Collaborators Section

|11| Mentor Team Form

Format:

Complete Mentor Team Form at the conclusion of this document. Attach this information as a PDF file.

Content:

1. Describe the team's evaluation of this scholar's background and potential for a successful academic clinical/translational research career (½ page, single-spaced).
2. Describe the intended long-term career path the team envisions for this scholar (½ page, single-spaced).
3. Describe the 3-year timeline with specific mileposts for the clinical scholar's development in education, research, and networking (½ page, single-spaced).
4. Describe the nature, frequency and extent of interaction planned between the team and the clinical scholar during the award period (½ page, single-spaced).
5. How will the mentoring team support the career development of the scholar (½ page, single-spaced).

|12-15| Plans and Statements of Mentors

All KL2 applications should identify a primary mentor, secondary, and biostats/informatics mentor. All mentors must provide a statement as described below, along with an NIH Biosketch, Other Support Page (if applicable), and NIH Training Table for each mentor. The Training Table should list 5-10 trainees (postdoctoral students and junior faculty) the mentor has advised in the past 10 years in chronological order beginning with the most recent.

Format:

Follow the page limits for the Plans and Statements of Mentors in the NIH Table of Page Limits . Training Table form can be found at the conclusion of this document. Append plan, statement, biosketch, other support, and training table together and upload as a single PDF file for each mentor.

Content:

Each must document their role and willingness to participate in the project, and explain how they will contribute to the development of the candidate's research career. Each statement should include all of the following:

1. The plan for the candidate's training and research career development. Include information not only about research, but also about other developmental activities, such as seminars, scientific meetings, training in RCR, and presentations. Discuss expectations for publications over the entire period of the proposed project. Define what aspects of the proposed research project the candidate will be allowed to take with him/her to start their own research program.
2. The source of anticipated support for the candidate's research project for each year of the award period.
3. The nature and extent of supervision and mentoring of the candidate, and commitment to the candidate's development that will occur during the award period.
4. The candidate's anticipated teaching load for the award period (number and types of courses or seminars), clinical responsibilities, committee and administrative assignments, and the portion of time available for research.
5. A plan for transitioning the candidate from the mentored stage of his/her career to the independent investigator stage by the end of the project period of the award. Describe the mentor's (or co-mentor's) previous experience as a mentor, including type of mentoring (e.g., graduate students, career development awardees, postdoctoral students), number of persons mentored, and career outcomes.

Note for co-mentor statements: Co-mentors must also address the nature of their role in the career development plan and how the responsibility for the candidate's development is shared with the mentor. Describe respective areas of expertise and how they will be combined to enhance the candidate's development. Also describe the nature of any resources that will be committed to this award.

|16| Mentor-Mentee Compact with Primary Mentor (and Co-Primary Mentor, if applicable)

Format:

Complete Mentor-Mentee Compact form on the KL2 webpage. Attach this information as a PDF file.

Content:

Mentors and scholars will complete this compact, designed to help facilitate the discussion of expectations and goals. We also encourage you to refer to the program expectations as you work through this form. Step 1) The mentor and scholar should electronically fill out their respective columns Step 2) Set up a meeting with your scholar to discuss the compact Step 3) Work together to create a final compact Step 4) Mentor and Scholar both sign the compact.

|17| Letters of Support from Collaborators, Contributors, and Consultants

From whom are letters of support required? From whom are letters not required?

Letters of support from collaborators, contributors, and consultants will be required for any such person who will contribute to the KL2 application's proposed project in any substantive, meaningful way.

Format:

Follow the page limits for the Letters of Support from Collaborators, Contributors, and Consultants in the NIH Table of Page Limits .

Attach all appropriate letters of support. The letters must be appended together and uploaded as a single PDF file. See NIH's Format Attachments page.

Content:

Letters from consultants should include rates/charges for consulting services.

Applications should identify collaborators, contributors, and consultants involved with the proposed research and career development program not already included in the "Plans and Statements of Mentors" section. Letters should briefly describe their anticipated contributions and document their role and willingness to participate in the project.

Environment and Institutional Commitment to Candidate Section

|18| Description of Institutional Environment

Format:

Follow the page limits for the Description of Institutional Environment in the NIH Table of Page Limits . Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

The sponsoring institution must document a strong, well-established research program related to the candidate's area of interest, including the names of key faculty members relevant to the candidate's proposed developmental plan. Indicate how the necessary facilities and other resources will be made available for both career enhancement and the research proposed in this application; refer to the resources description in G.220 - R&R Other Project Information Form, Facilities and Other Resources in your "Description of Institutional Environment" Attachment. Describe opportunities for intellectual interactions with other investigators, including courses offered, journal clubs, seminars, and presentations.

|19| Institutional Commitment to Candidate's Research Career Development

Format:

Follow the page limits for the Institutional Commitment to Candidate's Research Career Development in the NIH Table of Page Limits . Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

The institution should provide a document on institutional letterhead that describes its commitment to the candidate and the candidate's career development, independent of the receipt of the KL2. It is also essential to document the institution's commitment to the retention, development, and advancement of the candidate during the period of the award.

The "Institutional Commitment to Candidate's Research Career Development" attachment should generally document the institution's agreement to provide adequate time, support, equipment, facilities, and resources to the candidate for research and career development activities. See the list below for specific items to include in the document.

In the document describing its institutional commitment, the applicant organization must:

1. Agree to release the candidate from other duties and activities so that the candidate can devote the required percentage of time for development of a research career.
    a. Commitment of at least 75 percent or nine person months of time is required.
    b. NIH and other PHS agencies use the concept of "person months" as a metric for determining percent of effort. For more information about calculating person months, see NIH's Frequently Asked Questions on Person Months.
2. Describe actions that will be taken to ensure that the candidate can devote the required time to research career development (e.g., reduction of the candidate's teaching load, committee and administrative assignments, and clinical or other professional activities for the current academic year). If the candidate's clinical or teaching responsibilities will be reduced, describe how this will be accommodated (e.g., hiring additional staff, reassigning staff, etc).
3. Describe the candidate's academic appointment, bearing in mind that the appointment must be full-time, and that the appointment (including all rights and privileges pertaining to full faculty status if in an academic setting) and the continuation of salary should not be contingent upon the receipt of this award.
4. Describe the proportion of time currently available for the candidate's research and what the candidate's institutional responsibilities will be if an award is made.
5. Describe how the institution will provide the candidate with appropriate office and laboratory space, equipment, and other resources (including access to clinical and/or other research populations) to carry out the proposed Research Plan.
6. Describe how the institution will be supportive of any proposed mentor(s) and/or other staff consistent with the career development plan.

Signatures:

The institutional commitment must be dated and signed by applicant's Dean and Division Head or Departmental Chair. The signatures must appear over the signers' name and title at the end of the statement.

Human Subjects Section

|20| Protection of Human Subjects

Who must complete the "Protection of Human Subjects" attachment:

Include the "Protection of Human Subjects" attachment if activities involving human subjects are planned at any time during the proposed project at any performance site. Include attachment even if the proposed project is exempt from regulations for the Protection of Human Subjects, or if activities involving human subjects are anticipated within the period of award but plans are indefinite.

If human subjects are not involved but your proposed research involves human specimens and/or data from subjects, you must provide a justification in this section for your claim that no human subjects are involved.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Do not use the "Protection of Human Subjects" section to circumvent the page limits of the Research Strategy.

Content:

Refer to Supplemental Instructions, Part II for instructions on this section.

For more information:

Refer to the NIH's Research Involving Human Subjects website.

|21| Data Safety Monitoring Plan

Who must complete the "Data Safety Monitoring Plan" attachment:

Include the "Data Safety Monitoring Plan" attachment if the proposed research includes a clinical trial.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Refer to Supplemental Instructions, Part II, Section 4.1.5: Data and Safety Monitoring Form for instructions on this section.

|22| Inclusion of Women and Minorities

Who must complete the "Inclusion of Women and Minorities" attachment:

Include an "Inclusion of Women and Minorities" attachment if you answered "Yes" to the question "Are human subjects involved?" and the research does not fall under Exemption 4. Refer to the NIH Exempt Human Subjects Research Infographic.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Refer to Supplemental Instructions, Part II, Section 4.2: Inclusion of Women and Minorities for instructions on this section.

Additionally, refer to G.500 - PHS Inclusion Enrollment Report as well as the Supplemental Instructions, Part II (Section 4.3: Instructions for Completing the PHS Inclusion Enrollment Report, and Section 5.6: NIH Policy on the Inclusion of Women and Minorities in Clinical Research) for more information on submitting the PHS Inclusion Enrollment Report as part of your application.

|23| Inclusion of Children

Who must complete the "Inclusion of Children" attachment:

Include an "Inclusion of Children" Attachment if you answered "Yes" to the question "Are human subjects involved?" and the research does not fall under Exemption 4. Refer to the NIH Exempt Human Subjects Research Infographic.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Refer to the Supplemental Instructions, Part II (Section 4.4: Inclusion of Children and Section 5.8: NIH Policy on Inclusion of Children) for instructions on this section.

Other Research Plan Sections

|24| Vertebrate Animals

Who must complete the "Vertebrate Animals" attachment:

Include the "Vertebrate Animals" attachment if activities involving vertebrate animals are planned at any time during the proposed project at any performance site. Note that the generation of custom antibodies constitutes an activity involving vertebrate animals. Include an attachment if animal involvement is anticipated within the period of award but plans are indefinite.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Do not use the Vertebrate Animals section to circumvent the page limits of the Research Strategy.

Content:

If vertebrate animals are involved in the project, address each of the following criteria:

1. **Description of Procedures:** Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the "Research Strategy" section. Identify the species, strains, ages, sex, and total numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.
2. **Justifications:** Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g. computational, human, invertebrate, in vitro).
3. **Minimization of Pain and Distress:** Describe the interventions, including analgesia, anesthesia, sedation, palliative care and humane endpoints that will be used to minimize discomfort, distress, pain, and injury.

Provide a concise, complete description of the animals and proposed procedures. In addition to the 3 points above, you should also:

- Identify all project/performance or collaborating site(s) and describe activities of proposed research with vertebrate animals in those sites.
- Explain when and how animals are expected to be used if plans for the use of animals have not been finalized.

See the following pages for more information:

- NIH's Office of Laboratory Animal Welfare website
- NIH's Vertebrate Animals Section Worksheet
- Supplemental Instructions, Part III, Section 2.2: Vertebrate Animals (an applicable Animal Welfare Assurance will be required if the grantee institution does not have one)

|25| Select Agent Research

Who must complete the "Select Agent Research" attachment:

Include the "Select Agent Research" attachment if your proposed activities involve the use of select agents at any time during the proposed project period, either at the applicant organization or at any performance site.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

For more information:

Select agents are hazardous biological agents and toxins that have been identified by HHS or the U.S. Department of Agriculture (USDA) as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. The Centers for Disease Control and Prevention (CDC) and the Animal APHIS Select Agent Programs jointly maintain a list of these agents. See the Federal Select Agent Program website.

See also the Supplemental Instructions, Part III, Section 2.13: Select Agent Research.

Content:

Excluded select agents: If the activities proposed in your application involve only the use of a strain(s) of select agents which has been excluded from the list of select agents and toxins as per 42 CFR 73.3, the select agent requirements do not apply. Use this "Select Agent Research" section to identify the strain(s) of the select agent that will be used and note that it has been excluded from this list. The CDC maintains a list of exclusions which is available on the Select Agents and Toxins Exclusions website.

Applying for a select agent to be excluded: If the strain(s) is not currently excluded from the list of select agents and toxins but you have applied or intend to apply to HHS for an exclusion from the list, use this section to indicate the status of your request or your intent to apply for an exclusion and provide a brief justification for the exclusion.

All applicants proposing to use select agents: Address the following three points for each site at which select agent research will take place. Although no specific page limitation applies to this section, be succinct.

1. Identify the select agent(s) to be used in the proposed research.
2. Provide the registration status of all entities* where select agent(s) will be used.
    - If the performance site(s) is a foreign institution, provide the name(s) of the country or countries where select agent research will be performed.

- *An "entity" is defined in 42 CFR 73.1 as "any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity."

3. Provide a description of all facilities where the select agent(s) will be used.
    - Describe the procedures that will be used to monitor possession, use and transfer of select agent(s).
    - Describe plans for appropriate biosafety, biocontainment, and security of the select agent(s).
    - Describe the biocontainment resources available at all performance sites.

|26| Consortium/Contractual Arrangements

Who must complete the "Consortium/Contractual Arrangements" attachment:

Include the "Consortium/Contractual Arrangements" attachment if you have consortium/contracts in your budget.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

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 ultimate performer of the activities, should be the grantee.

Note: The signature of the authorized organization representative in G.200 - SF 424 (R&R), Authorized Representative signifies that the applicant and all proposed consortium participants understand and agree to the following statement:

The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency's consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.

For more information:

Refer to the NIH Grants Policy Statement, Section 15: Consortium Agreements for more information.

|27| Resource Sharing

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Sharing Model Organisms: All applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible. **For more information**, see Supplemental Instructions, Part III, Section 1.5.2: Sharing Model Organism Policy and the NIH Guide Notice on Sharing Model Organisms for Biomedical Research.

Genomic Data Sharing (GDS): Applicants seeking funding for research that generates large-scale human or non-human genomic data are expected to provide a plan for sharing of these data. Examples of large-scale genomic data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data. Supplemental Information to the NIH GDS provides examples of genomic research projects that are subject to the Policy. **For more information**, see the NIH GDS Policy, the NIH Guide Notice on Genomic Data Sharing Policy, and the GDS website.

Note on GDS: For proposed studies generating human genomic data under the scope of the GDS Policy, an Institutional Certification may be submitted at the time of application submission, but it is not required at that time. The Institutional Certification, however, will be requested as Just-in-Time (JIT) information prior to award. The Institutional Certification, or in some cases, a Provisional Institutional Certification, must be submitted and accepted before the award can be issued.

For more information:

NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds, and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. See Supplemental Instructions, Part III, Section1.5: Sharing Research Resources.

|28| Authentication of Key Biological and/or Chemical Resources

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. A maximum of one page is suggested.

More information:

Key biological and/or chemical resources are characterized as follows.

- Key biological and/or chemical resources may or may not be generated with NIH funds and: 1) may differ from laboratory to laboratory or over time; 2) may have qualities and/or qualifications that could influence the research data; and 3) are integral to the proposed research. These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.
- Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals.
- See NIH's page on Rigor and Reproducibility for more information.

STATISTICAL SUPPORT PLAN

(Use additional pages as necessary)

This statistical support plan must be included in your application

Name of KL2 Applicant: _____

Name of Biostatistics/Informatics Mentor or BDAC Consultant:_____

_____ _____

Biostatistics/Informatics Mentor/Consultant's Signature **Date**

Statistical Support Plan: Below, describe the level of biostatistics support required by the project and the amount, if any, needed to budget in research proposal. Include name of biostatistics/informatics mentor or consultant-recommended biostatistics mentor. To be completed during consultation - handwritten is acceptable.

Recommended Biostatistics Mentor *(for BDAC consultations only)*: _____

Plan Details, including anticipated costs for budgeting:

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DETAILED BUDGET FOR INITIAL BUDGET PERIOD

FROM	THROUGH

List PERSONNEL *(Applicant organization only)*
Use Cal, Acad, or Summer to Enter Months Devoted to Project
Enter Dollar Amounts Requested *(omit cents)* for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
	PD/PI							
SUBTOTALS →								

CONSULTANT COSTS	
EQUIPMENT *(Itemize)*	
SUPPLIES *(Itemize by category)*	
TRAVEL	
INPATIENT CARE COSTS	
OUTPATIENT CARE COSTS	
ALTERATIONS AND RENOVATIONS *(Itemize by category)*	
OTHER EXPENSES *(Itemize by category)*	

CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)*		**$**
CONSORTIUM/CONTRACTUAL COSTS	FACILITIES AND ADMINISTRATIVE COSTS	
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		**$**

BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD

BUDGET CATEGORY TOTALS	INITIAL BUDGET PERIOD *(from Form Page 4)*	2nd ADDITIONAL YEAR OF SUPPORT REQUESTED	3rd ADDITIONAL YEAR OF SUPPORT REQUESTED	4th ADDITIONAL YEAR OF SUPPORT REQUESTED	5th ADDITIONAL YEAR OF SUPPORT REQUESTED
PERSONNEL: *Salary and fringe benefits. Applicant organization only*.					
CONSULTANT COSTS					
EQUIPMENT					
SUPPLIES					
TRAVEL					
INPATIENT CARE COSTS					
OUTPATIENT CARE COSTS					
ALTERATIONS AND RENOVATIONS					
OTHER EXPENSES					
DIRECT CONSORTIUM/ CONTRACTUAL COSTS					
SUBTOTAL DIRECT COSTS *(Sum = Item 8a, Face Page)*					
F&A CONSORTIUM/ CONTRACTUAL COSTS					
TOTAL DIRECT COSTS					

TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD	**$**

JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.

MENTOR TEAM FORM

(3 pages maximum)

Scholar Name:_____

1. Describe the team's evaluation of this scholar's background and potential for a successful academic clinical/translational research career (½ page, single-spaced).
2. Describe the intended long-term career path the team envisions for this scholar (½ page, single-spaced).
3. Describe the 3-year timeline with specific mileposts for the clinical scholar's development in education, research, and networking (½ page, single-spaced).
4. Describe the nature, frequency and extent of interaction planned between the team and the clinical scholar during the award period (½ page, single-spaced).
5. How will the mentoring team support the career development of the scholar (½ page, single-spaced).

Mentors participating on CTSI-sponsored projects are required to meet with their scholar-mentee regularly, attend the annual CTSI Poster Session, and required to participate in a CTSI-developed mentoring online learning module, in addition to providing data, submitting reports, and attending occasional CTSI events as requested. It is expected that the mentoring team will work closely with the applicant in the development of the application.

Mentor Names and Signatures

_____

Primary Mentor (print name and sign) **By signing this form you are agreeing that you have reviewed the application*

_____

Secondary Mentor (print name and sign) **By signing this form you are agreeing that you have reviewed the application*

_____

Tertiary Mentor (If applicable) (print name and sign) **By signing this form you are agreeing that you have reviewed the application*

_____

Biostatistics Mentor (print name and sign) **By signing this form you are agreeing that you have reviewed the application*

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Mentor Training Form

Name of Mentor	School	Department	Area of Expertise		Current NIH funding
Name of trainee (status while in training)	Training Period	Degree Sought	Title of Research Project while training with this mentor	Current or last known position	Current or last known research topic AND NIH grant numbers