B. D RG Application

Use the **D RG** Application Template provided. It has been pre-formatted to the preferences of FPTR – please do not alter. The **D RG** Application should have the following sections led by a header for each: **Specific Aims, Significance, Innovation, Approach, and Citations**. Follow the instructions below as to the contents for each heading within the **D RG** Application.

I. Specific Aims: 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 exert on the research field(s). 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 a new technology). **This section is limited to 1 page in Adobe PDF.**

II. Significance: Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses. Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice within the field to address the identified problem or barrier. Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved. **This section is limited to 1 page in Adobe PDF.**

III. Innovation: Explain how the application challenges and seeks to shift 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. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions. **This section is limited to 1 page in Adobe PDF.**

IV. Approach: Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. 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 a strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work. Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. Discuss any Preliminary Studies, data, and/or experience to this application. **This section is limited to 8 pages in Adobe PDF.**

V. Scientific Rigor and Transparency: Describe how your experimental design and methods will achieve robust and unbiased results. For additional guidance related to this, please visit: https://grants.nih.gov/policy/reproducibility/index.htm **This section is limited to 1 page in Adobe PDF.**

VI. Citations: Cite published experimental details in the Approach. Provide full reference in the Bibliography and References Cited section**.** List all references. Each reference must include title, names of all authors, book, or journal, volume number, page numbers, and year of publication. References should be limited to relevant and current literature. It is important to be concise and to select only those literature references pertinent to proposed research. There is no page limit for citations.

Once completed, save the template and submit the attachment as one Adobe PDF file.

C. D RG Human Subjects/Vertebrate Animals

Use the **D RG** Human Subjects Vertebrate Animal Template provided. It has been pre-formatted to the preferences of FPTR – please do not alter. Address the Protection of Human Subjects Plan, along with Women, Minorities, and Children Inclusion OR Vertebrate Animals. Use section headers and follow the instructions below for contents of either.

STUDIES INVOLVING HUMAN SUBJECTS

I. Protection of Human Subjects Plan: If research involving human subjects is determined by your Institutional Review Board (IRB) to be NON-EXEMPT and your institution has determined that IRB Approval is necessary, then you must provide sufficient information for reviewers to determine that the proposed research meets: 1) the requirements of the DHHS regulations to protect human subjects from research risks; and 2) the requirements of Foundation policy on inclusion of women, minorities, and children. If no human subjects are involved and your research has been determined to be EXEMPT, please state so. The Foundation does not provide IRB review or make a determination regarding whether IRB Approval is necessary. Address each item within your Protection of Human Subjects Plan.

A. Risks to Human Subjects

1. Human Subjects Involvement, Characteristics, and Design: Describe the proposed involvement of human subjects outlined in the Application section. Describe and justify the characteristics of the subject populations, including their anticipated numbers, age range, and health status, if relevant. Describe and justify the sampling plan, as well as the recruitment and retention strategies and the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. Note that "prisoners" includes all subjects involuntarily incarcerated (for example, detention centers) as well as subjects who become incarcerated after the study begins. If relevant to the proposed research, describe procedures for assignment to a study group. As related to human subjects protection, describe and justify the selection of an intervention's dose, frequency, and administration. List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research. Explain how data will be obtained, managed, and protected.

2. Sources of Materials: Describe the research material obtained from living individuals in the form of specimens, records, or data. Describe any data that will be collected from human subjects for the project(s) described in the application. Indicate who will have access to individually identifiable private information about human subjects. Provide information about how the specimen records, and/or data are collected, managed, and protected as well as whether material or data that include individually identifiable private information will be collected specifically for the proposed research project.

3. Potential Risks: Describe the potential risks to subjects (physical, psychological, financial, legal, or other) and assess their likelihood and seriousness to the human subjects. Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits of alternative treatments and procedures, to participants in the proposed research.

B. Adequacy of Protection Against Risks

1. Recruitment and Informed Consent: Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed study will include children, describe the process for meeting requirements for parental permission and child assent. Include a description of the circumstances under which 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. If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver. Informed consent documents need not be submitted unless requested.

2. Protections Against Risk: Describe planned procedures for protecting against or minimizing potential risks, including risks to privacy of individuals or confidentiality of data, and assess their likely effectiveness. Research involving vulnerable populations must include additional protections. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in case of adverse effects to the subjects. Studies that involve clinical trials must include a general description of the plan for data and safety monitoring of clinical trials and adverse event reporting to the IRB and others as appropriate to ensure safety of subjects.

3. Potential Benefits of the Proposed Research to Human Subjects and Others: Discuss the potential benefits of the research to research participants and others. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.

4. Importance of Knowledge to Be Gained: Discuss the importance of the knowledge gained or to be gained as a result of the proposed research. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

5. Data and Safety Monitoring Plan: If the proposed research includes a clinical trial, include a Data and Safety Monitoring Plan. Provide a general description of a monitoring plan that you plan to establish as the overall framework for data and safety monitoring. Describe the entity that will be responsible for monitoring and the process by which Adverse Events will be reported. Be succinct. The frequency of monitoring will depend on potential risks, complexity, and the nature of the trial; therefore, a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a: Primary Investigator (required); IRB (required); independent individual/safety officer; designated medical monitor; Internal Committee or Board with explicit guidelines; data and Safety Monitoring Board (see NIH requirements). A detailed Data and Safety Monitoring Plan must be submitted to the applicant's IRB and for approval prior to the accrual of human subjects.

II. Inclusion of Women, Minorities, and Children:

A. Women and Minorities

Address, at a minimum, the following four (4) points:

1. The targeted/planned distribution of subjects by sex/gender and racial/ethnic groups. If using existing specimens and/or data without access to information on the distribution of women and minorities, so state and explain the impact on the goals of the research as part of the rationale that inclusion cannot be described. Alternatively, describe the gender and minority composition of the population base from whom the specimens and/or data will be obtained.

2. A description of the subject selection criteria and rationale for selection of sex/gender and racial/ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.

3. A compelling rationale for proposed outreach programs for recruiting sex/gender or racial/ethnic group.

4. A description of proposed outreach programs for equitable recruitment of members of sex/gender and racial/ethnic group as subjects.

B. Inclusion of Children

Address, at a minimum, the following four (4) points:

1. Provide either a description of the plans to include children, or, if children will be excluded from the proposed research, application, or proposal, present an acceptable justification for the exclusion.

2. If children are included, the description of the plan should include a rationale for selecting a specific age range of children. The plan must also include a description of the expertise of the investigative team in working with children, the ages included, the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

3. When children are involved in research, please address additional protections to children involved as subjects in research under Protections Against Risk.

4. Address any exclusion of any specific age group and justify the exclusion.

STUDIES INVOLVING ANIMAL RESEARCH

I. Vertebrate Animals: Research protocols on animal subjects must be reviewed by an Institutional Animal Care and Use Committee (IACUC). If vertebrate animals are involved in the project, address each of the five (5) points below. If all or part of the proposed research involving vertebrate animals will take place at alternate sites, identify those sites and describe the activities at those locations.

A. Provide a detailed description of the proposed use of the animals in the work outlined in the Application section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.

B. 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.

C. Provide information on the veterinary care of the animals involved.

D. 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 analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.

E. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the current recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations. If involvement of animals is indefinite, provide an explanation and indicate when it is anticipated that animals will be used.

There is no page limitation for this section but be succinct and do not use this section to circumvent the page limits of the **DFRG** Application. **Once completed, save the template and submit the attachment as one Adobe PDF file.**

D. DFRG Environment/Resources

Describe facilities, special equipment, consultative services, and other relevant resources available for the proposed project. This information is important in determining whether resources available are capable of supporting successful completion of proposed project. If any of these are to be obtained through collaborative arrangements, letters confirming arrangements must be included in application. Some aspects to discuss are:

- **Facilities:** Briefly identify types of facilities available and indicate their capacity, proximity and availability.
- **Equipment:** List special/important equipment already available for project.
- **Consultant and Secretarial Support Services:** Describe and list available consultant and secretarial support services available or planned for project.
- **Consortium/Contractual/Arrangements:** Explain programmatic, fiscal, and administrative arrangements to be made between applicant's organization and consortium organization(s). If consortium/ contractual activities represent a significant portion of overall project, explain why applicant organization, rather than ultimate performer of activities, should be grantee.

There is no page limitation for this section but be succinct and do not use this section to circumvent the page limits of the **DFRG** Application. **Once completed, save the template and submit the attachment as one Adobe PDF file.**

E. DFRG Biosketches

A biographical sketch must be provided for all key project personnel (**individuals with Person Records in Section III. PEOPLE except for the Institutional Official).**

Each biosketch is limited to 5 pages using the NIH format. Faculty should use the NIH biosketch form for non-fellowships. Use the biosketch templates here: https://grants.nih.gov/grants/forms/biosketch.htm

In Addition to the PI's biosketch the following information is needed only for the PI – No page limit (separate page):

- List all Pending, Current, and Completed (the last 3 years) Support; include all past or current support received from FPTR. If you list only the last 3 years of completed support, then you must include your top 10 highest dollar amount grants awarded regardless of agency, mechanism, or year (even if long ago).
- Each research support listing must include the following: Role, Agency, Mechanism, and Total Dollar Amount.

Scan all biosketches (ordered together by person) into one Adobe PDF file.

F. DFRG Support Letters

Applicants should provide letters of support and collaboration for the grant project.

Your institution must provide a Letter of Support for facilities, equipment, and personnel release time.

Letters from all consultants must be obtained confirming roles in project. Consultant letters should include rate/charge for consulting services.

Also, the consortium investigator and authorized official at consortium institution(s) must provide a signed statement or confirming letters that appropriate programmatic and administrative personnel of each organization are necessary to complete project.

Scan/combine all Support/ Collaboration/ Consortium/ Contractual/ Consultant(s) letters confirming role(s) in project and submit as one Adobe PDF file.

G. DFRG Approvals/Exemptions/Certifications

Please review the below and provide information regarding:

- Institutional Review Board (IRB) review **and** Human Subjects Research Training Certification.
- **AND/OR** Institutional Animal Care Use Committee (IACUC) review, as appropriate.

PLEASE NOTE: IRB/IACUC Approval is not required at time of application submission, but a description of plans is needed if not obtained yet. If approval or exemption has been received at time of application, include the letter/approval as described below**.** If an award is made, payment will not be issued until IRB/IACUC approval is received by the FPTR Scientific Program Administrator. **If approval or exemption has not been received at time of application, include a description of plans for obtaining it.**

For Human Subjects Research include:

Human Subjects: Institutional Review Board (IRB) Approval: If data is collected on human subjects or if data used in the project contains identifiable private information that can be linked to human subjects, a copy of IRB Approval or exemption (if already obtained) should be scanned into a PDF file and attached**. If IRB Approval is needed but not currently obtained it must be before the start of the grant. Include a description of plans for obtaining approval/exemption if this is the case.** Should an awarded project have IRB approval that will expire in September or later, re-approval must be received by the Foundation 30 days prior to the date of expiration. If the proposed project has more than one site, IRB approval or exemption must be obtained for every site in the project before funding. Finally, the institution sponsoring the project's research must be covered by an assurance agreement indicating compliance with Department of Health and Human Services (DHHS) regulations governing the protection of human subjects.

Human Subjects: Research Training Certification: ALL project personnel contributing to the execution of the project (i.e., anyone with a Person Record) must provide certificates demonstrating completion of human subject protections training. A certificate from a recognized credentialing agency (e.g., HPPERT, CITI) must be provided for **all individuals with Person Records in III. PEOPLE** (except the Institutional Official) or it will be considered INCOMPLETE, which could result in administrative disqualification. The documentation must also provide the period of validity for the training and the training must be valid according to the dates listed on the certificate. If you do not provide the period of validity for training or the dates on the certificate do not fall within the period of validity, your application will be considered INCOMPLETE, which could result in administrative disqualification. If a letter is submitted rather than a certificate, the application will be subject to administrative disqualification.

For Vertebrate Animal Research include:

Vertebrate Animals: Institutional Animal Care Use Committee (IACUC) Approval: If vertebrate experimental animals are involved in the study, attach the institution's Animal Care Use Committee (IACUC) approval if currently obtained. Projects including animal subjects must follow APTA's Position on Biomedical Research.

Scan relevant approval/exemption/certificate documents together and submit as one Adobe PDF file.

H. DFRG Budget/Budget Justification

Use the **DFRG** Budget Form/Budget Justification Template provided. It has been pre-formatted to the preferences of FPTR – please do not alter. **Complete the Budget template for each year of your grant project (i.e., for 2-year projects complete the template twice, convert to PDF, and combine the files together).** Follow the instructions below as to the contents for each item.

FPTR grant funding follows current NIH policies on investigator salaries caps. Please check with your Institutional Official to be sure your requests are in compliance with current limits. For reference, please see: https://grants.nih.gov/grants/policy/salcap_summary.htm

Budget: Insert all project expenses (in US dollars) into appropriate categories. Insert numbers only, no characters (i.e., dollars signs, percent signs, commas).

Personnel: List all individuals who will be participating in research project regardless of whether salary support has been requested. Indicate percentage of effort each will spend working directly on this research project. In all categories, indicate support requested from FPTR and total anticipated cost associated with project. Describe specific role each individual will have on project in the Budget Justification.

Consultant(s): Related costs should not exceed 10% of total amount of Grant request. Regardless of whether costs are involved, provide information on all consultants involved with project. Briefly describe services to be performed and related costs in the Budget Justification.

Equipment: Observe limitation for use of funds (support for purchase of major pieces of permanent equipment is limited to 20% or less of the total award). Itemize equipment to be purchased and justify purchase in the Budget Justification. Requests for computers and major software packages must have a detailed justification clearly showing that such items are essential to project and not otherwise available.

Supplies: Itemize supplies in categories, not individually (i.e., software, copying supplies, office supplies, etc.). If animals are involved, state species, number, unit cost, cost of care, etc.

Travel: All requests for support of travel must be justified thoroughly in the Budget Justification. Requests may include reasonable travel in the 48 continental United States to present research results during period of funding. No funds may be used for travel to foreign countries unless it is specifically and directly related to conduct of proposed project.

Patient Costs: Indicate number of patients, number of treatments, and cost per treatment anticipated; indicate what charge is for (e.g., equipment use). In the Budget Justification, provide names of facilities to be used and amount requested for each location. Indicate basis for estimating costs in this category.

Other: Itemize by category. Section may include cost of publication, computer charges, rentals and leases, equipment maintenance, etc. Explain in the Budget Justification.

Budget Justification: Describe specific functions of personnel, consultants, equipment purchases, etc. Identify individuals with appointments of less than full-time. Provide detail for all categories of expenditure. If other proposals for funding this project are pending, describe in detail how the research plan, budget, and time allocation will be adjusted if both proposals are funded. **There is no page limitation for this section** but be succinct and do not use this section to circumvent the page limits of the **DFRG** Application.

Once completed, save the template and convert to PDF, combine multi-year files, and submit the attachment as one Adobe PDF file. You must ensure that all sections are unobscured in the conversion from Excel to PDF.

I. DFRG Appendix 1: Publications

Applicants can scan up to three (3) of the following types of publications only:

- manuscripts and/or abstracts accepted for publication but not yet published;
- manuscripts and/or abstracts published, but a free, online, publicly available journal link is NOT available;
- and patents directly relevant to the project.

In addition to these three publication types, a full listing of peer-reviewed publications or abstracts also may be included. **Combine into one Adobe PDF file** and upload here.

J. DFRG Appendix 2: Project Supplements

Applicants can scan surveys, questionnaires, data collection instruments, and clinical protocols into **one Adobe PDF file** and upload here.

VI. APPROVAL

Institutional Approval and Submission of your Application

An authorized administrative official must approve your **DRG** Application. This should be done after all your Letters of Recommendation are submitted. To initiate the institutional approval and submission process, click "Select your approval invitee" and find the individual who is responsible for this approval from the Person Records. **Remember, you must add this official in "III. PEOPLE (Personnel)."** Click "Create Approval."

After creating the approval record and clicking "FINALIZE," this official will be immediately sent an email and asked to review, validate, and submit your **DFRG** Application. **Only click "FINALIZE" after you have reviewed your submission and are ready to submit your DFRG Application to FPTR. Before clicking, make sure all your attachments are complete, include all requested information, and are in the correct format.** (For example, including all needed human subjects training certificates; or appropriately addressing IRB status or plans to obtain in your submitted content.) **Be sure to check that all attachments are your final versions as well.**

If you are missing any required information or attachments, a message will appear with a list of requirements needed. If all components are present/uploaded, the submission will be finalized and content cannot be changed (unless the institutional official declines approval). It is recommended that you locally save all the components of your submission.

When the Institutional Official accesses this link, reviews, attests to its validity, and approves your application by clicking the applicable boxes, your application will then be considered submitted to FPTR. It is the Applicant's responsibility to make sure the Institutional Official has enough time and approves the application before the submission deadline. **APPROVAL OF YOUR APPLICATION MUST OCCUR BEFORE THE SUBMISSION DEADLINE (it is not considered fully submitted until approval is received)**.

You will receive an email confirming approval once it is done. You can also check the status by logging onto the submission system and going to the mechanism and clicking on your submission link.

QUESTIONS?

For content questions and guidance, please contact: **lizjackson@foundation4pt.org**
For any technical assistance in using the submission site, please contact: **foundation4pt@aibs.org**
