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# 2020 Grant Application Guidelines

## Important Information

**Competition Launch Date:** July 10, 2019
**Submission deadline:**11:59pm Eastern Standard Time on March 2nd, 2020 via [Submittable](https://riat.submittable.com/)
**Decision Announced:** anticipated April 2020

**Total grant money available:** up to$150,000 USD, depending on nature of project
**Individual Grant Amount:** up to $150,000 USD, depending on nature of project

## Expression of Interest

Please let us know if you are thinking of applying. Email support@restoringtrials.org.  This step is optional, but will help us with our planning.

## Submission of Proposals

Submissions must be received by 11:59 pm U.S. Eastern Standard Time on March 2nd, 2020. Applications must be submitted electronically through the online system found at <https://riat.submittable.com>. Applications will not be accepted by any other means of submission. *Note: Applications in progress can be saved within the submission system.*

## Eligibility

As a minimum requirement for this competition, applicants should have completed and be prepared to submit evidence of steps 1-3 (issue a call to action, confirm trial abandonment, and obtain trial data) of the RIAT methodology outlined in the ‘Proposal Details’ section below. These steps may take several weeks to complete and must be done prior to submission.

Applicants are encouraged to contact the RIAT Support Center (support@restoringtrials.org) during the application process for help/guidance on carrying out any steps.

## Proposal Requirements

The application should consist of the following items: cover letter, project abstract, project description, team information, budget table, budget narrative, and supplementary materials. You may use the template found here to facilitate the writing of your application.

A description of what is required in each section and word limits are found below:

**Title**

Provide a descriptive title for your application.

**Cover Letter**

The cover letter should include the following information:

* Names, affiliations (institutional or otherwise), and email addresses of all investigators, and a designation of the principal investigator(s);
* Name and email of your organization’s authorized individual
* Overall amount being requested from the RIAT Support Center

**Lay Summary (250 words)**

A lay summary of the project aim and its significance (if funded, this summary, or an edited version of it, will appear on the RIAT Support Center website [www.restoringtrials.org](http://www.restoringtrials.org))

**Team Description (500 words, excluding references).**

This section should list each member of the research team, briefly describe each person’s anticipated contribution to the project, and any potential conflicts of interest. Please also provide evidence that the team is capable of carrying out the proposed project. You may include references to previous work as well as other relevant accomplishments. In the supplementary material, you may include applicant CVs, but this is not required.

**Abstract (250 words)**

The project abstract should include the following headings and information:

* Background (outline the need for a RIAT)
* Objective (include the type of restoration [misreported or unpublished trial])
* Methods (detail progress to date through each RIAT step (see below), as relevant; state which data have been obtained)
* RIAT Impact (impact on healthcare and science)

**Proposal Details (2500 words, excluding references)**

This section should describe the rationale for the proposed RIAT, the RIAT steps that have been completed or that are to be done, the clinical importance/significance of the project. ***Please note, items 1-3 below are a prerequisite for this proposal.*** If your application is successful, you will be asked to publicly share the contents of this ‘Proposal Details’ section, as a protocol for your RIAT.

***Background:*** Provide evidence of misreporting or non-publication as rationale for why the trial needs restoration. Be sure to include the objectives (in PICO format) of the original trial.

* 1. For misreported trials: summarize or describe scientific literature summarizing the misreporting (in the form of research studies or published letters).
	2. For unpublished trials: describe a systematic literature search done by you or others confirming that there is no primary publication of the trial. Provide confirmation from the original trial sponsor or the current responsible party that no publication exists (Provide documentation of this confirmation in the ‘Supplemental Materials’).

***Objective:***

State the objective of the restoration and clearly indicate the type of restoration being done (misreported vs unpublished trial)

***RIAT methodology:***

Describe your progress through each of the following steps, adapted from the [RIAT declaration](http://www.bmj.com/content/346/bmj.f2865). *Note:* items 1-3 may take several weeks to complete and must be done in order to be eligible to apply.

Accompanying documentation for each step should be included in ‘Supplemental Materials’:

1. **Issue a “call to action”**

*Call to action:* If not already done, applicants should issue a public call to action for the restoration by the submission date. The call to action must outline your possession of sufficient data to carry out the proposed RIAT. The call to action should include, as a minimum: trial registration identifiers (e.g. CT.gov number[s]) or a note that the trial is not registered, number of participants, date completed, nature of the reporting problem (i.e., misreported vs. unpublished trial), and level of access to trial data (including the types and quantity of data/documents in your holding). The call to action will act as your public intent to restore the trial and can be achieved in multiple ways:

* Issue a ‘rapid response’ to the [RIAT declaration](http://www.bmj.com/content/346/bmj.f2865) published in the BMJ by following this link: <https://www.bmj.com/content/346/bmj.f2865/submit-a-rapid-response>
* By publishing a commentary/editorial/analysis/blog in a publicly available and accessible source.

*Give fair notice:* Send a copy of your call to action by email to trial sponsors (for unpublished trials) or authors (for published trials) requesting confirmation that the correct party has received the information. This offers original sponsors/trialists an opportunity to publish or formally correct their studies before a RIAT.

1. **Confirm abandonment**

After original trial investigators/sponsors are notified of the deficiencies of their trial, 3 general responses can be anticipated, 2 of which will necessitate a restoration.

* 1. Response confirms original sponsors/trialists’ intent to restore the trial within specified time period. (No need to perform a RIAT)
	2. Response confirms original sponsors/trialists’ intent to not restore the trial (i.e., do nothing) (Need to perform a RIAT)
	3. No response received from original sponsors/trialists’ (Need to perform a RIAT). Provide evidence of at least 3 attempts to contact the original trial investigator/sponsors, allowing for a sufficient time period (6 weeks) to elapse before declaring lack of response/acknowledgment of the problem.

In this section, please note whether any responses to your “call to action” exist (public or otherwise). Please summarize the response of trial investigators/sponsors, time elapsed since initial call to action, and the consequent need for third party restoration. Provide documentation of your communications with original trial sponsors/investigators in the Supplementary materials (e.g. by creating a PDF of all correspondence).

1. **Describe clinical study reports and any other study data in your possession**

Applicants are required to have obtained access to the trial data needed for the restoration by the time of submission. It is not sufficient to only be in the process of applying for access to data; you must have already obtained access. State which study documents & data you have obtained, how much data is in your possession (e.g. number of pages), whether you hold the data or only have access to data (but do not hold it yourself), and detail how/from where they were obtained (e.g., from the [Clinical Study Data Request website](https://www.clinicalstudydatarequest.com/Study-Sponsors-Info.aspx)). Please note the version of the study protocol and statistical analysis plan and whether it is *a priori* (i.e. a version prior to participant enrollment) or not. Please either provide a link to the data, if publicly available, or documentation confirming that data has been obtained (this can be included in ‘Supplemental Materials’).

1. **Indicate plan for carrying out the restoration**

Applicants should detail their team’s approach to carrying out the restoration, including reference to the original protocol, statistical analysis plan, and any planned deviations. Please include any details of bias-reducing measures that will be taken by your team (i.e. *a priori* decisions on how to handle data, verification of data and analysis, blinding, etc.).

1. **RIAT publication**

Applicants should outline their plan for publication and dissemination of the RIATed study.

*Plan for publication:*

* RIAT-friendly journals are listed on the [RIAT website](http://restoringtrials.org/riat-friendly-journals/). Applicants should describe their approach to journal selection, inquiry, and submission of the RIAT manuscript, including their plan for open access publication (see guiding principles).
* Please also indicate how you will comply with transparency and reporting requirements (below).

*Plan for dissemination:* Applicants are expected to make their final product public as well as help distribute it to relevant parties. Please explain how you will ensure widespread dissemination of your study, beyond publication. For instance, if you are restoring a trial that impacts on clinical practice guidelines, please outline your plan for ensuring the RIAT restoration is distributed to the relevant parties.

***RIAT Impact***

Applicants should explain the importance of topic and of the specific trial and the restoration from clinical and scholarly perspectives. The impact on healthcare and science should be made clear.

***References***

References should appear in consecutive order and be continuous for the entire application, rather than new numbering for each section. Use Vancouver style formatting for all references, with square brackets (not superscript) to denote references in the text. (We have requested square brackets e.g. [1] because the online submission system does not allow superscript font.)

*E.g., here is how to cite a journal article [1] in Vancouver format*

1. Guilbert TW, Morgan WJ, Zeiger RS, Mauger DT, Boehmer SJ, Szefler SJ, et al. Long-term inhaled corticosteroids in preschool children at high risk for asthma. N Engl J Med. 2006 May 11;354(19):1985-1997.

**Supplementary Materials (maximum of 5 attachments, 10 pages in length each)**

*Required attachments:* Accompanying documentation for elements of the project proposal

1. Call to Action: publicly available call to action (e.g. a PDF copy of your rapid response or publication)
2. Confirmation of abandonment: communications/responses from trial sponsor/authors confirming the need to proceed with the restoration
3. Documentation of trial data that you either hold or have guaranteed access to

*Optional attachments:*

* Team CVs
* Other support for RIAT: letters of support, media coverage
* Other (please describe what this is and why it is relevant)

**Budget Table (use online table provided on the submission website)**

The maximum allowable amount request from the RIAT Support Center is $150,000 USD over the entire project period. The budget table should provide a snapshot of the following costs over a specified project period: Staffing, Consultants, Other Direct Costs, Travel, Indirect Costs, and Other Funding obtained for this project, if relevant. Details about what should be included in each category are outlined in the table below.

The budget worksheet in the online submission system (Submittable) will automatically calculate the total requested amount once amounts for each category and project year are filled out. The total amount requested from the RIAT Support Center in the table should match your own calculations; please get in touch with us if it does not (info@restoringtrials.org).

**Budget Narrative (1000 words)**

This section should be used to explain and justify the budget. Please refer to the categories and descriptions below for what is allowable in the budget and should be included in the narrative.

|  |  |
| --- | --- |
| Staffing | This category includes employees who will work on the proposed project. Please provide: name (if known), title/role, 12 month salary ("Salary"), percent of time devoted to project per period ("FTE%"), fringe/benefit percent ("Fringe%") and inflation adjustment percentage assumed over each period (if multiple periods). When estimating the FTE% allocation for new positions, it is important to consider the typical time lag between the start date of the grant and the new person actually being in place. Therefore, for positions to be hired we expect that you discount the FTE allocation in period 1 according to typical hiring delay. |
| Consultant | This category includes individuals who are working on the project, but are not your employees. Independent contractors are also considered consultants. One way to enter the requested budget for individual consultants is to calculate the fees as a daily rate multiplied by the number of days. |
| Other Direct Costs | This category typically includes supplies and equipment with a unit cost generally under $5,000. It also serves to capture everything that qualifies as direct cost (e.g. project specific materials, software) and does not fit any of the other categories. Please itemize and provide cost details for all of these in the budget details. |
| Travel | This category includes costs for travel or meetings. In the budget details area, for each anticipated trip, please provide: a short description of the purpose of the travel, the number and title of travelers (e.g., “4 researchers”), the number of days of travel, and estimates for travel costs per person, or other calculation information as applicable. If funds from the proposed grant would be used to pay the costs of hosting a meeting of any kind, please be sure to indicate a rationale for the meeting, how many attendees the meeting will have, how many days the meeting will last, cost per attendee (or other applicable calculation figures) and specific meeting-related costs that will be funded by the RIAT Support Center. |
| Indirect Costs | In line with policy from the Laura and John Arnold Foundation (LJAF), indirect costs must not exceed 10% of Total Direct Costs. The means Indirect Costs may not exceed $13,637 USD if you are requesting the maximum project amount of $150,000 USD (i.e. $136,363 Total Direct Costs + $13,637 Indirect Costs). LJAF policy defines indirect costs as organizational costs incurred for a common or joint purpose benefitting more than one project and not exclusively attributable or created for the project for which funds are being requested.  |
| Other Funding obtained for this project | This category should be used to outline the amount already obtained or being sought from another funding source to cover off any part of this project. Please provide the name of the funder, the funding reference number, if applicable, and the amount allocated to this project. Please make it clear whether you have already obtained other funds and whether completing your project is contingent on other/additional funds.  |

**Project Workflow (200 words)**

The proposal should include a brief summary or table of anticipated timeline/milestones over the project period. Provide a clear description of how the study will meet reporting and other grantee requirements outlined in the Grant Information and Administration Section below. *Note:* the maximum project period for grantees in the 2019 competition is 2 years.

## Grant Administration

If awarded, we will be in touch with your organization’s authorized individual to discuss the terms of the grant. We will aim for start date within 3 months after winner announcement.

## Grant Requirements

**Transparency & Reporting**

Applicants are expected to ensure their approach is transparent and auditable. We encourage grantees to make use of the [Open Science Framework](https://osf.io/) to make their proposal details, communications with original trial sponsors/authors, and final accepted manuscript publicly available. Other study documents may also be made available at the investigators discretion. Data used to carry out the RIAT should also be made publicly available, for example by using a public repository such as Zenodo.

*Manuscript reporting requirements:*

* Include explanation (with references) in the Introduction of why this trial is being restored
* Provide auditable record of decisions (use [RIATAR template](http://restoringtrials.org/wp-content/uploads/2018/04/RIATAR-RIAT-Audit-Record-CONSORT-based-audit-tool-20130129.docx)), documenting which parts of the clinical study report (page number and paragraph) were used
* Report analyses specified in trial’s original protocol
* Denote any analyses that were not prespecified
* Make all underlying data available electronically

**Administrative**

Within 6 months following the end of the grant period, grantees must be submit a final report indicating how they met their stated objectives and include a final manuscript of the RIAT that has been or will be submitted for publication.

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Please contact the RIAT Support Center (support@restoringtrials.org) during the application process for help/guidance/questions about the application process.