A "limited submission" refers to a grant program that places a limitation on the number of proposal applications a single eligible entity can submit each cycle. The University of Texas at San Antonio (UTSA) has a process in place to allow for an internal competition among interested PIs to determine which application(s) will move forward. Once a limited submission opportunity is identified, an internal call for pre-proposals is sent out to potential PIs. Those interested in being considered for full submission are required to submit a pre-proposal (ranging from one to five pages, depending on the type of program and sponsor) by a specified date. If more applications are received than the institution is allowed to submit to the sponsor, the applications are moved forward to a peer review process in order to make final selection(s).

That peer review process is what you are taking part in now. While we do want you to be aware that the proposals you review here are not finalized and will be expanded before they are submitted to the sponsor, we ask that you be as critical in your review as you would be if these applications were moving forward to a sponsor now. We are especially interested in your feedback on weaknesses of the applications and where improvements can be made either before they move forward through submission to this program or others.

If you are reviewing more than one application for this same program, we ask that you use the applications as a reference for one another in your scoring, knowing that the pool will be ranked based on scores received to determine which move(s) forward to the sponsor.
Limited Submission Scoring Matrix
NIEHS Outstanding New Environmental Scientist (ONES) Award Program

SCORING

Selection of applications to be submitted to the NIEHS Outstanding New Environmental Scientist (ONES) Award Program will be based on a 9-point scoring scale for criteria given below.

No. of applications allowed per institution this cycle: 1

- Ratings should be given in whole numbers (no decimals).
- Reviewers should consider not only the relative number of strengths and weaknesses, but also the importance of these strengths and weaknesses to the criteria or to the overall impact when determining a score.
  - For example, a major strength may outweigh many minor and correctable weaknesses

  Minor weakness: easily addressable weakness, does not substantially lessen impact
  Moderate weakness: lessens impact
  Major weakness: severely limits impact

SCORING RUBRIC

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Additional Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Exceptional</td>
<td>Exceptionally strong with essentially no weaknesses</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
<td>Extremely strong with negligible weaknesses</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
</tr>
<tr>
<td>Medium</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Very Good</td>
<td>Strong but with numerous minor weaknesses</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weaknesses</td>
</tr>
<tr>
<td>Low</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
<td>A few strengths and a few major weaknesses</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td>Very few strengths and numerous major weaknesses</td>
</tr>
</tbody>
</table>
Limited Submission Scoring Matrix
NIEHS Outstanding New Environmental Scientist (ONES)
Award Program

SCORED REVIEW CRITERIA

Reviewers will consider each of the review criteria below in the determination of scientific and technical merit, and give a separate score for each.

Below, please summarize the factors that informed your individual criteria scores:

1. **Significance**
   Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? How will the proposed research significantly advance knowledge in a defined problem in the environmental health sciences, specifically in terms of understanding the underlying disease processes relevant to environmental exposures, the human biology involved in the cause, prevention, or moderation of disease, or the population burden attributable to the exposure?

   **Specific to applications proposing clinical trials only:** Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

   **Strengths:** Click here to enter text.

   **Weaknesses:** Click here to enter text.

2. **Investigator(s)**
   Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project? Based on the future goals section and the biographical sketch, does the PD/PI have the potential to make important research discoveries? Does the PD/PI demonstrate a long-term commitment to environmental health sciences research?

   **Specific to applications proposing clinical trials only:** With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in study coordination, data management and statistics?

   **Strengths:** Click here to enter text.

   **Weaknesses:** Click here to enter text.
Limited Submission Scoring Matrix
NIEHS Outstanding New Environmental Scientist (ONES) Award Program

Strengths: Click here to enter text.

Weaknesses: Click here to enter text.

3. **Innovation**
   Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed? Are the anticipated results expected to lead to major research advances in the environmental health sciences or have important implications for clinical or environmental public health?

   **Specific to applications proposing clinical trials only:** Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?

Strengths: Click here to enter text.

Weaknesses: Click here to enter text.

4. **Approach**
   Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

Strengths: Click here to enter text.

Weaknesses: Click here to enter text.
5. **Environment**

   Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

   **Specific to applications proposing clinical trials only:** If proposed, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed? Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers?

   If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial? If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure?

<table>
<thead>
<tr>
<th>Strengths:</th>
<th>Click here to enter text.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weaknesses:</td>
<td>Click here to enter text.</td>
</tr>
</tbody>
</table>
## Approach: Study Design

**Specific to applications proposing clinical trials only:** Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested? Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? Given the methods used to assign participants and deliver interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results?

Are potential ethical issues adequately addressed? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity?

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s)? Does the application propose to use existing available resources, as applicable?

**Strengths:** Click here to enter text.

**Weaknesses:** Click here to enter text.

## Approach: Data Management and Statistical Analysis

**Specific to applications proposing clinical trials only:** Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed?

**Strengths:** Click here to enter text.

**Weaknesses:** Click here to enter text.
8. **Project Planning**  
**Specific to applications proposing clinical trials only:** Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?

Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

**Strengths:** Click here to enter text.

**Weaknesses:** Click here to enter text.

---

**ADDITIONAL COMMENTS TO APPLICANT**

Reviewers may provide guidance to the applicant or recommend against resubmission without fundamental revision.

**Additional Comments to Applicants** (Optional)

Click here to enter text.
Limited Submission Scoring Matrix
NIEHS Outstanding New Environmental Scientist (ONES) Award Program
EVALUATION SCORES

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Your Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Significance</td>
<td></td>
</tr>
<tr>
<td>2. Investigator(s)</td>
<td></td>
</tr>
<tr>
<td>3. Innovation</td>
<td></td>
</tr>
<tr>
<td>4. Approach</td>
<td></td>
</tr>
<tr>
<td>5. Environment</td>
<td></td>
</tr>
<tr>
<td><strong>For Clinical Trials Only</strong></td>
<td></td>
</tr>
<tr>
<td>6. Approach: Study Design</td>
<td></td>
</tr>
<tr>
<td>7. Approach: Data Management and Statistical Analysis</td>
<td></td>
</tr>
<tr>
<td>8. Project Planning</td>
<td></td>
</tr>
</tbody>
</table>

**TOTAL SCORE**