

O'Neal Invests Cancer Research Support Mechanisms for Basic and Population Sciences

Goal of O'Neal Invests

Provide support for UAB faculty to generate data that will provide a strong premise for extramural cancer-focused basic and population science research grants.

Who can apply for O'Neal Invests Grants?

<u>UAB Faculty who are O'Neal Members:</u> The O'Neal is committed to supporting the work of O'Neal members carrying out basic and population science research.

<u>UAB Faculty who are not O'Neal Members:</u> The O'Neal is especially interested in supporting UAB faculty that are not currently working in cancer but wish to apply their expertise to answering important questions in cancer. You <u>do not</u> have to be an O'Neal member to apply for O'Neal Invests funding opportunities. The O'Neal has established advisory groups to help investigators who are not working in cancer formulate their proposals and find cancer-focused collaborators if needed. To be put in touch with an appropriate advisory committee contact Dr. Susan Ruppert <u>CCC-oneal-invests@uab.edu</u>

General Guidelines

- Shared Resource Vouchers will be reviewed on a rolling basis.
- Catalyst, Pre-R01, Pre-P01 and Pre-SPORE proposals will be accepted and reviewed two cycles (spring and fall) per year.
- Pls and Co-Pls receive funding support, collaborators may provide effort but do not get funding support.
- No individual may be a PI or Co-PI on more than one mechanism (Catalyst, Pre-R01, Pre-P01, Pre-SPORE).
- In a single grant cycle, no individual may apply as a PI or Co-PI through more than mechanism (Catalyst, Pre-R01, Pre-P01, Pre-SPORE).
- Applications for a Pre-PO1 or Pre-SPORE must have prior approval of the O'Neal Director.
- Funds will be available only for personnel, supplies or services directly required for the project. Investigator salaries, indirect costs and travel are not allowed.
- All funds must be used for work at UAB.
- Applicants must be independent investigators and direct their own research laboratory.

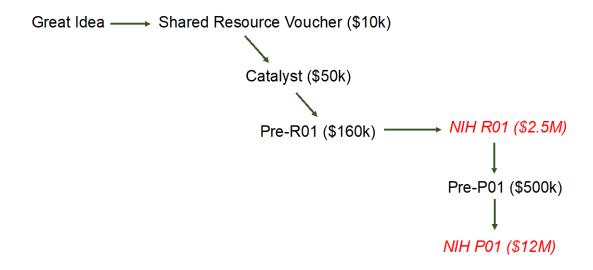
Programmatic Grants

Programmatic grants such as P01s and SPOREs are designed to support teams of highly qualified established investigators who are working together to carry out thematic science. For P01s it is also critical that the projects be highly integrated. These are very competitive grant awards that require a lot of up-front team preparation. The NCI currently funds 50-60 SPOREs and 90-100 P01s and there are 71 NCI designated Cancer Centers. The O'Neal is committed to working with thematically focused groups who wish to start on a path to applying for a P01 or SPORE. This includes helping to form and convene IABs and EABs to advise the group. Those groups interested in progressing towards a SPORE or P01 are encouraged to contact the O'Neal Director at an early stage to plan steps and milestones towards eventually applying for a Pre-P01 or Pre-SPORE award through

O'Neal invests at a point when they are within 2 years of putting in a competitive P01 or SPORE application.

O'Neal Invests Support Along the Research Funding Continuum

The O'Neal Invests Program wishes to support the great ideas of O'Neal investigators along the continuum of research funding. The diagram below is an example of how a great idea can be supported to extramural funding from the point of inception. This is just an example and investigators can enter and exit this continuum at different points to obtain the support they need.



For any questions, please contact Dr. Susan Ruppert CCC-oneal-invests@uab.edu

Shared Resource Voucher

Goal: To support the use of an O'Neal Shared Resource to carry out an analysisthat could lead to a new direction in cancer research in the investigator's laboratory.

Support: Up to \$10,000. If the cost is more than \$10,000 then the source of the balance should be indicated. Awarded funds must be utilized within 6 months.

Application: Up to two pages that address the following:

- What is the question you wish to answer?
- What is the new area in your lab that this work will nucleate? It can be related to, but not completely overlapping with, ongoing work.
- What is the broad hypothesis that the data obtained will provide a premise for?
- Why is this the key work needed to provide the premise?
- What do you expect would be the next phase of work (brief set of aims based on what you expect to find)?
- What will be your next step in supporting this work?

Supporting Material:

- Biosketch
- Other support
- Quote from Shared Resource for work
- Attestation form signed by Department Chair that you spend at least_70% of your time doing research and have laboratory space and support.

Process:

- Submit the application material to Dr. Susan Ruppert CCC-oneal-invests@uab.edu
- Applications will be considered on a rolling basis

Reporting:

 Recipients will be required to present a brief report of their findings and plans for next steps.

Catalyst

Goal: This mechanism will support 1-year projects in any area of cancer research. The major emphasis is on whether the proposal is foundational for a new line of cancer research in the investigator's laboratory. Upon completion, the investigator should be ready to apply for an R01 or O'Neal Pre-R01.

Support: \$50,000 for 1-year.

Application:

- General Formatting: Stay within the page limits set out below. The font size, line spacing and page margins should match those defined for NIH grant submissions. Arial 11 pt. or Times New Roman 12 pt. with a smaller font (8-9 pt.) for tables and figure legends and narrow margins (min. 0.5 inch) may be used. Please submit your application as a single document in Microsoft Word or pdf format. Applications that do not conform to this formatting or lack any of the required sections will not be reviewed.
- Cover sheet: (1 page) Please use the cover sheet provided.
- <u>Scientific Abstract:</u> (1/2 page) Please state your hypothesis and provide a description of your proposal in scientific terms. Describe its relevance, significance and innovation. Do not include figures or diagrams in your abstract.

<u>Lay abstract:</u> (1/2 page) Please provide a brief description of your project in lay terms. This is to inform non-scientist donors of the importance of the work proposed.

- Responsiveness to RFA: (1/2 page) State why you feel that this project is responsive to the RFA and why it is a new area of your lab(s). If it is a Co-PI application, explain what unique strengths each investigator brings.
 - Response to prior critiques: (1/2 page) Resubmissions should include a response to prior critiques.
- Approach and Preliminary Data: (3 pages) Provide specific aims, background and any key data needed to support your hypothesis within this 3-page section. Describe the approach you will use to test your hypothesis through your specific aims and summarize the expected outcomes. Explain why completing these studies will be foundational for a subsequent grant application.
- Next steps: (1/2 page) Describe your plan to apply for funding (and the type of funding) at the completion of the studies and what you anticipate the aims will be.
- Outcomes: (1/2 page) If you have previously received an O'Neal Invests Award, please list the outcomes with respect to grant applications and the status of these applications.
- Bibliography: No page limit. Use a format that includes article titles and all authors.

Supporting Material:

- Biosketch
- Other Support
- Budget: Please indicate how funds will be allocated. List all personnel with % effort and provide a brief description of their activities on the project.

Process:

- All proposals will be reviewed during twice-yearly O'Neal Invests study sections.
- Applications that are not funded may be resubmitted in a subsequent cycle with a half-page response to critiques.
- All funds must be expended during the 1-year period. Under special circumstances
 and with approval of the O'Neal unspent monies can be carried forward for a second
 year to complete goals outlined in the proposal. Any unspent monies at the end of
 the second year will be returned to the O'Neal.

Reporting:

• Upon completion, presentation of findings and plans for next scientific steps and funding.

Pre-R01

Goal: This mechanism will support new avenues of unfunded cancer research in the investigator's laboratory. It should describe experiments that will provide a strong premise for a competitive R01, and this work should be able to be completed, and the R01 submitted, **within two years.** Therapeutic clinical trials cannot be supported by this mechanism, but the inclusion of diagnostic or biomarker correlative studies related to a therapeutic protocol that are within the budget constraints will be considered. Co-PI applications that would lead to a multi-PI R01 are also included in this mechanism.

Support: \$160,000. \$80,000 for the first year with an additional \$80,000 for a second year based on successful completion of work the first year.

Application:

- General Formatting: Stay within the page limits set out below. The font size, line spacing and page margins should match those defined for NIH grant submissions. Arial 11 pt. or Times New Roman 12 pt. with a smaller font (8-9 pt.) for tables and figure legends and narrow margins (min. 0.5 inch) may be used. Please submit your application as a single document in Microsoft Word or pdf format with the sections in the order listed below. Applications that do not conform to this formatting or lack any of the required sections will not be reviewed.
- Cover sheet: (1 page) Please use the cover sheet provided.
- <u>Lay abstract:</u> (1/2 page) Please provide a brief description of your project in lay terms. This is to inform non-scientist donors of the importance of the work proposed.
- <u>Scientific Abstract:</u> (1/2 page) State your hypothesis and provide a description of your proposal in scientific terms. Describe its relevance, significance and innovation. Do not include figures or diagrams in your abstract.
- Response to prior critiques: (1 page) Resubmissions should include a response to prior critiques.
- Specific Aims: (1 page) Succinctly outline the significance and rationale for the proposed research and describe the hypotheses to be tested in each aim in a format similar to an R01 specific aims page.
- Relevance to catchment area: (1/2 page) Please identify how your project would address specific cancer needs of our catchment area (the State of Alabama). This is important for our NCI CCSG. We must explain how the research done at the O'Neal impacts the cancer burden and disparities of our catchment area. For additional information on specific cancer burdens and cancer disparities in the catchment area that your work may impact, please contact Claudia Hardy (chardy@uab.edu).
- Relevance to specific cancers: (1/2 page) If your proposal is not focused on a specific cancer, please indicate how your work is relevant to one or two types of cancer. This is

important as we have some funding that is restricted to specific cancers such as breast, lung, GI, hematologic cancers, and prostate. If your work is relevant to any of these cancers, it will increase the potential funding pool. If your proposal is clearly focused on a specific cancer, this section is not needed.

- Approach and Preliminary Data: (3 pages) Provide any key data needed to support your hypothesis within this 3-page section. Describe the approach you will use to test your hypothesis through your specific aims and summarize the expected outcomes.
- <u>Nine-month deliverables:</u> (1/2 page) List 3 key specific scientific deliverables that you expect to complete by 9 months. This should be a list of experiments that you proposed and plan to have complete, not plans to write papers and grants.
- Game Changing: (1 page) Explain why this is a new area for your lab, why you feel that
 it will lead to new extramural funding and what you envision to be the focus of the
 proposal for extramural funding. Discuss the work in your lab that is currently funded
 and explain why this proposal is different.
- Outcomes: (1/2 page) If you have previously received any O'Neal Invests funding, please list the outcomes with respect to grant applications and the status of these applications.
- Bibliography: No page limit. Use a format that includes article titles and all authors.

Supporting Material:

- Biosketch for PIs and Co-PIs
- Other Support for PIs and Co-PIs
- Appendix: You may include letters of support from key collaborators. Please do not include reprints, figures or other materials, as these will not be provided to reviewers.
- Budget: Please indicate how funds will be allocated. List all personnel with % effort and provide a brief description of their activities on the project.

Process:

- All proposals will be reviewed during twice yearly O'Neal Invests study sections.
- Proposals that are not funded can be resubmitted in a subsequent cycle with a response to critiques.
- At the end of the two-year period, unspent monies may be carried forward for up to one year with approval. Approval to carry these monies forward will depend on a plan to use these funds to continue or extend the aims of the initial proposal. Any monies remaining at the end of the third year will be returned to the O'Neal.

Reporting:

A meeting to review progress is required 9 months from the start of funding. Funding
for the second year is dependent on satisfactory progress towards achieving the 9month deliverables provided in the original application.

•	A meeting will be held at the end of the two-year period to discuss progress and next steps in research and applying for extramural funding. Awardees may be asked to present their findings at an O'Neal seminar.

Pre-P01

Goal: This mechanism will support team thematic science involving a group of well-established investigators that have come together to propose 3-4 independent research projects that are highly scientifically integrated. The group should clearly be within 2 years of submitting a P01, which would mean that the premise for each of the projects is well established and the remaining work will likely be focused on integration. Therapeutic clinical trials cannot be supported by this mechanism, but the inclusion of diagnostic or biomarker correlative studies related to a therapeutic protocol that are within the budget constraints will be considered.

Support: \$500,000. \$250,000 for the first year with an additional \$250,000 for a second year based on successful completion of work the first year.

Application:

- <u>Cover sheet:</u> (1 page) Provide the title of the project, the name of the main PI and their department. List each project title and the names of the PI/C0-PI and other key personnel.
- <u>Introduction:</u> (1 page): Overarching hypothesis being tested and its importance to cancer. Discussion of the team and why they are the right group to approach the problem.
- <u>Individual Projects:</u> Each of the individual projects (3-4) should submit the materials described in the instructions for the "Application" and "Supporting Materials" for the Pre-R01 award following the instructions and page limits.
- <u>Integration:</u> (2 pages) Describe how the work in each project informs the other projects. Investigators working together and sharing reagents is **not** integration. Integration is the results from one project that when combined with the results of another may synergize to, for example, promote new avenues of research or allow for new conclusions. This is a very important review criterion for P01s.
- Cores: (1 page) list the cores that you plan on having in your P01 application and discuss how they will be formed. Specifically, do you plan to use cores that already exist on campus and support them by perhaps hiring FTEs to work specifically on your P01 or will you be planning to form new cores. Indicate which projects will rely on each core. Please provide some indication of the amount of support you will request in a P01 application for each core. The cap on direct costs for NCI P01s is \$1.5M per year.
- Response to critiques: (1 page): If this is a resubmission then each project will have 1 page to respond to critiques, but you will also have 1 page to respond to critiques about integration, cores, etc.

Supporting Material:

- Supporting material for each of the projects is described in the Pre-R01 instructions.
- Correspondence (email) with an NCI Program Officer indicating enthusiasm for a P01 in the area.

- Report from an IAB meeting.
- Report from an EAB meeting.

Process:

- Pre-P01 applications require prior approval by the O'Neal Director
- All proposals will be reviewed during twice yearly O'Neal Invests study sections.
- Proposals that are not funded can be resubmitted at a subsequent cycle with a response to critiques.
- At the end of the two-year period, unspent monies may be carried forward for up to one year with approval. Approval to carry these monies forward will depend on a plan to use these funds to continue or extend the aims of the initial proposal. Any monies remaining at the end of the third year will be returned to the O'Neal.

Reporting:

- A meeting to review progress is required 9 months from the start of funding. Funding
 for the second year is dependent on satisfactory progress towards achieving the 9month deliverables provided in the original application.
- Awardees may be asked to present their work at O'Neal seminars.

Pre-SPORE

Goal: This mechanism will support work that represents team thematic science involving a group of well-established investigators that have come together to propose 3-4 independent research projects that all have a translational component with at least one, and preferably more than one, leading to an investigator initiated clinical trial. The group should clearly be within 2 years of submitting a SPORE, which would mean that considerable work has already been completed and some final key experiments are needed. Therapeutic clinical trials cannot be substantially supported by this mechanism, but IIT support in lines with current O'Neal IIT support is possible.

Support: \$500,000. \$250,000 for the first year with an additional \$250,000 for a second year based on successful completion of work the first year.

Application:

- <u>Cover sheet:</u> (1 page) Provide the title of the project, the name of the main PI and their department. List each project title and the names of the PI/C0-PI and other key personnel.
- <u>Introduction:</u> (1 page): Overarching hypothesis being tested and its importance to cancer. Discussion of the team and why they are the right group to approach the problem.
- <u>Individual Projects:</u> Each of the individual 3-4 projects should submit the materials described in the instructions for the "Application" and "Supporting Materials" for the Pre-R01 award following the instructions and page limits.
- <u>Cores:</u> (1 page) list the cores that you plan on having in your SPORE application and discuss how they will be formed. Specifically, do you plan to use cores that already exist on campus and support them by perhaps hiring FTEs to work specifically on your P01 or will you be planning to form new cores. Indicate which projects will rely on each core. Please provide some indication of the amount of support you will request in a SPORE application for each core.
- Response to critiques: (1 page): If this is a resubmission then each project will have 1
 page to respond to critiques, but you will also have 1 page to respond to general
 critiques about cores, etc.

Supporting Material:

- Supporting material for each of the projects is described in the Pre-R01 instructions.
- Correspondence (email) with an NCI Program Officer indicating enthusiasm for a SPORE in this area including indication of how many SPOREs are currently funded in this area.
- Report from an IAB meeting.
- Report from an EAB meeting.

Process:

• Pre-SPORE applications require prior approval by the O'Neal Director

- All proposals will be reviewed during twice yearly O'Neal Invests study sections.
- Proposals that are not funded can be resubmitted at a subsequent cycle with a response to critiques.
- At the end of the two-year period, unspent monies may be carried forward for up to one year with approval. Approval to carry these monies forward will depend on a plan to use these funds to continue or extend the aims of the initial proposal. Any monies remaining at the end of the third year will be returned to the O'Neal.

Reporting:

- A meeting to review progress is required 9 months from the start of funding. Funding
 for the second year is dependent on satisfactory progress towards achieving the 9month deliverables provided in the original application. A close-out meeting will be
 held at the end of two years
- Awardees may be asked to present their work at O'Neal seminars and at meetings with members of foundations that sponsored their research
- Awardees may be called upon to serve as reviewers in successive cycles of the O'Neal Invests Program.