O'Neal Comprehensive Cancer Center

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

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</u> <u>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 CCC-oneal-invests@uab.edu

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 per year. (Spring/summer and fall/winter)
- PIs and Co-PIs receive laboratory funding support. Collaborators may provide effort but do not receive laboratory funding support.
- No individual may be a PI or Co-PI on more than one mechanism (Catalyst, Pre-R01, Pre-P01, Pre-SPORE) at one time.
- In a single grant cycle, no individual may apply as a PI or Co-PI through more than one mechanism (Catalyst, Pre-R01, Pre-P01, Pre-SPORE).
- Applications for a Pre-P01 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.
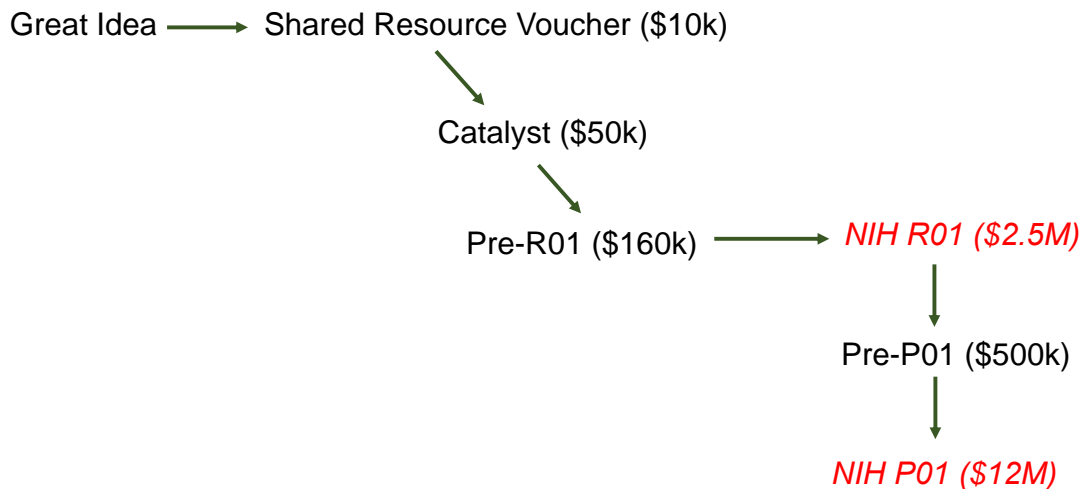- Applicants must be independent investigators and direct their own research laboratory.

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 exists 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 in achieving 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.

Great Idea ⟶ Shared Resource Voucher ($10k)

Catalyst ($50k)

Pre-R01 ($160k) ⟶ *NIH R01 ($2.5M)*

Pre-P01 ($500k)

NIH P01 ($12M)

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 in carrying out an analysis that 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.

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 for which the data obtained will provide a premise?
- 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 one-year research projects that are focused in specific areas congruent with the O'Neal Strategic Plan and identified by O'Neal Research Program leaders as areas of scientific need for building thematic research. Each O'Neal Invests cycle, there will be two specific focus areas announced for Catalyst applications. 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 provide the title of the project, the name of the PI/ Co-PIs and their department, and a list of other key personnel.

- Scientific Abstract: (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.

- Response to prior critiques: (1/2 page) One resubmission of Catalyst proposals will be allowed, even if the focus area is not included in subsequent cycles.

- Approach and Preliminary Data: (3 pages) Provide specific aims, background, and any key data needed to support your hypothesis within this three-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.

- <u>Bibliography:</u> 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 their respective percent effort, and provide a brief description of their activities on the project.
- <u>Attestation form</u>: Signed by your Department Chair confirming that the PI and Co-PI spends at least 70% of his/her effort on research and has adequate laboratory space and departmental support to complete these studies over a one-year period.

Process:
- All proposals will be reviewed during twice-yearly O'Neal Invests study sections.
- Proposals must be topically responsive to the themes highlighted in the RFA for the current cycle. The exception is resubmissions, which will be allowed once.
- All funds must be expended during the one-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. This work should be able to be completed within 2 years leading to submission of an R01. 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. **Applications that do not conform to this formatting or lack any of the required sections will not be reviewed.**

- Cover sheet: (1 page) Provide the title of the project, the name of the PI/ Co-PIs and their department, and a list of other key personnel.

- Lay abstract: (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.

- Scientific Abstract: (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. 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 Monica Baskin, PhD (mbaskin@uab.edu), the Associate Director for Community Outreach and Engagement.

- <u>Relevance to specific cancers:</u> (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.**

- <u>Approach and Preliminary Data:</u> (3 pages) Provide any key data needed to support your hypothesis within this three-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 three key specific scientific deliverables that you expect to complete in the first nine months. This should be a list of experiments that you propose and plan to have complete, not plans to write papers and grants.

- <u>Game Changing:</u> (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.

- <u>Outcomes:</u> (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.

- <u>Bibliography:</u> 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.
- Attestation form: Signed by your Department Chair confirming that the PI and Co-PI spends at least 70% of his/her effort on research and has adequate laboratory space and departmental support to complete these studies over a one-year period.

Process:
- 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 nine months from the start of funding. Funding for the second year is dependent on satisfactory progress towards achieving the nine-month 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 towards science and 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 <u>within two years</u> 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/Co-PI and other key personnel.

- <u>Introduction:</u> (1 page): Provide the overarching hypothesis being tested and its importance to cancer. Include 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. Exceptions are that individual projects do not need to have relevance to catchment area and relevance to specific cancers sections.

- <u>Relevance to catchment area:</u> (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 Monica Baskin, PhD (mbaskin@uab.edu), the Associate Director for Community Outreach and Engagement.

- <u>Relevance to specific cancers:</u> (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.**

- <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.

<u>Integration will be scored with one of four descriptors:</u>

Highly Integrated: The results of each project will inform at least one other project and each project is informed by the results of at least one other project. For example, "Informed" could be that the combined results of two projects potentially lead to a new important avenue of research or that the combined results allow for stronger conclusions and especially those leading to translation. Investigators providing advice or reagents is not "informed". The applicants should have clear examples of integration articulated in the proposal

Integrated: The results of some, but not all, projects are informed by at least one other project. With "Informed" as described above.

Minimally integrated: There does appear to be some integration potential between projects, but it has not been made clear.

Not integrated: No clear integration or integration potential.

- <u>Cores:</u> (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.

- <u>Response to critiques:</u> (1 page): If this is a resubmission, then each project will have one page to respond to critiques, but you will also have one 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 nine months from the start of funding. Funding for the second year is dependent on satisfactory progress towards achieving the nine-month 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 <u>within two years</u> 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/Co-PI and other key personnel.

- <u>Introduction:</u> (1 page): Provide the overarching hypothesis being tested and its importance to cancer. Include 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. Exceptions are that individual projects do not need to have relevance to catchment area and relevance to specific cancers sections.

- <u>Relevance to catchment area:</u> (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 Monica Baskin, PhD (mbaskin@uab.edu), the Associate Director for Community Outreach and Engagement.

- <u>Relevance to specific cancers:</u> (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.**

- <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 one page to respond to critiques, but you will also have one 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 nine months from the start of funding. Funding for the second year is dependent on satisfactory progress towards achieving the nine-month deliverables provided in the original application.
- Awardees may be asked to present their work at O'Neal seminars.