Oral Anticancer Agents:
Utilization, Adherence, and Health Care Delivery (R01, R21)

Epidemiology and Genomics Research Program
Behavioral Research Program
Health Care Delivery Research Program
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  - Conference #: 1-650-479-3207
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- This webinar is being recorded
Webinar Presenters

- Wendy Nelson, PhD, MPH
  Program Director, Basic Biobehavioral and Psychological Sciences Branch, NCI

- Kate Castro, RN, MS, AOCN
  Program Director, Healthcare Delivery Research Program, NCI

- Kelly Filipski, PhD, MPH
  Program Director, Clinical and Translational Epidemiology Branch, NCI
Agenda

- Background
- FOA Details
- Resources
- Questions

Questions about specific aims or grant application details will not be addressed
The **Division of Cancer Control and Population Sciences (DCCPS)** aims to reduce cancer morbidity and mortality, as well as enhance the quality of life for cancer survivors.

[nci website](cancercontrol.cancer.gov)
Grant Mechanisms – R01 and R21

<table>
<thead>
<tr>
<th>NIH Research Project Grant (R01) PA-17-060</th>
<th>NIH Exploratory/Developmental Grant (R21) PA-17-061</th>
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<tbody>
<tr>
<td>▪ Supports discrete, specified, circumscribed research projects</td>
<td>▪ Supports exploratory/developmental research projects</td>
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<tr>
<td>▪ Most commonly used grant mechanism</td>
<td>▪ May be used for pilot or feasibility studies</td>
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<tr>
<td>▪ No specific dollar limit</td>
<td>▪ Preliminary data not required</td>
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<td>– Advance permission required for ≥$500K direct costs in any year</td>
<td>▪ Direct costs for the two-year project period may not exceed $275K</td>
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<td>▪ 3-5 years of funding</td>
<td>▪ 2 years of funding</td>
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<tr>
<td>▪ Standard receipt dates</td>
<td>▪ Standard receipt dates</td>
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For more information: grants.nih.gov/grants/funding/funding_program.htm#RSeries
FOA Details

Oral Anticancer Agents: Utilization, Adherence, and Health Care Delivery
Motivation

- Targeted oral anticancer (OAC) medications have transformed cancer care
- OAC medications offer many potential advantages over traditional IV chemotherapy
  - Superior effectiveness
  - Convenient home-based treatment
  - A sense of control over treatment
  - Avoid IV infusions, trips to infusion center

- Potential downsides of OAC medications
  - Complex treatment regimens, often in addition to other medication regimens
  - OAC medications require strict adherence to be effective
  - Patients/caregivers are responsible for symptom management
  - Financial burden
  - Difficulties acquiring OAC medication
Why do we need this funding opportunity announcement?

- **Utilization**
  - Little information is available on the adoption of newly approved targeted oral agents
  - Little information is available on off-label use of oral agents
  - Are targeted oral agents being prescribed appropriately?

- **Adherence**
  - Strict adherence is critical to achieving an optimal clinical outcome
  - Suboptimal adherence may lead to relapse, side-effects, unnecessary treatment changes, increased use of health care resources

- **Health Care Delivery**
  - Health care systems need to establish new roles, responsibilities, safety standards, patient education strategies for targeted oral therapies
  - Home-based treatment with targeted oral therapy requires new models of care coordination
Purpose

- Assess and describe the current state of oral anticancer medication utilization, adherence, and delivery

- Identify the structural, systemic, and psychosocial barriers to adherence

- Develop models and strategies to improve safe and effective delivery of oral anticancer agents so that clinical outcomes are optimized
Considerations

- Applicants should focus on at least one of the following:
  - Specific type of cancer
  - Class of drugs
  - Patients subject to disparities

- Studies may be observational/descriptive or include interventions; observational studies should emphasize modifiable factors for future interventions.

- Studies may focus on utilization, adherence, or health care delivery issues related to oral anticancer agents (no need to study everything).

- Consult your Program Director if you have questions.
Research Priorities

- Cross-disciplinary collaborations (e.g., pharmacists, research nurses, social workers, financial navigators)
- Studies focused on newer molecularly targeted therapies
- Primary data collection is encouraged
Utilization Challenges

- Understand how targeted therapies are being prescribed and used
  - Disparities in access
  - Off-label use

- Potential research questions:
  - What are the patient and provider characteristics associated with prescribing and use of molecularly targeted agents?
  - Are there sociodemographic or health-related factors (e.g., comorbidities) that affect utilization?
  - What are current trends in utilization of newly approved targeted oral therapies?
Adherence Challenges

- Understand how cognitive, affective, and motivational processes influence adherence behavior
  - Beliefs about the safety and effectiveness of a “pill”
  - Depression, anxiety

- Potential research questions:
  - How do patients perceive the risks associated with oral therapy, and how do these risk perceptions influence adherence?
  - Are there major differences in patterns of adherence depending on the duration or complexity of the treatment regimen?
  - How do financial considerations (e.g., out-of-pocket costs) influence adherence?
Health Care Delivery Challenges

- Understand how health care delivery systems are adapting to meet safety standards and the educational needs of patients and caregivers
  - Symptom management
  - Coordination of care

- Potential research questions:
  - What system, health care team, provider, and patient-level factors are associated with the safe administration of oral agents?
  - How does reimbursement affect symptom management and monitoring?
  - What features of health care delivery systems lead to improved safety and adherence?
Resources

Oral Anticancer Agents: Utilization, Adherence, and Health Care Delivery
Read the FOAs Carefully

- PA-17-060 (R01); PA-17-061 (R21)
- Upcoming R01 application due dates: June 5, 2017; October 5, 2017
- Upcoming R21 application due dates: June 16, 2017; October 16, 2017
- Start the process early! Allow time for registration in Grants.gov and NIH eRA Commons
- Verify successful submission by checking the eRA Commons
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Questions

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Next Steps

- Email additional questions to ncidccpsbrpadvances@mail.nih.gov.

- Today’s webinar and list of Q&As (both leading up to and following the webinar) will be posted online:
  - cancercontrol.cancer.gov/brpwebinars
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