



## ***Major Grants Research Program***

# **Adherence to Oral Chemotherapeutic Agents Research Grant (RE37)**

Funded by:

*Research Consortium Partners: GlaxoSmithKline and  
Novartis Pharmaceuticals Corporation*

**Level of Funding: One \$160,000 Research Grant**

***An Online Application system is now used for all aspects of the application submission. Please see <http://www.onsfoundation.org/apply/re/Adherence> for instructions and details.***

**Letter of Intent Due: March 19, 2012**  
**Online Application Submission Due: April 16, 2012**

# ONS FOUNDATION ADHERENCE TO ORAL CHEMOTHERAPEUTIC AGENTS RESEARCH GRANT (RE37)

*Funded by: Research Consortium Partners: GlaxoSmithKline and  
Novartis Pharmaceuticals Corporation*

## ***GENERAL INSTRUCTIONS TO APPLICANTS***

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### **DEADLINE DATES:**

- ◆ Letter of Intent Due: March 19, 2012
- ◆ ONLINE Grant Application Submission Due: April 16, 2012
- ◆ Notification of Funding: July 2012
- ◆ Funding available: July 2012

### **PURPOSE OF GRANT:**

Applications are invited for research proposals that address nursing interventions to promote and maintain adherence to oral chemotherapeutic agents, including targeted therapies, a high-priority topic area identified by the agenda. A major goal of the ONS Foundation is to provide funding to support the 2009-2013 ONS Research Agenda. The agenda's focus is on areas where gaps exist in the knowledge base for oncology nursing practice.

Many oral chemotherapeutic agents are available for treatment, each with its own precautions, dosages, and side effects. Administration of chemotherapeutic agents is a complex task for people with cancer and their families since they now assume full responsibility for administering and monitoring chemotherapeutic agents. Adherence becomes a function of understanding the regimen and side effects while balancing quality of life due to unpleasant and unmanageable side effects and cost of the agent. Research addressing the different components of oral treatment adherence is needed including compliance, barriers to adherence, patient education, safety, and nursing interventions that affect adherence.

Only proposals addressing the effect of nursing care on promoting and maintaining adherence to oral chemotherapeutic agents, including targeted therapies, will be considered for funding. Section F1. of the 2009-2013 ONS Research Agenda identifies specific priority adherence research areas (<http://www.ons.org/media/ons/docs/research/2009-2013onsresearchagenda.pdf>). Adherence funding priorities include:

**F.1.** Evaluate the effect of nursing care on promoting and maintaining treatment adherence.

F.1.1. Understand predictors (risk model), costs, settings, side effects, educational approaches, population, health literacy, and cognitive changes associated with adherence to oral chemotherapeutic agents.

F.1.2. Evaluate strategies for various innovative models of care (e.g., APN-led teams, patient-centered medical home, chronic care models) and the cost effectiveness related to adherence of care issues.

F.1.3. Explicate the issues of adherence in all aspects of a plan of care, including clinical trial participation, medications such as oral chemotherapeutic agents, diet, and self-care strategies.

F.1.4. Evaluate strategies for the identification and prevention of adverse events related to treatment, such as vascular devices.

F.1.5. Develop or test interventions that support adherence to care.

ONS Foundation and the ONS Research Agenda address the importance of developing new researchers. Therefore, all research teams must include an experienced investigator and a junior investigator. The inclusion of an Advanced Practice Nurse (APN) on the research team is strongly encouraged for all clinical studies to facilitate the eventual translation to practice and to develop the APN as a research team member. Interdisciplinary teams are encouraged.

**ELIGIBILITY:**

The principal investigator must be actively involved in some aspect of cancer patient care, education, or research. Preference will be given to early stage PhD and/or DNSc prepared researchers. If the PI has not received research funding of \$25,000, it is recommended that a senior researcher also be on the team or as a consultant. Funding preference is given to projects that involve nurses in the design and conduct of the research activity and that promote theoretically based oncology practice. Membership in ONS is not required for eligibility. Interdisciplinary research teams are encouraged.

**Individuals who have received previous Oncology Nursing Society Foundation research funding and have a delinquent final report are not eligible for funding. Oncology Nursing Society Foundation Board of Trustee members are also not eligible for funding.**

**FUNDING PERIOD:**

The maximum funding period is for two years from the receipt of the award.

Funding will be distributed for each year of the grant – **up to \$80,000 for year one and up to \$80,000 for year two.** A detailed budget for each year must be submitted with the application. First year funding will be available by July 2012.

**NO ‘no cost extensions’ are permitted.**

**GENERAL INSTRUCTIONS:**

- Applicants who are early in their research career and have not received previous research funding of greater than \$10,000, (junior investigator), must have a doctorally-prepared oncology nurse scientist as a co-investigator, who has received research grant awards of greater than \$25,000 (experienced investigator). Junior investigator applicants should work with a consultant to support content areas beyond their expertise. The consultant can also be helpful in providing an objective overall critique of the proposal. One of the goals of the ONS Foundation Major Research Grant Program is to support new researchers as they develop their programs of research and can then go on to submit grant proposals to other funding organizations. The National Institute of Health (NIH) and other funding organizations are increasingly emphasizing the importance of an interdisciplinary research team. The ONS Foundation Major Grant provides the opportunity to start building a research team. The ONS Foundation Research Department can provide assistance in finding a co-investigator or consultant.

**A LETTER OF INTENT is due 1 month prior to the application submission date and must be submitted via email. For instructions and the form, go to:**  
**<http://www.onsfoundation.org/apply/re/Adherence>**

- **APPLICATION FEE:** A non-refundable fee of \$50.00 is required at the time the application is submitted. This fee is used to offset the costs of processing the applications.  
**The application fee is to be paid through ONS e-Source at**  
**(<http://esource.ons.org/ProductDetails.aspx?sku=04GNAPPMRG>).**
- The application fee can be paid by credit card (Visa, M/C, Amex, or Discover). Upon receipt of payment, an email will be sent to the applicant with an, “Order Confirmation Number.” **This Confirmation Number will be requested during the online application submission process and must be entered in order to complete the submission.**

- **GRANT RE-SUBMISSIONS:** A previously non-funded proposal may only be resubmitted two times to the Oncology Nursing Society Foundation for consideration for funding. A cover letter is required if this application is a resubmission from any previous Oncology Nursing Society Foundation grant cycle (small grants, major grants, and fellowship programs). The resubmission cover letter form can be downloaded from the ONS Website at: <http://www.onsfoundation.org/apply/re/Adherence> .

The letter is limited to three pages and must be **uploaded** as part of your grant application. The letter must identify the type of previous award the investigator applied for, year of application, the major points described in the critique provided by the previous reviewers, and a description of how the current application was modified to address these points. All modifications to the study must be italicized within the body of the proposal.

- **Receipt of the application will be confirmed via e-mail.** If no response has been received within two days after the application deadline, contact the ONS Foundation Research Department at: Phone: **412/859-6298** or Email: [research@onsfoundation.org](mailto:research@onsfoundation.org)
- **Applications that are incomplete or not prepared according to the instructions will not be reviewed.**

## **INSTRUCTIONS FOR COMPLETION OF THE APPLICATION:**

### **ONLINE SUBMISSION INFORMATION:**

**Enter the following information as requested in the online submission.**

- **Application Fee Confirmation Number.** A fee of \$50.00 is required at the time the application is submitted (See *General Instructions above*). The application fee is to be paid through ONS E-Source at: <http://esource.ons.org/ProductDetails.aspx?sku=04GNAPPMRG>. An order confirmation number will be emailed to you upon receipt of payment. **This Confirmation Number will be requested during the online application submission process and must be entered in order to complete the submission.**
- **Grant Re-Submission.** Check the box on the title page section, if this is a resubmission and indicate the year of the previous submission and the type of grant for which you applied. Follow the instructions for **uploading** the resubmission cover letter.
- **Title of Project.** Limit to 65 characters.
- **Principal Investigator (PI).** Name the one individual who is primarily responsible for implementing this proposal and for reporting to the Oncology Nursing Society Foundation. Enter your position and institutional address. Also enter the home, work and fax phone numbers. The preferred mailing address and email address will be used for all future communications.
- **Total Budget Requested (U.S. Currency).** Budget requested should not exceed \$160,000. See the section entitled "Line Item Budget and Budget Narrative".
- **Dates of Project.** The project should be confined to a maximum of two years.
- **Research on Human/Animal Subjects.** The principal investigator must obtain approval from an Institutional Review Board (IRB) or Animal Welfare Committee if the proposed project pertains to human or animal research. The IRB must be registered with the office for Human Research Protections, DHHS and the assurance identification number must be provided as instructed in the application submission process. If approval has been received, list the approval date and **upload the approval letter**. If approval is pending, indicate this in the appropriate place in the submission process and **upload proof of submission to the IRB**. The application may be submitted with only IRB approval from the PI's institution for multi-institutional projects. However, confirmation of IRB approval at all sites is required before initiating any data collection activities. The PI should submit

the appropriate letters of approval from all sites to the ONS Foundation Research Department as received.

If the PI's institution does not permit IRB submission until notification of funding is received, indicate this by checking the appropriate box in the submission process.

*No funds will be released until IRB approval has been confirmed.*

- **Research Team.** Provide the names, credentials, institutions and role on the team, i.e., co-investigator, consultant, research assistant, statistician, for all members of the research team. Please enter this information as instructed for the online submission.
- **Immediate Supervisor/Chairperson.** This should be the Principal Investigator's immediate supervisor either in the clinical or academic setting. An email is needed from this person confirming approval of the proposed study. **Upload** the email message as instructed for the online submission.
- ◆ **Institutional Official.** This is usually the person in the organization's sponsored research office. Please include their name, credentials, address and contact information in the online submission form.
- ◆ **Acceptance of Terms and Responsibilities.** The applicant must read the research award agreement, included in the online application instructions, and enter his/her name as proof of acceptance of these terms and responsibilities.

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**ABSTRACT:** *(To be uploaded as a PDF document)*

At the top of the abstract page, list the title of the project; name of the applicant(s); name of mentor or advisor if applicable; institutional affiliation for each person identified; and if project is a pilot, or full study. The body of the abstract is limited to 500 words and should contain the following headings:

Purpose/Specific Aims, Rationale/ Significance of Study, Conceptual or Theoretical Framework, Main Research Variable(s), Design, Setting, Sample, Methods, and Implications for Practice. Limit the abstract to one page (500 words) and indicate the number of words in the abstract at the bottom of the page.

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**PROJECT NARRATIVE (APPROACH):** *(To be uploaded as a PDF document)*

The narrative (Purpose through Data Analysis) is not to exceed **12 single-spaced typewritten pages using a 12-point font** (preferably Times New Roman, Arial, or Courier) with ½ inch margins. The consistent use of one format (APA, AMA, etc.) for the text, citations and reference list is required. Please number all pages of the narrative.

**PRESENT THE INFORMATION IN THE FOLLOWING ORDER:**

**Purpose and Specific Aims.** Clearly state the purpose of the study and list specific aims in numerical sequence.

**Significance, Framework, and Review of Literature.**

- ◆ Explain the background of problem
- ◆ Describe the significance to oncology nursing. Animal studies must address how the research will contribute to the understanding of human responses and to advances in nursing science or clinical practice. Also address the following NIH criteria: Describe what will be the effect of this study on the concepts, methods, technologies, treatment, services or preventative interventions that drive oncology nursing.
- ◆ Identify and describe the conceptual or theoretical framework for the study.
- ◆ Present a succinct, focused, and critical review of the literature.

- ◆ Identify how the study will address a knowledge gap, including how it addresses the ONS Research Priorities and Research Agenda.

**Preliminary Work.** Describe any previous research that has been done on the topic by the PI or the research team and provide preliminary findings, if any.

**Methods and Design.** Use the following subheadings:

- ◆ **Design.** Identify the research design. Indicate if the project is a pilot study. Some reasons for conducting a pilot study include:
    - To determine the feasibility of a larger study
    - To develop or refine a nursing intervention
    - To develop a protocol or set of procedures for implementing an intervention
    - To identify design and methodologic problems
    - To determine if the sample is representative of a larger population or whether the sampling technique is effective
    - To test the reliability and validity of instruments and refine instruments or data collection procedures
    - To try out and refine data analysis techniques
  - ◆ **Sample and Settings.** For qualitative and quantitative studies, describe the number and type of participants and all sampling and assignment procedures. Indicate the rationale for the sampling process and sample size determination. If a power analysis was conducted to justify the sample size, include the results of this analysis. Describe the process for recruitment of participants. Acknowledge potential problem areas and include alternative strategies. **Provide a rationale for the use of the selected setting(s). This is especially important if the proposed study is a multi-site project.**
  - ◆ **Experimental Variables (experimental and quasi-experimental designs).** Describe the independent and dependent variables in sufficient detail to allow evaluation of its clinical soundness and operational definition. A more complete description of the intervention or experimental manipulation may be appended for further clarification.
  - ◆ **Instruments.** List and describe all instruments and include a discussion of the validity and reliability of each. If qualitative research, include information on the instrument's rigor. Describe scoring procedures. *Append a copy of all instruments and any permission letters.*
  - ◆ **Data Collection Schedule and Procedures.** Describe how and when data will be collected and any procedures for standardizing data collection.
  - ◆ **Data Analysis and Interpretation.** Describe the statistical or analytic techniques that will be used to answer each research question of the project.
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#### **OTHER COMPONENTS OF THE PROPOSAL SUBMISSION PROCESS:**

*(Not part of the 12-page narrative)*

**(You will be asked to provide 1-2 paragraphs addressing each of the following areas: (This information can be entered or uploaded in a PDF format)**

- **Protection of Human Subjects or Animals Used for Research.** Describe in 1-2 paragraphs (up to 300 words) how informed consent will be obtained and steps taken to protect participants' rights or the welfare of animals. Identify any potential risks associated with participation in the project. **Upload** in a PDF format in the designated area of the online application.

- **Women and Minority Inclusion in Clinical Research.** The inclusion of women and minorities must be addressed in developing a research design appropriate to the scientific objectives of the study. Inclusion is required unless a clear and compelling rationale shows that inclusion is inappropriate with the respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. Provide, in **1-2 paragraphs (up to 300 words)**, information on the composition of the proposed study population in terms of sex/gender and racial/ethnic group and provide a rationale for selection of such subjects in terms of the scientific objectives and proposed study design. The description may include (but is not limited to) information on the population characteristics of the disease or condition under study, national and local demography, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned study. **Upload** in a PDF format in the designated area of the online application.
- **Innovation.** Describe in **1-2 paragraphs (up to 300 words)** how the project challenges existing paradigms or clinical practice; addresses an innovative hypothesis or critical barrier to progress in the field. If applicable, describe how the project develops or employs novel concepts, approaches, methodologies, tools or technologies in the area. **Upload** in a PDF format in the designated area of the online application.
- **Facilities and Resources (Environment).** Describe in **1-2 paragraphs (up to 300 words)** the facilities and resources available to carry out the project at all research sites, e.g., computers, statistical and data management support, office space, equipment, etc. **Upload** in a PDF format in the designated area of the online application.
- **Implications for Practice and Research.** Describe the following in **1-2 paragraphs (up to 300 words)**. **Upload** in a PDF format in the designated area of the online application.
  - ◆ Describe the implications for oncology nursing practice.
  - ◆ Identify future research that may develop from this project.
  - ◆ Describe how this project will provide the groundwork for seeking additional funding in the future.

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## **APPENDICES (Not included as part of the 12-page narrative)**

***(The following items will all need to be uploaded as separate documents (PDF format). Follow the online submission instructions for each area.)***

- **Reference List.** The reference list should follow the format chosen for the project narrative (APA, AMA, Chicago, etc). **Upload** in a PDF format.
- **Timetable for Accomplishing the Work.** The timetable should reflect a realistic work schedule so the project can be completed within the funding period. **Upload** in a PDF format.
- **Human Protection Education.** It is an expectation of the Oncology Nursing Society Foundation that the researcher will incorporate, into the study proposal, key ethical principles and federal regulations to protect human participants or animals throughout the research process. The PI is required to include, in the appendices, a current certificate of completion from either the NIH Human Participant Protections Education for Research Course or a similar course available at a university. The NIH course is available at <<http://ohsr.od.nih.gov>>. If animal subjects are involved, documentation of animal participant protections education must be **uploaded**.

Documentation of human or animal participant protections education for all key personnel (all individuals responsible for the design and conduct of the study, including PI, co-investigators and data collectors) must be **uploaded** after the funding notification is received. However, it is encouraged that education documentation for key personnel be submitted with the application.

- **Letters of Support.** Include letters of support from key administrators, agency personnel, and consultants, as necessary. Letters of support should document access to performance sites and research participants, institutional resources committed to the project, and matching funds, if any. Consultants should describe their role and involvement with the research project. All letters of support should be **uploaded in a PDF format**. The system will only allow for uploading one document. Therefore, multiple letters of support will need to be scanned into one PDF document prior to uploading.
- **Mandatory Letters of Support:**
  - **Salary Support or in-kind Personnel.** If requesting salary support OR in-kind time support for the PI or Co-PI, a letter must be submitted from the individual's immediate supervisor that gives assurance that release time will be provided from existing job responsibilities. The percentage of release time must reflect the percentage of salary support requested in the budget and/or in-kind personnel contributions.
  - **ONS sponsored projects** must include a letter(s) of support from the project team leader or SIG chairperson.
  - **ONS Chapter President** must provide a letter of support if the chapter is submitting a grant.
- **Biographical Sketches. (INVESTIGATORS)** Use the USPHS Form 398 (6/09) biographical sketch form. Submit a biosketch for the PI and any key participants, e.g., all co-investigator(s), consultant(s), clinician collaborators and mentors. *Each biosketch is limited to 2-4 pages.* Biosketches must be **uploaded**. The system will only allow for uploading one document. Therefore, multiple biosketches will need to be scanned into one PDF document prior to uploading.
- **Instrument(s).** Include all instruments or interview schedules that will be used to collect data. Include any letters of permission to use a copyrighted instrument. These may be **uploaded** during the online submission process, if applicable. Multiple documents will need to be scanned into one PDF prior to uploading
- **Consent Form.** Include a copy of the consent form that will be presented to potential subjects for their signature. These may be **uploaded** during the online submission process, if applicable. Multiple documents will need to be scanned into one PDF prior to uploading.
- **Miscellaneous.** Miscellaneous items include conceptual models, diagrams, a detailed description of an intervention or intricate laboratory procedure, list of performance sites, etc. These may be **uploaded** during the online submission process, if applicable. Multiple documents will need to be scanned into one PDF prior to uploading.

## **BUDGET ISSUES:**

### **The ONS Foundation Does Not Fund The Following:**

- ◆ Projects that have begun data collection or projects that are nearly completed
- ◆ Payment of tuition
- ◆ Travel for conference attendance or presentations
- ◆ Printing of theses or dissertations

### **Distribution of Award Funds**

A maximum of up to \$80,000 will be distributed the first year and the remaining amount, up to \$80,000, will be available for distribution the following year, upon receipt and approval of an annual report on or after July 15, 2013.

**Line Item Budget.** Research project-related expenses may be itemized using the budget worksheet provided. One two-year line item budget may be submitted for the entire project or separate budgets are permitted from each performance site. Consortium or contractual arrangements and costs should be itemized.

A total budget for a maximum award of up to \$160,000 should be submitted, including both direct expenses and indirect institutional allowances up to 10%. Items labeled as miscellaneous will not be funded. The line item budgets should include the following items:

- ◆ **Personnel:** All project personnel, consultants, & clerical support on a personnel sheet or USPHS Form 398. Include the name, position, % time devoted to project, fringe benefit percent and amount, total fringe requested, and total salary requested. If in-kind contributions of personnel are relevant, please include percentage of time and role.
- ◆ **Supplies:** Supplies are defined as items with a unit cost of \$500 or less. Examples include: photocopying, telephone, postage, computer time, paper, envelopes, transcription machines, cassette tapes, floppy disks, etc.
- ◆ **Equipment:** Equipment is defined as items with a unit cost greater than \$500.
- ◆ **Software:** Include the name, version number, and unit cost.
- ◆ **Other Expenses:** Do not list as miscellaneous. These must be listed very specifically, i.e., lab fees or supplies, lab assays, standardized testing, or reimbursement of study participants.
- ◆ **Other Support:** Identify total amount of other sources of funding for the study. Specify source, amount and funding period.
- ◆ **Total Funds Requested**

**Budget Justification.** The justification is a description that includes a rationale for *all itemized expenses* including personnel. Each section of the justification should: (1) list the specific items or project personnel noted below, (2) describe why the items or personnel are *essential* to the conduct of the study, and (3) include any cost calculations. The lack of institutional resources for particular items should be described. One budget justification may be submitted for the entire project or separate justifications from each performance site.

- ◆ **Personnel.** A description of the activities and role of each person involved in the project including the principal investigator, co-investigators, consultants, research assistants, secretaries, data collection and data management staff, statistician, curriculum development personnel, etc. Include the % time devoted to the project by each person.
- ◆ **Equipment.** Equipment requests should not represent a major portion of the budget or the only budget item. The justification for equipment requests should: (1) identify the availability of matching funds, if any, or other funds that will contribute to the purchase of the item, (2) explain why the item is absolutely essential to the study, (3) identify where the equipment will be housed during and after the completion of the study, and (4) list the expected depreciation of the item over a 2 year period and the estimated value of the item 2 years after purchase. Ownership of the item at the completion of the study will be individually assessed.
- ◆ **Travel.** Only reasonable travel for data collection will be considered. Specify the purpose, personnel involved, distance, number of trips, mode of travel, and cost of travel.
- ◆ **Software.** Request software only if the institution does not provide it. Software purchases will be considered if the unit price reflects the current discounted or retail rate.

- ◆ **Other Support.** Identify any additional funding that has already been awarded for the proposed study, including any funding obtained by a co-investigator. Explain how the work supported by other sources is different from the present request. Overlaps in funding are generally not funded unless it is convincingly explained how the present award is designed to support a portion of the project that is not covered by the overlapping funds.
- ◆ **Pending Funding.** If there is other pending funding for the proposed project, identify the amount, agency, and date the funding is expected to be initiated, if awarded. Explain how the present award will be adjusted if funding is received from more than one pending source, e.g., one of the awards will be turned down, more performance sites will be added, the sample size will be increased, additional staff will be hired, etc. Please notify the ONS Foundation Research Department of any additional funding that is awarded after the submission deadline. If no additional funding is available or pending for the project, write “Not Applicable” in this section of the justification. The USPHS Form 398 Page entitled, “Other Support” may be submitted.

**APPLICATION SUBMISSION COMPONENTS:**

<b><u>Submission includes the following:</u></b>
<ul style="list-style-type: none"> <li>• <b>\$50.00 Application Fee (Confirmation Number:</b> Upon receipt of payment at the <u>ONS eSource site</u> at: (<a href="http://esource.ons.org/ProductDetails.aspx?sku=04GNAPPMRG">http://esource.ons.org/ProductDetails.aspx?sku=04GNAPPMRG</a>), an email will be received with a confirmation number. This number must be entered during the online submission process.</li> </ul> <p><b>Note:</b> <i>You will not be able to complete your submission until this number has been entered.</i></p>
<ul style="list-style-type: none"> <li>• <b>Resubmission Cover Letter</b> (only if this application is a resubmission)</li> </ul>
<ul style="list-style-type: none"> <li>• <b>IRB or animal welfare committee approval letter, proof of submission to IRB:</b> (If IRB is to be submitted upon notification of funding, you will be able to indicate this during the submission process).</li> </ul>
<ul style="list-style-type: none"> <li>• <b>Email from immediate Supervisor/Chairperson:</b> (confirming approval of the proposed study) This email will need to be uploaded during the submission process.</li> </ul>
<ul style="list-style-type: none"> <li>• <b>Abstract</b> (1-page, 500 words) <i>(To be Uploaded in a PDF format)</i></li> </ul>
<ul style="list-style-type: none"> <li>• <b>Project Narrative:</b> 12 typewritten, single-spaced and numbered pages <i>(To be uploaded in a PDF format)</i></li> </ul>

<b><u>As part of the online submission process, you will be asked to either enter or upload text on the following areas:</u></b> (See page 7 for details on the following areas)
<b><u>NOTE:</u></b> <i>The following areas are all part of the evaluation criteria for the reviewers.</i>
<ul style="list-style-type: none"> <li>• <b>Protection of Human Subjects or Animals Used for Research:</b> Upload a PDF document providing 1-2 paragraphs (up to 300 Words) on informed consent and participants' rights.</li> </ul>
<ul style="list-style-type: none"> <li>• <b>Women and Minority Inclusion in Clinical Research:</b> Upload a PDF document providing 1-2 paragraphs (up to 300 Words) with information on the population composition.</li> </ul>
<ul style="list-style-type: none"> <li>• <b>Innovation:</b> Upload a PDF document providing 1-2 paragraphs (up to 300 Words) on how the project challenges existing paradigms or clinical practice.</li> </ul>
<ul style="list-style-type: none"> <li>• <b>Facilities and Resources (Environment):</b> Upload a PDF document providing 1-2 paragraphs (up to 300 Words) on the available facilities and resources.</li> </ul>
<ul style="list-style-type: none"> <li>• <b>Implications for Practice and Research:</b> Upload a PDF document providing 1-2 paragraphs (up to 300 Words) on the implications for oncology nursing practice.</li> </ul>

**The following documents will need to be Uploaded in a PDF format.**

- Reference List:
- Timetable:
- Certificate of completion of a human participants protection education course: *(All certificates are to be uploaded in a PDF format)*
- Support letters: *(All letters are to be scanned into one PDF document prior to uploading)*
- Biographical sketches: One will be needed for each member of the research team (Use a PHS Form 398) or download from the forms area at the bottom of the following ONS Website (<http://www.onsfoundation.org/apply/re/Adherence>). *(All biosketches are to be scanned into one PDF document prior to uploading)*
- Instrument(s): *(Multiple documents will need to be scanned into one PDF document prior to uploading)*
- Consent Form(s): *(Multiple documents will need to be scanned into one PDF document prior to uploading)*
- Miscellaneous: Upload any other documents needed in a PDF format. *(Multiple documents will need to be scanned into one PDF document prior to uploading)*
- Itemized Budget: (Use attached Budget Worksheet or download from the forms area at the bottom of the following ONS Website (<http://www.onsfoundation.org/apply/re/Adherence>)).
- Budget Justification:

Research Classification Categories: Review the categories below and be prepared to indicate the appropriate areas that pertain to your study during the submission process.

**SUBMISSION INSTRUCTIONS:**

**All application submissions must be finalized by 11:59 p.m. on April 16, 2012.**

Detailed instructions of the online application submission process and the link to access the online application can be found or downloaded from: <http://www.onsfoundation.org/apply/re/Adherence>

**NOTE:** Investigators are encouraged to review all submitted materials for completeness and accuracy **PRIOR** to hitting "Submit" as **no** editing will be allowed once the application submission is completed.

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## **EXPECTATIONS FOR RECIPIENTS:**

- **PROGRESS AND FINAL REPORTS:**

For all funded projects, annual progress reports are required. A final report of expenditures and a final scientific report **must** be submitted to the ONS Foundation Research Department, 60 days following the original project funding period.

**No “no cost extensions” are permitted.**

Guidelines for submitting these reports are provided to all grant recipients. Unexpended funds revert to the ONS Foundation. Please note, the final report guidelines request a summary of results and abstract suitable for posting online to promote dissemination of findings to practicing nurses and the lay public.

Recipients also agree to complete a follow-up survey at one, three, and five years after the completion of the funding project. The purpose of the survey is to track dissemination activities and additional funding which have occurred related to the ONS Foundation funded project.

- **ACKNOWLEDGEMENT OF FUNDING:**

Investigators **must** acknowledge that this research was funded by the **ONS Foundation through an unrestricted grant from Research Consortium Partners: GlaxoSmithKline and Novartis Pharmaceuticals Corporation** in all publications and presentations regarding their research.

- **DISSEMINATION OF RESULTS:**

The ONS Foundation is committed to the dissemination of research findings to support practice changes. A summary of results and final abstract will be posted online and shared with the ONS Public Relations Manager to promote dissemination of results from ONS Foundation funded projects. Publication of project results in peer-reviewed scientific or professional journals is expected. Funding recipients are encouraged to submit ONS Congress abstracts and to publish their final results in the *Oncology Nursing Forum* or *Clinical Journal of Oncology Nursing*.

- **INCOME TAX CONSIDERATIONS:**

The ONS Foundation is required by the Internal Revenue Service to report grant awards on Form 1099-Misc. The award recipient's institution will receive an IRS 1099-Misc. form no later than January 31 of the year following each year of funding. If additional compensation is received from the award recipient's employer/institution regarding this award, then it is their responsibility to issue to the recipient a W-2 or Form 1099-Misc. Award recipients will be asked to designate how the funds should be distributed at the time the award is made.

## Oncology Nursing Society Foundation Research Classification Form

**INSTRUCTIONS:** As part of the online submission, you will be asked to check which of the following categories best describe the purpose and aims of your research proposal. This form will be provided online and does not need to be completed in this format. It is simply provided for your information and review, so that you can easily select the appropriate areas during the submission process.

This information is needed by the Oncology Nursing Society Foundation to share with other cancer research funders who classify their research portfolios in the same way. This information is provided to the public on the International Cancer Research Portfolio Website at [www.cancerportfolio.org](http://www.cancerportfolio.org). Funded studies that have been classified using this unified classification system, the Common Scientific Outline, are available on the website. Additional information on this form is needed for the Oncology Nursing Society Foundation's Grants Database.

### **Biology:**

- 1.1 Normal functioning
- 1.2 Cancer initiation: alterations in chromosomes
- 1.3 Cancer initiation: oncogenes & tumor suppressor genes
- 1.4 Cancer progression & metastasis
- 1.5 Resources & infrastructure

### **Etiology:**

- 2.1 Exogenous factors in the origin and cause of cancer
- 2.2 Endogenous factors in the origin and cause of cancer
- 2.3 Interactions of genes and/or genetic polymorphisms with exogenous and/or endogenous factors
- 2.4 Resources & infrastructure related to etiology

### **Prevention:**

- 3.1 Interventions to prevent cancer: personal behaviors that affect cancer risk
- 3.2 Nutritional science in cancer prevention
- 3.3 Chemoprevention
- 3.4 Vaccines
- 3.5 Complementary & alternative prevention approaches
- 3.6 Resources & infrastructure related to prevention

### **Early Detection, Diagnosis & Prognosis:**

- 4.1 Technology development and/or marker discovery
- 4.2 Technology and/or marker testing in a clinical setting
- 4.3 Technology and/or marker evaluation with respect to fundamental parameters of method
- 4.4 Resources & infrastructure related to detection, diagnosis or prognosis

### **Treatment:**

- 5.1 Localized therapies- discovery and development
- 5.2 Localized therapies - clinical applications
- 5.3 Systematic therapies - discovery and development
- 5.4 Systematic therapies - clinical applications
- 5.5 Combinations of localized & systemic therapies
- 5.6 Complementary & alternative treatment approaches
- 5.7 Resources & infrastructure related to treatment

### **Cancer Control, Survivorship & Outcomes Research:**

- 6.1 Patient Care and Survivorship Issues (note: this includes symptom management and quality of life)
- 6.2 Surveillance
- 6.3 Behavior
- 6.4 Cost analyses & health care delivery
- 6.5 Education and communication
- 6.6 End of life care
- 6.7 Ethics & confidentiality in cancer research
- 6.8 Complementary & alternative approaches for supportive care of patients & survivors
- 6.9 Resources & infrastructure related to cancer control, survivorship & outcomes research

## Oncology Nursing Society Foundation Research Classification Form

<b>Scientific Model Systems:</b>	
<input type="checkbox"/>	7.1 Development & characterization of model systems
<input type="checkbox"/>	7.2 Application of model systems
<input type="checkbox"/>	7.3 Resources & infrastructure related to scientific model systems

<b>Other:</b>	
<input type="checkbox"/>	Long-term Morbidity
<input type="checkbox"/>	Quality of Life
<input type="checkbox"/>	Pain Management
<input type="checkbox"/>	Prevention of Treatment Related Toxicities
<input type="checkbox"/>	Psychological Impacts of
<input type="checkbox"/>	Cancer
<input type="checkbox"/>	Reproductive Issues
<input type="checkbox"/>	Rehabilitation
<input type="checkbox"/>	Symptom Management
<input type="checkbox"/>	Survivorship
<input type="checkbox"/>	None

<b>Symptom Management:</b>	
<input type="checkbox"/>	Difficulty Concentrating
<input type="checkbox"/>	Fatigue
<input type="checkbox"/>	Hair Loss
<input type="checkbox"/>	Mucositis
<input type="checkbox"/>	Nausea
<input type="checkbox"/>	Pain
<input type="checkbox"/>	Shortness of Breath
<input type="checkbox"/>	Sleep Disturbances
<input type="checkbox"/>	None
<input type="checkbox"/>	Other

<b>Treatment Type:</b>	
<input type="checkbox"/>	Biotherapy
<input type="checkbox"/>	Chemotherapy
<input type="checkbox"/>	Radiation Therapy
<input type="checkbox"/>	Surgery
<input type="checkbox"/>	Transplant
<input type="checkbox"/>	Other
<input type="checkbox"/>	None

<b>Cancer Type:</b>	
<input type="checkbox"/>	Basic Research, not site specific
<input type="checkbox"/>	Bladder Cancer
<input type="checkbox"/>	Brain Tumor
<input type="checkbox"/>	Breast Cancer
<input type="checkbox"/>	Cervical Cancer
<input type="checkbox"/>	Endometrial Cancer
<input type="checkbox"/>	Esophageal Cancer
<input type="checkbox"/>	Gall Bladder Cancer
<input type="checkbox"/>	Hodgkin's Disease
<input type="checkbox"/>	Kaposi's Sarcoma
<input type="checkbox"/>	Kidney Cancer
<input type="checkbox"/>	Laryngeal Cancer
<input type="checkbox"/>	Liver Cancer
<input type="checkbox"/>	Lung Cancer
<input type="checkbox"/>	Nasal Cavity & Paranasal Sinus Cancer
<input type="checkbox"/>	Neuroblastoma
<input type="checkbox"/>	Non-Hodgkin's Lymphoma
<input type="checkbox"/>	Oral Cavity & Lip Cancer

**Oncology Nursing Society Foundation  
Research Classification Form**

<b>Cancer Type (Continued):</b>	
<input type="checkbox"/>	Ovarian Cancer
<input type="checkbox"/>	Pancreatic Cancer
<input type="checkbox"/>	Parathyroid Tumor
<input type="checkbox"/>	Penile Cancer
<input type="checkbox"/>	Pharyngeal Cancer
<input type="checkbox"/>	Pituitary Tumor
<input type="checkbox"/>	Prostate Cancer
<input type="checkbox"/>	Salivary Gland Cancer
<input type="checkbox"/>	Small Intestine Cancer
<input type="checkbox"/>	Soft Tissue Sarcoma
<input type="checkbox"/>	Stomach Cancer
<input type="checkbox"/>	Testicular Cancer
<input type="checkbox"/>	Thymoma, Malignant
<input type="checkbox"/>	Thyroid Cancer
<input type="checkbox"/>	Uterine Cancer
<input type="checkbox"/>	Vascular Sarcoma
<input type="checkbox"/>	Vaginal Cancer
<input type="checkbox"/>	Wilm's Tumor
<input type="checkbox"/>	None

<b>Age:</b>	
<input type="checkbox"/>	Adult
<input type="checkbox"/>	Children
<input type="checkbox"/>	Elderly
<input type="checkbox"/>	Combination
<input type="checkbox"/>	None

<b>Gender Focus:</b>	
<input type="checkbox"/>	Male
<input type="checkbox"/>	Female
<input type="checkbox"/>	Both
<input type="checkbox"/>	None

<b>Type of Research:</b>	
<input type="checkbox"/>	Qualitative
<input type="checkbox"/>	Quantitative
<input type="checkbox"/>	Both
<input type="checkbox"/>	None

<b>Research Setting:</b>	
<input type="checkbox"/>	Multisite
<input type="checkbox"/>	NCI
<input type="checkbox"/>	Cooperative Group
<input type="checkbox"/>	Single Site

<b>Scope:</b>	
<input type="checkbox"/>	International
<input type="checkbox"/>	Local
<input type="checkbox"/>	National
<input type="checkbox"/>	None

<b>Subject:</b>	
<input type="checkbox"/>	Animal
<input type="checkbox"/>	Cancer Patient
<input type="checkbox"/>	Cancer Survivor
<input type="checkbox"/>	Family/Caregiver
<input type="checkbox"/>	Nurses
<input type="checkbox"/>	Other Healthcare Provider

**Oncology Nursing Society Foundation  
Research Classification Form**

<b>Subject (Continued):</b>
<input type="checkbox"/> Other
<input type="checkbox"/> None Quantitative

<b>Ethnicity Focus:</b>
<input type="checkbox"/> American Indian/Alaskan Native
<input type="checkbox"/> Asian
<input type="checkbox"/> Black or African American
<input type="checkbox"/> Hispanic or Latino
<input type="checkbox"/> Native Hawaiian or Other Pacific Islander
<input type="checkbox"/> White

<b>Research Design:</b>
<input type="checkbox"/> Descriptive
<input type="checkbox"/> Health Services
<input type="checkbox"/> Interventional
<input type="checkbox"/> Program Evaluation
<input type="checkbox"/> Research Utilization/Evidence-Based Practice
<input type="checkbox"/> None

<b>2008 ONS Research Priorities:</b>
<input type="checkbox"/> Quality of Life
<input type="checkbox"/> Pain
<input type="checkbox"/> Late effects of treatment
<input type="checkbox"/> Access to care
<input type="checkbox"/> Palliative care
<input type="checkbox"/> Palliative care decision making
<input type="checkbox"/> Neuropathy
<input type="checkbox"/> Coping
<input type="checkbox"/> End of life
<input type="checkbox"/> Stress management
<input type="checkbox"/> Diet/nutrition
<input type="checkbox"/> Screening/early detection
<input type="checkbox"/> Treatment decision making
<input type="checkbox"/> Fatigue
<input type="checkbox"/> Caregiving
<input type="checkbox"/> Cancer recurrence
<input type="checkbox"/> Continuum of care
<input type="checkbox"/> Family adjustment to cancer
<input type="checkbox"/> Functional Impairment
<input type="checkbox"/> Mucositis
<input type="checkbox"/> None

<b>ONS Research Agenda Content Areas (2009-2013):</b>
<input type="checkbox"/> <b>Health Promotion</b>
<input type="checkbox"/> Health behavior interventions
<input type="checkbox"/> Health screening interventions
<input type="checkbox"/> <b>Cancer Symptoms and Side Effects</b>
<input type="checkbox"/> Causal pathways, outcomes, measure development, interventions
<input type="checkbox"/> Systems of care that integrate symptom management
<input type="checkbox"/> <b>Late Effects of Treatment &amp; Survivorship</b>
<input type="checkbox"/> Interventions to decrease long-term/late effects of cancer treatment
<input type="checkbox"/> Delivery of high quality care to survivors
<input type="checkbox"/> <b>End of Life Issues</b>
<input type="checkbox"/> Symptom management at end of life
<input type="checkbox"/> QOL at end of life

**Oncology Nursing Society Foundation  
Research Classification Form**

<input type="checkbox"/> <b>Individual &amp; Family Psychosocial Research</b>
<input type="checkbox"/> Psychosocial Outcomes
<input type="checkbox"/> Impact of high risk for cancer
<b>ONS Research Agenda Content Areas (2009-2013) (Continued):</b>
<input type="checkbox"/> <b>Nursing-Sensitive Patient Outcomes</b>
<input type="checkbox"/> Adherence to treatment interventions
<input type="checkbox"/> Relationship between physical functioning and outcomes (including falls)
<input type="checkbox"/> <b>Translational Research</b>
<input type="checkbox"/> Implementation science methods and techniques
<input type="checkbox"/> Refine interventions with demonstrated effectiveness to targeted interventions

## ONS FOUNDATION

### TIPS FOR GRANT PREPARATION

- ◆ If you are early in your research career, i.e., this is your first or second grant submission; you must find a doctorally-prepared oncology nurse scientist who is an expert in your content area to work with you as a co-investigator. If you are having trouble finding a co-investigator, the ONS Foundation Research Department can assist you in finding one.
- ◆ If you are a junior investigator, a consultant should be selected to support content areas beyond your expertise. They also can be helpful in providing an objective overall critique of the proposal. If you are having trouble finding a consultant, the ONS Foundation Research Department can assist you in finding one.
- ◆ Use your consultant to help you develop and critique the proposal. Incorporating their suggestions in the final grant can strengthen proposals. Choose a consultant wisely. They should be known, i.e., have publications or presentations in the content area of the grant. A useful strategy is to have them read and critique the proposal in the early, formative stages.
- ◆ Use the grant application and instructions as your road map. Read and follow them carefully--in the beginning, in the middle, and at the very end--to be sure that you have followed the rules and have not forgotten anything that pertains to your particular study.
- ◆ A full-scale study is often proposed when a pilot study would be far more appropriate. A pilot study is useful to determine an effect size; assess the feasibility of a design, instrument, or method; as well as to assess the safety, acceptability, side effects and compliance with an intervention. If you are proposing a pilot study, keep your aims, method, and analysis consistent with the intent of a pilot study. For example, don't propose statistical hypotheses testing when you really are trying to estimate variance and effect size.
- ◆ Be sure to make a compelling case regarding why the study is significant to oncology nursing even if the relevance may seem obvious to you. Animal studies must also address relevancy.
- ◆ Use the biosketches to highlight the expertise of the investigators and consultants. Include those studies and/or publications relevant to the area of the study itself. If there is still room, include oncology related material. Do not exceed the two-page limit by attaching resumes or curriculum vitae.
- ◆ Make your presentation pleasant to look at and to read. Use a clean style font no less than 12 characters per inch. Do not use a dot matrix printer. Use subheadings, tables, figures, and other creative approaches to present your work. Do not disregard the rules and put off the reviewers by adjusting the margins or decreasing the font to squeeze in more content.
- ◆ Write clearly in an organized fashion using active voice and non-sexist language. Use an editor to help you with your writing and punctuation. Typographical errors and misspellings reflect poorly on your attention to detail.
- ◆ Use your appendices to support, not replace, the body of the proposal. Weight does not increase the value of your work, as your reviewer has to carry and read all of the appendices. Be as purposeful in developing your appendices as you are in preparing your narrative.
- ◆ Make sure your support letters are written specifically about your proposal and your work. Be cautious with generic letters that show that the writer has little knowledge of your proposal. Provide support letters that address specific types of support such as release time, space, equipment, statistical support, or access to a patient population.
- ◆ Only request allowable budget expenses. Justify your budget carefully. The reviewer should be able to comprehend why the expenditure is needed and how you reached each calculation.
- ◆ Check your own work looking for fatal flaws such as inadequate sample size, low significance to oncology nursing, or projects with too large of scope. Ask your colleagues to review it and offer constructive feedback. Your proposal must show that your research is significant; "do-able" with the resources, budget, and time frame allowed; as well as scientifically sound.
- ◆ Check the integrity of your proposal for your own purposes. Draw a diagram identifying the purpose, specific aims, concepts and interrelationships, design, sample, variables, instruments, and data analysis plan. Are the various components consistent and appropriate? Are there any holes or gaps in the project that may result in a fatal design flaw? Have you adequately developed a thread(s) to connect each specific aim to the other sections of the proposal? Have you lost anything or have you added something that is unrelated to your aims? Have you justified your choice of methods or measures where alternatives may be available? Stay focused.
- ◆ Make sure you differentiate between ethnicity and culture. Cross-culture research goes beyond the translation of tools. If you are planning a study in which you address such issues, seek consultation.

**If questions or concerns arise about the feasibility of the study ideas or the mechanics of preparing the application and budget, the ONS Foundation Research Department can provide assistance or referral.**



**ONS Foundation Adherence to Oral Chemotherapeutic  
Agents Research Grants**  
(RE37)

*Research Consortium Partners: GlaxoSmithKline and  
Novartis Pharmaceuticals Corporation*

Level of Funding: One \$160,000 Research Grant

**FORMS NEEDED**

- ◆ *Biographical Sketch Form*
- ◆ *Budget Worksheet*
- ◆ *Resubmission Cover Letter*  
*(only if proposal is being resubmitted)*

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Principal Investigator/Program Director (Last, First, Middle):

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### **BIOGRAPHICAL SKETCH**

Provide the following information for the senior/key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

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NAME		POSITION TITLE	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY

**NOTE:** The Biographical Sketch may not exceed four pages. Items A and B (together) may not exceed two of the four-page limit. Follow the formats and instructions on the attached sample.

- A. Personal Statement.** Briefly describe why your experience and qualifications make you particularly well-suited for your role (e.g., PD/PI, mentor) in the project that is the subject of the application.
- B. Positions and Honors.** List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.
- C. Peer-reviewed publications or manuscripts in press (in chronological order).** Limit the list of selected peer-reviewed publications or manuscripts in press to no more than 15. Do not include manuscripts submitted or in preparation. The individual may choose to include selected publications based on recency, importance to the field, and/or relevance to the proposed research.
- D. Research Support.** List both selected ongoing and completed (during the last three years) research projects (Federal or non-Federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and your role in the research project. Do not list award amounts or percent effort in projects.

Principal Investigator/Program Director (Last, First, Middle):											
<b>Oncology Nursing Society Foundation Adherence to Oral Chemotherapeutic Agents Grant</b>											
<b>BUDGET WORKSHEET</b>											
	<b>Year 1</b>					<b>Year 2</b>					<b>Grand Totals</b>
	<b>Salary</b>		<b>Fringe</b>		<b>Year 1 Total</b>	<b>Salary</b>		<b>Fringe</b>		<b>Year 2 Total</b>	
	% Effort	\$	%	\$		% Effort	\$	%	\$		
<b>Personnel</b>											
<b>Supplies</b>											
<b>Equipment</b>											
<b>Travel</b>											
<b>Software</b>											
<b>Other Expenses</b>											
<b>TOTAL</b>											

(See application instructions for a detailed description of each budget category)

**Note:** The budget justification must include a justification of all of the above itemized expenses including personnel. Each section of the justification should describe why the items or personnel are essential to the conduct of the study. The lack of institutional resources for particular items should be described.

**Note:** If the study cannot be completed with the funds requested, it is essential to report "Other Support" to demonstrate how the remaining costs will be covered to assure that the study can be done.



**ONS Foundation Research Grants Program**

**GRANT RE-SUBMISSION COVER LETTER**

**Grant Resubmission Instructions:** A previously non-funded proposal may only be resubmitted 2 times to the ONS Foundation for consideration for funding. A cover letter is required if this application is a resubmission from any previous ONS Foundation grant cycle (small grants, major grants, or fellowship award). **The letter is limited to 3 pages** and must be uploaded with the online application submission in a PDF format. All modifications to the study must be *ITALICIZED* within the body of the proposal.

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**Year of Previous Application:** \_\_\_\_\_

**Type of Award Applied for:** \_\_\_\_\_

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**List the weaknesses described in the critique provided by the previous reviewers and how you have modified the proposal to address these weaknesses:**