

CLINICAL RESEARCH GUIDE

The goal of this concise guide is to assist faculty, practicing physicians, and medical students in conducting clinical research. Summarized below, are the various steps involved in successfully translating an idea to a well-developed research project.

Step 1: Develop an idea and formulate a hypothesis

Coming up with an innovative idea is the first step. The idea should be focused (Start Small!), feasible, thought-provoking and contribute new information to the medical knowledge base. A research hypothesis should then be formulated. Based on your hypothesis, a list of specific aims can be developed to test your hypothesis.

RESOURCES FOR STEP 1

You can contact one of the following personnel to help develop your idea, hypothesis and specific aims.

a. R. V. Balaji: 593-2304

b. Chris Knisely: 593-2214

c. Jay Shubrook: 593-2137

d. Good Practices in Clinical drug trials: <http://www.fda.gov/oc/gcp/default.htm>

Step 2: Perform a thorough literature review

A complete and thorough literature search is important:

- to learn about other ongoing and completed research in your area
- to ascertain that your hypothesis has not been tested already by other researchers
- to build your case for funding requests

Databases differ in their record size, search capabilities and research topics; hence, it may be a good idea to search in more than one journal database to make sure that your literature is thorough.

RESOURCES FOR STEP 2

a. Satellite Library at Irvine 190 (593-0799): Contact Susan Foster-Harper or Debra Orr

b. Learning Resource Center: Contact Bobbi Conliffe (593-2297)

c. Online search databases:

- PubMed: <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi>

- E-Journal Gateway: <http://www.library.ohiou.edu/find/articles-ejg.html>

- Health and Medicine Databases @ Alden:

<http://infotree.library.ohiou.edu/byform:articledb/health-and-life-sciences/medicine/>

Step 3: Search for funding opportunities

FUNDING OPPORTUNITIES @ OU / OUCOM:

a. OU Research Committee (OURC): Seed money is available for new projects or for projects where no other funding is available. Priority is placed on supporting faculty who are new to OU. See:

www.ohiou.edu/research/fundingsources.html for eligibility and evaluation criteria. Deadline – End of January

b. Baker Fund Awards: Request for proposals for the Baker Fund Awards are typically released in the winter quarter. All regular tenured and tenure-track members of the faculty and full-time continuing administrative staff are eligible to submit proposals in any field of study. See: www.ohiou.edu/research/fundingsources.html for eligibility and evaluation criteria. Deadline – Mid-January

c. RSAC: The Research & Scholarly Affairs Committee (RSAC) releases a call for proposals annually. All proposals have to go through an application and review process. The selected proposals will be awarded up to \$6,500 (small award) or \$25,000 (large award) as seed money. In addition to support for research projects, RSAC also awards funds for travel, publications and statistical support. Proposals requesting these funds can be submitted on an as-needed basis. Please contact Gillian Ice (Chair, 593-2128) for questions about RSAC awards. Deadline – Mid-April

d. RSAF: Funds for second year medical students in the form of stipends are available through the Research and Scholarly Advancement Fellowship (RSAF) to work with faculty mentors on research projects. Contact R. V. Balaji (593-2304) for details about the fellowship. Deadline – end of January

RESOURCES FOR STEP 3

a. Chris Knisely: 593-2214 & R.V. Balaji: 593-2304

- b. ORG's online funding request form: http://www.oucom.ohiou.edu/r&g/funding_search_request.htm
- c. Susan Loughridge @ ORSP: 593-0374
- d. SPIN: http://spin2000.infoed.org/new_spin/spinmain.asp

Step 4: Develop a strong research team

A proposal can be significantly strengthened by collaborating with OU faculty or faculty from other institutions. Having well-qualified collaborators with complementary skills will further strengthen your grant proposal.

RESOURCES FOR STEP 4

- a. Chris Knisely: 593-2214, Jay Shubrook: 593-2137 & R.V. Balaji: 593-2304

Step 5: Apply for a grant

RESOURCES FOR STEP 5

- a. **RSAC REVIEW:** Members of the Research and Scholarly Affairs Committee (RSAC) can review your proposal and provide valuable feedback. This will improve the quality of your proposal and improve the chances of funding. For more details visit:

<http://www.oucom.ohiou.edu/r&g/Internal%20Grant%20Review%20Process.pdf>

- b. Transmittal form: http://www.ohiou.edu/orsp/orsp_transmittal.htm

Note: Allow sufficient time for the transmittal form and the budget to be processed by ORSP; this way, any changes required by ORSP can be made well ahead of the deadline. Proposals whose transmittal forms and budgets have not been processed (as indicated by Shane Gilkey's signature on the transmittal form) cannot be submitted.

- c. Budget Template: <http://www.ohiou.edu/orsp/budget/budaid.html>

- d. Contact Chris Knisely (593-2214) and R. V. Balaji (593-2304) to seek assistance in the grant application process

- e. Proposal preparation FAQ: <http://www.ohiou.edu/orsp/budget/faq.html>

Step 6: Approach the Institutional Review Board (IRB) for approval

All research projects dealing with human subjects need prior approval from the IRB. *****No part of the project can be started prior to receiving the formal approval notice from the IRB*****. For timely approval, the following steps are recommended:

- a) Request a lay individual (non-clinical or non-scientific) to read your IRB proposal;
- b) If possible, be present at the IRB meeting or be available by phone;
- c) Take advantage of the Pre-review system;
- d) Plan ahead of time and check the IRB meeting schedule (see link below)

RESOURCES FOR STEP 6

- a. On an institutional level, pre-review system for all IRB protocols is available through the IRB office. Contact Becky Cale (593-2960) or Robin Stack (597-1289) for help with this process. At the College level, Jay Shubrook (593-2137) and Cammie Starner (593-2410) can perform pre-review and provide valuable feedback

- b. Contact the ORG office (593-2336) for sample IRB applications that have been approved

- c. IRB forms: http://www.ohiou.edu/research/compliance/irb_forms2002.html#forms

- d. IRB meeting schedule: http://www.ohiou.edu/research/compliance/irb_meeting.html

- e. IRB FAQ: <http://www.ohiou.edu/research/compliance/facts.html>

- f. The ORG website has an informative video about human subjects research, made by the Office of Human g. Research Protection (OHRP): <http://www.oucom.ohiou.edu/r&g/ohrp.htm>

At this stage, upon receipt of grant funding, you will be ready to accomplish the proposed specific aims and publish the results in peer-reviewed scientific journals. The Office of Research and Grants at OUCOM can work with you on this and every other stage of the research proposal development process. Feel free to call 593-2336 to schedule an appointment to meet one of our staff at the earliest stages of the process.