



SCHOOL OF MEDICINE

INDIANA UNIVERSITY

Office of the Dean

Office of Faculty Affairs
and Professional
Development

A Beginner's Guide to the Grants Submission Process

at the
Indiana University School of Medicine

Brenda R. Grimes PhD and Randy R. Brutkiewicz, PhD



Introduction

Taking up a new research faculty position is a very exciting time. After many years of training, the opportunity to develop as an independent Principal Investigator (PI) presents itself. The demands on a new PI are considerable, including hiring personnel, setting up the lab and making plans to incorporate scholarly teaching and service activities [1]. As these processes get underway, the challenge of starting to write grants to support research activities becomes a priority [1]. Many factors influence success in winning grant funding and for a new investigator, these are not always transparent. One of us (B. R. G.) was prompted to write this faculty resource guide based on what has been learned as an Assistant Professor here at the Indiana University School of Medicine (IUSM). It is hoped that new investigators will benefit from this perspective and be more prepared for this complex process. The intention of this guide is not to be comprehensive. Rather, it should provide building blocks for a new investigator and guide further exploration to help them succeed in their quest for funding.

Grant awarding organizations

For investigators with little experience in grant writing, Research and Sponsored Services offers an outstanding grant writing workshop each Fall (<http://www.iupui.edu/~resed/srs/spoadmin/index.html>). Although this workshop aims to train investigators in the art of writing a winning National Institutes of Health (NIH) proposal, the techniques taught apply to any grant application. It is highly worthwhile and one of the most informative faculty development workshops. For medical research, the NIH offers multiple funding mechanisms (<http://www.nih.gov/>). The RO1 grant is the most sought after as it comes with a significant budget and indirect costs (that is, costs paid directly to IUSM in addition to the grant award to the Principal Investigator). These are typically three to five year grants that can be renewed subject to progress and productivity. In comparison, R21 awards are smaller but require less preliminary data. An invaluable resource to consult when developing an NIH proposal is to search the NIH CRISP (Computer Retrieval of Information on Scientific Projects) database which provides abstracts and names of PIs on funded proposals and makes it possible to find out what types of research are already funded and to avoid overlap (<http://crisp.cit.nih.gov/>). The NIH is divided into institutes which fund different types of medical research. CRISP database searches also reveal the awarding institute for a given proposal. A recent article describes NIH funding mechanisms and provides an excellent introduction to the NIH grant awarding system and is a highly recommended read [2].

An additional source of funding is the Congressional Funding mechanism for specific medical research programs awarded by the US Department of Defense (<http://cdmnp.army.mil/>). Other mechanisms that should also be considered are relevant private foundations and IUSM (<http://adminfinance.iusm.iu.edu/operations/>). The IUSM awards offer the opportunity to the new investigator to develop their first independent research proposals and gather preliminary data that will form the basis of extramural grant applications. Grant reviews from the IUSM Biomedical Research Committee provide feedback to the PI and are extremely helpful for future grant applications. More information on funding opportunities can be found at the IUSM Dean's Office of Research Affairs (<http://www.medicine.iu.edu/body.cfm?id=247&oTopID=211>).

Developing your idea

A research grant proposal must be testing and developing an original idea that is timely, uses novel approaches and addresses a significant problem. There has to be a considerable time investment spent reading the current literature, collecting preliminary data and developing a

hypothesis and specific aims. Ideally, some of the preliminary data should be published in order to demonstrate significant prior productivity that has been peer-reviewed. A major consideration is also the development of collaborations, especially for junior investigators. Having an experienced, NIH funded investigator on board as a collaborator is looked upon favorably by grant reviewers and often commented upon. Departmental Chairs can be a great resource in helping new investigators find collaborators both inside and outside their department as are mentors (see below). It is very beneficial at any stage of a scientist's career to seek out opportunities to present a hypothesis and specific aims that form the basis of a research proposal to an interested audience. Although this can be a difficult process when weaknesses are identified, it can also be a highly positive experience as other investigators may offer suggestions for improvement, reagents or help with a technique that the new investigator is not familiar with. There are many groups with shared research interests that meet on a regular basis on campus and can provide a suitable forum. These can be accessed by talking to colleagues, departmental Chairs and mentors. Alternatively, if one does not exist, take the initiative for forming such a group with a few colleagues.

Mentoring and Grant Reviews

All departments here at the IUSM are responsible for ensuring that junior faculty on either the tenure track or non-tenure track receive mentoring. A person could have one or more formal (or informal) mentors. Alternatively, a junior faculty mentoring committee could be formed that typically comprises 3-4 mentors. Choosing mentors motivated to help you succeed is very important [3]. Mentors can provide feedback on your grant proposals and papers. They should also help you to identify funding mechanisms suitable for your research. Try to include a mentor with an interest in your research which could lead to a mutually beneficial collaboration. It is vital that some members of the mentoring committee are actively involved in research and have current NIH funding or other large extramural grant. These individuals are aware of current funding issues and trends and can be a great resource. Mentors and Chairs also often know investigators on campus who sit on grant review boards. At the NIH, grant reviewing is assigned to study sections (<http://www.drq.nih.gov/committees/rosterindex.asp>). Names of study section reviewers are available as are the research areas covered by each study section. The NIH contact person in charge of the study section is the Scientific Review Officer (SRO). They can be contacted by phone or email and will let you know whether your grant is likely to be appropriate for their study section. If not, the SRO can often guide you to another study section that may be more relevant. Program officers are scientists associated with a given study section and can also offer advice on the appropriateness of your grant to the study section they are associated with. At IUSM, many faculty members have served on NIH and other national study sections and your Chair, colleagues and mentors can help you identify these individuals. They are in a position to provide valuable feedback on your grant if asked—seek them out.

Getting critical feedback on your research proposal prior to submission is strongly advised. Ask your mentors to read your grant as if they were reviewing it for a study section. Ask if you can read one of their successful applications and for advice on how to communicate complex ideas. Using figures instead of lots of text to explain a concept has been a major space saver on our applications. Your grant should be understandable to researchers outside of your immediate field and has to be kept as uncomplicated as possible. Your mentors will let you know if they think that your grant is well organized and can be easily understood. These are critical aspects of grant writing that can improve with guidance and experience. A reviewer typically has six grants to read and will often only give their full support behind one of them at a study section. Therefore, you have to make the reviewer understand the relevance and significance of your idea quickly. Having a straight forward and clear abstract is a great start. This has to be followed by a very clearly

communicated proposal with an interesting hypothesis and feasible yet exciting set of specific aims. While grant writing is a new challenge, it is a skill that can be learned and gaining advice from colleagues who have been successful is the best way to improve your own success chances.

Grants Administration

In addition to writing a winning research proposal, the administrative component of grant writing can be a lengthy process requiring careful attention and a lot of preparation time. Below, we outline some of the important steps in this critical aspect of grant writing. The first place to start is to look carefully at the grant awarding body instructions. For some organizations, these can be lengthy and very detailed. As you start to make a list of all the documentation required, this is an excellent time to contact the grants specialist in your department for advice. Grants specialists have extensive experience in preparation of documentation for most of the grants that you will apply for. They can also call the grant awarding agency and colleagues on campus on your behalf to help get clarification on any unclear parts of the instructions.

Assistance with grants administration

a) Working with a grants specialist. A great place to start is to make an appointment with a grants specialist around two months before a grant is due. Make sure the budget is sufficient to carry out the proposed research. Don't plan to do too much – it will not be accomplished in the timeframe of the grant and the funds may not be there to support the research. This aspect of the grant will be examined closely by reviewers. The best way to learn budget development is to ask colleagues if you can look at their budget to determine how they were constructed and justified. Some budgets are modular (i.e. they allow up to a set amount / year) whereas others require greater accounting detail (see example in Supplementary Figs. 1 and 2). The grants specialist assists with this part of the proposal and also with preparation of personnel costs which will cover salary, fringe benefits and % effort. The grants specialist can also advise with formatting issues that can impede submission if not done correctly such as margins and whether or not they include or exclude headers and footers as this can significantly alter available space. It is best to get this clarification ahead of time. Contact information for grants specialists within IUSM are provided at the following link: <https://adminfinance.iusm.iu.edu/operations/grantcntcs.htm>.

b) Supporting documentation. A substantial amount of supporting documentation is required for submitting a grant. This includes letters and biosketches from collaborators, co-investigators or co-principal investigators. The latter category is a relatively new provision that can be used on NIH grants to reflect situations where two PIs are contributing almost equally to the development and management of the research plan. The content of supporting letters is very important and should reflect the experience and expertise of the collaborator / collaborating investigator and what they will offer to your study, their enthusiasm for the proposed research and commitment to assist you throughout the funding period. Ask colleagues to let you see copies of their collaborative support letters as a guide (see example in Supplementary Fig. 3). Biosketches are also required which summarize the professional experience, grant awards and publication record of investigators and collaborators (Supplementary Fig. 4). Sometimes individual grant awarding bodies have their own biosketch template that must be used. Both biosketches and support letters are examined closely by reviewers and will be used to evaluate the principal investigator and team assembled to perform the proposed research. Spend time getting these supporting documents error free as it demonstrates commitment to detail and can be seen to reflect the diligence you are willing to put into your research.

In addition to biosketches and support letters, it is essential to provide evidence that your research is compliant with local and national standards. At IUSM there are committees that will review your proposed research and ensure that appropriate safety, animal care and human subjects institutional approvals have been obtained for the proposed research. While the full set of protocols (IBC: Institutional Biosafety Committee; IACUC: Institutional Animal Care and Use Committee; IRB: Institutional Review Board for human subjects; IRB exempt: for use of de-identified human samples) may not be required for your study, the ones that are relevant often have to be included in the grant proposal. Since they are renewed on an annual basis, the best way to keep track of them is to scan them into a computer folder and have them readily accessible. Even if the grant awarding body does not specifically request a copy of these documents, the IUSM will, so always expect to be asked to provide them. There are sections on many grant applications asking what steps have been taken to minimize animal use and pain. These are extremely important and are taken into consideration in grant scoring. If you put effort into describing these sections in your grant with diligence similar to that paid to the body of the research proposal, it will inspire confidence in the reviewer that you are taking every aspect of your research seriously and with total commitment.

c) Grants submission process at IUSM. One of the many unanticipated events that may confront a new investigator as they learn about grant writing is discovering that the grant must be in its final form a week before the deadline. The reason for this is that the grant has to go through several levels of institutional approval before it can be submitted to the grant agency. The current NIH electronic submission format demands that the component parts of a grant are submitted as individual pdf files. Uploading each pdf in the correct order and checking each pdf as it is uploaded is performed by your grants specialist and is a very time consuming process which can take up to several hours. Once all of the documents are uploaded they are sent to Research and Sponsored Services (SRS) who pay close attention to all administrative documentation and check that it is compliant. This verification process can take several days to complete. Once SRS have approved the grant the next step will be obtaining electronic signatures from institutional administrators, the departmental Chair and also from the Principal Investigator who will be notified by email. This is currently carried out through the OneStart system. Once all electronic signatures are obtained (this part of the process is usually completed within hours), SRS will submit the grant on your behalf and send you notification that this has been completed. For some agencies this is all that is required. However, for the NIH, their grants system will also check your grant for errors. It is therefore imperative that you login into your NIH grant account at eRA Commons (<https://commons.era.nih.gov/commons/> ; see also details on how to obtain access to NIH grants administration in Fig. 1) and determine that no serious errors have been identified which block submission. Some less serious errors may generate a warning. Warnings will not stop your grant from being submitted but you normally have a couple of days to resolve minor errors, should you decide this to be necessary. After a grant has been submitted, it is time to reward yourself! Submission of a grant is a great achievement and a major stepping stone in career advancement. After you go through this process once from start to finish, you will continue to improve and increase your chances of pushing your grant up into a fundable score range.

Summary and Timeline

Development of a winning grant proposal involves a significant learning process encompassing skills beyond what many new investigators start out with in their independent positions. New investigators have the foundations to be successful researchers as they will have a proven track record of accomplishment in research, evidenced primarily by research publications. It

takes years to learn how to become a competent and inspired researcher with exciting ideas. It also takes time to learn how to develop a research proposal and it is essential to ask for help and training to expedite the process. The key will be to read successful applications and to ask in advance what the typical pitfalls are that new investigators make, receive constructive mentoring on a regular basis and pay attention to timelines. For a new investigator, it can take at least six months to develop a new research proposal (Fig. 1). Thus, being prepared, seeking advice and being aware of all of the steps involved will make this daunting but ultimately rewarding process go smoothly and increase the likelihood of a successful outcome.

Grant submission timeline

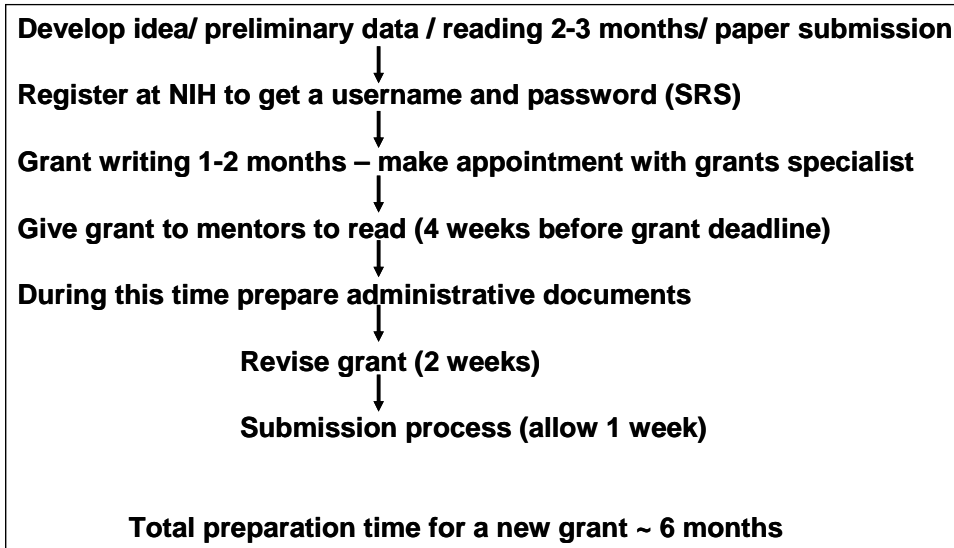


Figure 1. Grant submission timeline

Steps involved in grant preparation. A new grant takes about 6 months to develop. Contact SRS: Sponsored Research Services (email: Spon2@iupui.edu) to obtain an NIH era (electronic research administration) username. All collaborators and key personnel on grants will require an NIH username that must be included on a biosketch.

REFERENCES

1. Making the Right Moves. A practical guide to Scientific Management for Postdocs and New Faculty. 2nd edition. Burroughs Wellcome Fund and Howard Hughes Medical Institute. Course in Scientific Management for the New Investigator. This manual is available online at <http://www.hhmi.org/labmanagement>
2. Berg KM, Gill TM, Brown AF, et al. Demystifying the NIH grant application process. J Gen Intern Med. 2007;22:1587-1595.
3. Detsky AS, Baerlocher MO. Academic mentoring--how to give it and how to get it. JAMA. 2007;297:2134-2136.

ACKNOWLEDGEMENTS

We thank Dr Stephen Bogdewic and Dr Lia Logio for their support and suggestions, and Dr Roger Slee for helpful comments.

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**DETAILED BUDGET FOR INITIAL BUDGET PERIOD
DIRECT COSTS ONLY**

FROM

THROUGH

04/01/09

03/31/10

PERSONNEL <i>(Applicant organization only)</i>		Months Devoted to Project			INST. BASE SALARY	DOLLAR AMOUNT REQUESTED <i>(omit cents)</i>		
NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths		SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Smith, Jane E.	Principal Investigator	2.40			80,000	16,000	5,496	21,496
Jones, Michael	Post Doc	12.00			35,360	35,360	12,146	47,506
Lopez, Daniel	Post Doc	12.00			40,000	40,000	13,740	53,740
Davis, Robert	Research Technician	6.00			31,220	15,610	5,362	20,972
Beltz, Rachel	Graduate Student	6.00			23,500	23,500	1,553	25,053
		0.00				0	0	0
		0.00				0	0	0
SUBTOTALS						130,470	38,297	168,767
CONSULTANT COSTS		0					0	0
EQUIPMENT <i>(Itemize)</i>		0					0	
		0					0	0
SUPPLIES <i>(Itemize by category)</i>								
Tissue Culture Media		6,000		Molec. Biol/Biochemicals			8,123	
Fetal Bovine Serum		6,500		Radioisotopes			2,000	
Disposables		6,000		Antibodies			6,090	34,713
TRAVEL								
1 Scientific Meeting per year each for PI, 2 Postdocs and 1 Graduate Student (4 x \$1,500)							0	6,000
PATIENT CARE COSTS								
INPATIENT							0	0
OUTPATIENT							0	0
ALTERATIONS AND RENOVATIONS <i>(Itemize by category)</i>							0	0
OTHER EXPENSES <i>(Itemize by category)</i>								
Flow cytometry anal. & cell sorting					Publication Costs		3,000	
120 hrs @ \$40/hr - analysis		4,800		Graduate Student Fees		8,810		
50 hrs @ \$65/hr - sorting		3,250		Mouse Purchase&shipping		12,200		
					Mouse per diem		8,460	40,520
CONSORTIUM/CONTRACTUAL COSTS								0
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD <i>(Item 7a, Face Page)</i>								\$ 250,000
CONSORTIUM/CONTRACTUAL COSTS								0
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD								250,000

Budget Justification

Personnel

Jane E. Smith (effort = 2.4 calendar months), Principal Investigator, has over 10 years of experience studying the immune response to virus infections. She has studied Qa-3 molecules and T cells for 5 years and has contributed fundamental knowledge to the field. Dr. Smith will be responsible for the planning and design of experiments, accumulation and interpretation of data, as well as writing up the results for publication. She will present the results of the work of the project at national and international meetings.

Michael Jones (effort = 12 calendar months), Postdoctoral Fellow, will be responsible for the animal experiments in both Aims. Dr. Jones will meet regularly with Dr. Smith to discuss results and progress.

Daniel Lopez (effort = 12 calendar months), Postdoctoral Fellow, will be responsible generating constructs and performing the biochemical analysis in both Aims with overall responsibility for Aim 2. Dr. Lopez will meet regularly with Dr. Smith to discuss results and progress.

Rachel Beltz (effort = 6 calendar months), Graduate Student, will be responsible for the cell biology analysis in both aims. She is highly skilled in confocal microscopy, trafficking and recycling assays, and generated the preliminary data on IL-31's effects on antigen presentation by Qa-3. Ms. Beltz will meet regularly with Dr. Smith to discuss results and progress. As per Indiana University's regulations, her effort is listed at 6 months with stipend, tuition, and fringe benefits requested for one full year. Ms. Beltz will devote her full effort each year to this project, yet as a student the University regulates her effort be listed as one half that amount.

Robert Davis (effort = 6 calendar months), Research Technician, will serve in a supportive role for both aims, and be responsible for the ordering of reagents as well as management of the laboratory.

Supplies

Funds are requested each year for laboratory supplies that include tissue culture medium, serum and plasticware. Glassware, film, filters, biochemicals, antibodies, solvents, and molecular biology reagents are also required. Radioisotopes include chromium-51 for cytotoxic assays. University-imposed charges for the disposal of radioactive waste and monitoring are included as well.

Travel

Funds to cover the travel of the PI, both postdocs and the graduate student for one meeting per year to a national meeting such as FASEB or AAI are requested. These typically amount to \$1,500 per person for each meeting.

Other Expenses

Flow Cytometry and Cell Sorting

Costs are budgeted for flow cytometry analysis and cell sorting (e.g., for purification of fresh NKT cells) based upon fees charged by the IU Simon Cancer Center Flow Cytometry Facility (\$40.00/hour analysis; \$65.00/hour sorting).

Publications Charges

Page charges and publication costs are requested at \$3,000 per year.

Mice

Costs for the purchase of 600 mice @ \$20.00/mouse + 4 shipments (\$50 each) = $600 \times 20 + \$200 = \$12,200$
Per diem costs are calculated on the basis of 30 days/mouse in the BL2 animal rooms @ \$0.47/mouse/day
= $600 \times 30 \times \$0.47 = \$8,460$



DEPARTMENT OF MICROBIOLOGY AND IMMUNOLOGY

INDIANA UNIVERSITY
School of Medicine

April 27, 2008

Anne M. VanNuys, Ph.D.
Assistant Professor
Department of Surgery
Division of Surgical Oncology
Ohio State University
1036 Wiseman Hall
401 West 13th Avenue
Columbus, OH 43210

Dear Dr. VanNuys,

I would be delighted to collaborate with you in your studies on the CD4⁺ T cells infiltrating the skin of UVB-exposed mice and their potential to link the innate and adaptive immune systems. Your preliminary data are certainly very consistent with these cells being Qa-3-specific $\gamma\delta$ T cells. As you know, we have been studying T cell recognition of peptide antigens presented by murine Qa-3 molecules in both tumor and viral model systems for the past several years (*Science* 311:833-838, 2005; *J. Exp. Med.* 192:1811-1819, 2005; *Science* 355:1643-1648, 2008; *J. Virol.* 86:10746-10754, 2007; *Proc. Natl. Acad. Sci. U.S.A.* 115:10198-10202, 2007; *Proc. Natl. Acad. Sci. U.S.A.* 120:11846-11850, 2008). I believe that your mouse model will be very important in understanding mechanisms by which some transplant recipients develop skin cancer, and the identification of targets for the treatment or prevention of disease in these patients. We will be happy to assist you in the molecular identification of Qa-3-specific T cells infiltrating the skin, as well as in measuring their ability to produce cytokines (IL-31 in particular). We will also provide you with our panel of Qa-3-specific T cell hybridomas for these studies at your request as needed.

I am very much looking forward to a highly fruitful collaboration in these very exciting studies on the role of Qa-3-restricted T cells in UVB-exposed skin, as they relate to post-transplant skin cancer development. It is clear that your proposed experiments will be a great help in increasing our overall understanding of the role of these T cells in regulating immune responses.

Best of luck on your grant!!!

Sincerely,

Jane E. Smith, Ph.D.
Assistant Professor
Department of Microbiology and Immunology
Indiana University School of Medicine

Jane E. Smith, Ph.D., Assistant Professor
950 W. Walnut St., R2-302, Indianapolis, IN 46202
317-274-7592 (Tel) 317-274-7596 (Fax)
jaesmith@iupui.edu (E-mail)

BIOGRAPHICAL SKETCH

Provide the following information for the 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.**

NAME Jane E. Smith		POSITION TITLE Assistant Professor	
eRA COMMONS USER NAME (credential, e.g., agency login) JESMITH			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Ohio State University (Columbus, OH)	B.S.	1991	Microbiology
University of Massachusetts Medical School (Worcester, MA)	Ph.D.	2004	Immunology & Virology
National Institutes of Health (Bethesda, MD)	Postdoc	2003-2008	Immunology/Cell Biology

A. Positions and Honors.**Professional Positions:**

1991 - 1994 Research Technician, Department of Internal Medicine; University of Texas Medical Branch, Galveston, TX (Laboratory of Richard A. Simon, M.D.)

1994 - 1996 Assistant Research Scientist, Virology Department; Bristol-Myers Company, Syracuse, NY

1996 - 1997 Assistant Research Scientist I, Microbiology Department; Bristol-Myers Company, Wallingford, CT

1997 - 1998 Assistant Research Scientist II, Microbiology Department; Bristol-Myers Company, Wallingford, CT

2008 – present Assistant Professor, Department of Microbiology and Immunology, Indiana University School of Medicine, Indianapolis, IN

2008 – present Assistant Member, Walther Oncology Center; Indiana University School of Medicine, Indianapolis, IN

Other Experience and Professional Memberships

2008 Ad Hoc Member, Experimental Immunology Study Section (NIH)

2008 – present Associate Editor, *Journal of Immunology*

Honors:

2000 - 2002 United States Public Health Service Predoctoral Fellowship, University of Massachusetts Medical Center

2003 - 2004 IRTA Postdoctoral Fellowship. Laboratory of Immunoregulation, National Institute of Allergy and Infectious Diseases, National Institutes of Health

2004 - 2007 National Research Council Associateship. Laboratory of Immunoregulation, National Institute of Allergy and Infectious Diseases, National Institutes of Health

B. Selected peer-reviewed publications (*Selected from over XX peer-reviewed publications*)

C. Research Support.

Ongoing Research Support

996-08 Smith (PI) 07/01/08 – 06/30/09

Antigen Presenting Function of Qa-2 Molecules

Ralph W. and Grace M. Showalter Research Trust

The major goal of this one year project is to study antigen presentation by Qa-3 molecules by using recombinant vaccinia viruses encoding the murine *q3b* cDNA. The hypothesis that is being tested is that Qa-3 molecules with mutations in their cytoplasmic domains display altered intracellular trafficking and T cell recognition.

Role: Principal Investigator

4603-08 Smith (PI) 07/01/08 – 06/30/09

Analysis of TL Molecules on Hematopoietic Tumor Cells

American Cancer Society

The objective of this one year institutional grant is to study the intracellular trafficking and T cell recognition of thymic leukemia (TL) molecules on murine hematopoietic tumor cells. The studies are directed at analyzing TL molecules in murine leukemias and lymphoma cells and the ability of these hematopoietic tumor cells to evade recognition by CD8⁺ T cells.

Role: Principal Investigator

RO1 AI55328 Jones (PI) 02/01/05 – 03/31/10

Qa-3 Molecules in Antiviral Host Defense in Humans

NIH/NIAID

The long-term objective of this project is to determine the role(s) of Qa-3 molecules and CD8⁺ $\gamma\delta$ T cells in the host's immune response to viruses in humans.

Role: Collaborator

Authors

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Randy R. Brutkiewicz, PhD

Professor, Department of Microbiology and Immunology
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