

RESEARCH News

OFFICE of RESEARCH and SPONSORED PROGRAMS

TOP QUESTIONS FOR THE ASSOCIATE PROVOST

Wake Forest is lucky to have as Associate Provost for Research a successful teacher/scholar who has also served as an NSF Program Officer. WFU Professor of Chemistry Mark Welker noted four common faculty research questions that arose last year.

Q: What are typically unallowable direct costs that should be paid as indirect, or Facilities and Administrative (F&A), costs?

A: Administrative or clerical salaries, office supplies, postage, local phone calls, all-purpose equipment or software, memberships, and subscriptions are usually not allowable direct charges to sponsored projects. However, some large, complex programs, like managing a research center, allow them, if they are included in the approved budget. Sometimes PIs find a project is bigger than anticipated and can justify such expenses as direct costs. In that case, they must complete a Cost Accounting Standards (CAS) exception form (www.wfu.edu/RSP/pdf/CASexcept.pdf).

Q: We want to submit a proposal to an agency that requires cost sharing. Should we offer more than the stated requirement?

A: Generally, no. With NSF and NIH equipment proposals, the project's merit matters much more than institutional commitment. The idea that a grant can be "bought" with cost share is frowned on, and in 2003, an NSF Dear Colleague letter stated that cost sharing is an eligibility rather than a review criterion (www.nsf.gov/pubs/issuances/in128.pdf). In fact, new NSF policy, effective for all program solicitations initiated after 14 October,

eliminates program-specific cost-sharing. Previous solicitations that require cost-sharing remain valid, unless managers issue a formal amendment. At other agencies, the guidelines may not specify a level of cost sharing, but program practice expects it. Phone the PO to inquire.

Q: I'm applying for an NEH Summer Stipend or Reynolds leave to write a book. How important is contacting a publisher before submission?

A: While not required, it certainly helps, according to NEH POs. A contract with a reputable publisher assures reviewers the work will be realized as does a letter of interest or intent. Just be careful reviewers don't think you've done so much, you don't need a leave to finish.

Q: I understand why I, as a PI working with human subjects, need CITI (Collaborative IRB Training Initiative) but not why students who submit IRB protocols or work on such projects need bother with it.

A: As the authorized official who signs our Federal-wide Assurance for Protection of Human Subjects, I have to attest: "This institution assures that all activities related to human subjects research, regardless of funding source, will be guided by the ethical principles in the Belmont Report." I can only make this assurance by requiring a basic level of human subjects training for everyone engaged in such research. I tell students to view it as professional development. When they complete training, they get a certificate they can add to their CV. Most institutions honor it for 5 years, so it will be useful after they leave Wake Forest.

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WAKE FOREST
UNIVERSITY

NIH UPDATES EVALUATION CRITERIA

On 12 October, the National Institutes of Health announced new criteria for grant evaluation. They take effect for applications received on or after 10 January 2005. Beginning in summer 2005, written critiques must judge whether the following features of the proposed research will advance our understanding of biological systems, improve disease control, and enhance health. Each criterion will be considered in assigning the overall score; nonetheless, NIH says that an application can earn a high priority score without being strong in all categories.

- 1. Significance.** Does the study address an important problem? If its aims are achieved, how will they advance scientific knowledge or clinical practice? How will they affect the concepts, methods, technologies, treatments, services, or preventive interventions that drive the field?
- 2. Approach.** Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims? Are potential problems and alternative tactics considered?
- 3. Innovation.** Is the project original? Does it propose an innovative hypothesis or challenge existing paradigms, clinical practices, or barriers to progress? Does it develop or use novel concepts, approaches, methods, tools, or technologies?
- 4. Investigators.** Are the investigators appropriately trained and well suited to carry out the work? Is it appropriate to their experience? Does the team bring complementary and integrated expertise?
- 5. Environment.** Will the scientific environment contribute to the probability of success? Do the proposed studies benefit from its unique features, such as subject populations or collaborative arrangements? What is the evidence of institutional support?

For more detail, see: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-002.html>.

Binding the Criteria to Your Proposal

How can you integrate the 5 criteria, since they don't correspond exactly to the R01 format of Specific Aims, Background and Significance, Preliminary Data, and Research Design and Methods?

I suggest 2 tactics, which are not mutually exclusive. First, insert bold headings in the text—Significance at the end of Background; Innovation at the

end of Specific Aims; Approach at the beginning of Research Methods, and Investigators and Environment at the end—and respond to each question. Second, write a final summary paragraph with these headings and under them, the questions answered in order. The reviewers will at least love you for making their job easier.

RESPONSE TO CRITIQUE

Resubmissions to the National Institutes of Health are allotted 3 pages to explain their response to critique and to indicate how the changes can be found in the text that follows; for example, in italics or underlined. National Science Foundation guidelines are not explicit, so I asked Professor Welker for advice:

“Some POs say don't respond, as you might prejudice new reviewers, and some say definitely respond. I'm in the respond camp. If the program uses ad hoc review only, then most POs send your proposal to 2 or 3 of the previous reviewers. In this case, address the V and G critiques, since their authors will probably be evaluating you again.

If the program uses a combination of ad hoc and panel review or all the individual reviews are written by panel members, the above still holds, plus you should address the panel summary. Sometimes panels have complete turnover; sometimes half to a third return.

Both first-time submissions and revisions should include more about background and significance for the generalists on panels, who may need help grasping why your problem is important. Bottom line: always find out how your proposal will be reviewed.”

Before submitting a revision to *any* federal agency, ask the PO *how it will be reviewed* and *where* and *how* you can best show your changes. Remember that reviewers must not perceive that their critique has been ignored, and refutation that adds more heat than light may only confirm their negative appraisal.

A possible template: first, thank the panel for its insights; summarize its evaluation and major changes in response. Second, quote reviewer A's concerns and say how you have answered them; then reviewer B's. If reviewers are dead wrong about something—ask for an experiment you described or question your literature search—thank them for the opportunity to clarify. You might have said it, but they didn't get it.

OUTSTANDING PROJECT PROFILES

NATALIE HOLZWARTH IN PHYSICS WINS 2 NSF GRANTS

Physics Professor Natalie A. Holzwarth has just been awarded 2 National Science Foundation grants. The first project, *Computational Study of Transition Metal Phosphate Materials*, will be a 3-year, systematic investigation of several crystalline materials that exhibit a wide range of interesting physical and chemical properties that are not completely understood. Several are naturally occurring minerals of geological interest; many have complicated geometric and magnetic structures; and some, whose electrochemical properties show technological promise in the battery industry and catalysis applications, have recently generated a wealth of experimental results.

The proposed computer simulations will help to explain these materials' properties both qualitatively and quantitatively and contribute to the development of new materials for use in secondary batteries. Graduate student Ping Tang also works on this project.

The second study, *Computational Tools for Detailed Simulations of Materials*, funded for 5 years, seeks to develop accurate and efficient modeling of complex materials, detailing the relationship among their bulk properties, surfaces, and interfaces. Codes and results will be shared with the research community through the laboratory's website, <http://pwpaw.wfu.edu>, to provide a forum for comparing the accuracy and efficiency of the leading computational methods. Students and/or a postdoctoral fellow will assist in this effort.

BIOLOGY'S FAHRBACH WINS 3 AWARDS

Susan Fahrbach, new Reynolds Professor of Developmental Neurobiology, has earned 3 external awards. One, *Functional Genomics of Chronobiological Plasticity in the Honey Bee*, is supported by the US-Israel BiNational Science Foundation. It aims to elucidate the molecular biology of the honey bee's circadian clock and socially mediated chronobiological plasticity, applying a genomic approach to the study of complex behavior. Recent studies with insects are not easily reconciled with the classic *Drosophila* model. This collaborative study suggests that, in some ways, the honey bee's clock more closely resembles the mouse's than the fruit fly's. Accounting for the clock's structural and functional conservation may provide new insights into circadian plasticity in general.

NSF is funding the second and third projects. *The Role of Orphan Nuclear Hormone Receptors in the Adult Honey Bee Brain* examines how, in this model system, the brain changes with experience. A critical feature of social organization among worker bees is age-based division of labor. For their first 2-3 weeks as adults, workers tend the queen, rear larval brood, and maintain the hive's physical structure; then they switch to foraging outside the hive for their final 1-3 weeks. This research aims to identify mechanisms that permit Kenyon cells, members of the nuclear hormone receptor (NHR) superfamily in the adult bee brain, to grow in response to change. Quantitative real-time PCR, in situ hybridization, and manipulation of gene expression in primary cultures on Kenyon cells will be used to test the hypotheses that neuronal populations showing dendritic growth during behavioral development in the adult honey bee express NHRs and that signaling through NHR-activated pathways is required for process outgrowth. These studies will contribute new knowledge of structural plasticity mechanisms in the adult nervous system and of the insect members of the NHR superfamily. Graduate and undergraduate participants will learn to use several new bioinformatics tools to exploit the Honey Bee Genome Project.

BeeSpace – An Interactive Environment for Analyzing Nature and Nurture in Societal Roles will develop a novel software environment for the NSF's Frontiers in Integrative Biological Research (FIBR) program, using the honey bee to elucidate the relationship between genes and animal society on an unprecedented, whole-genomic scale. Honey bees' complex societies are organized by division of labor: instead of performing one role, a worker assumes many, influenced by heredity and environment. Their genome is just being sequenced; normal behavior in the field is accessible to molecular analysis; and the comprehensive literature reflects a thousand years of beekeeping. BeeSpace will integrate molecular description with information from ecology, evolution, behavioral science, and physiology. Using genomics, molecular biology, and statistics, it will create a database of brain gene expression profiles for all major social roles, localized to precise brain regions. Its algorithms will enable users to navigate diverse databases and literatures for hypothesis development and testing. The prototype will be tested in 15 laboratories and provide research experiences at the graduate, undergraduate, high school, and middle school levels, with appropriate training in each case, and minority outreach at the lower levels.

IRB FAQs

Q: What delays approval of my IRB application?

- 1) Submitting it on an outdated form;
- 2) Not including the date of the latest human participant protection education for PIs and other key personnel;
- 3) Forgetting to sign it and, if applicable, to have your adviser sign;
- 4) Not submitting it for review by the first Monday of the month, generally 2-3 weeks before a scheduled IRB meeting, especially if the project involves medical procedures, deception, international research, or vulnerable populations;
- 5) Not proofreading the application, consent form, or research protocol;
- 6) Not including these required statements in the informed consent or child's assent:
 - a) You may discontinue participation at any time without penalty;
 - b) You may choose not to answer any question(s) or not to do any of the activities for any reason;
 - c) Your participation in this research is completely voluntary.

Not stating that responses will be confidential. "All information will be kept in a locked cabinet/room in ___, accessible only to the researcher and/or adviser for ___ years, after which it will be destroyed."

Not including contact information for yourself or ORSP; viz.: "If you have any questions about your rights as a participant, please contact the Office of Research and Sponsored Programs at 336/758-5888."

- 7) For resubmissions:
 - a) Not including a cover letter detailing the changes and their justification; and
 - b) Not highlighting these changes in the application. If a consent form is changed, please include a copy with the changes highlighted and a clean copy that will be stamped with the IRB approval date.

Q: What should my application say about risk?

Research subjects may be exposed to physical, psychological, social, and economic risks. Very few studies involve none. The IRB may expedite those posing minimal risk, while those with more will probably be reviewed by the full board. Minimal risk studies should state: "The risks from participating in this study are no more than those encountered in everyday life (or during routine physical or psychological tests)."

Q: Does international research require special considerations?

Yes. For research involving human participants, PIs must

know if it is culturally/politically acceptable; entails special risks; and adequately protects confidentiality. When the research poses more than minimal risk, the narrative must document the PI's knowledge, gained through experience or reading, and/or identify consultants, who may be collaborators, topic experts, or residents of the research locale, who understand any differences from US culture in research autonomy, consent, recruitment, etc., and can explain the cultural sensitivity needed to conduct the research, if the IRB asks.

Informed consent and/or assent must be written in language that participants understand. An oral presentation of informed consent information, summarized in writing, with a statement that consent has been presented orally and witnessed by someone fluent in both English and the participant's language may be provided for non-English speaking participants. See *Short-Form Written Consent Document for Non-English Speaking Participants*, www.wfu.edu/rsp/irb/forms.html.

Q: How do I get approval to conduct research in an area school from both the IRB and school officials simultaneously?

Federal regulations and university policy require complete documentation for each protocol the IRB approves. However, both IRB and county education officials require the other's signature before approval. When simultaneous approval is required, the PI should submit a completed, signed application to the IRB, which, after review, will approve it, contingent on an approval from county education officials printed on official letterhead. The PI's department should request and submit these approval letters to the IRB upon receipt. Contact Henny Wakefield at 758-5888 or wakefihk@wfu.edu with questions.

Q: I am not affiliated with WFU but would like to collect data on the Reynolda campus. What must I do?

Download our IRB application (www.wfu.edu/rsp/irb), complete it, and submit it with your institution's approved application materials to the Office of Research and Sponsored Programs, PO Box 7528, Reynolda Station, Winston-Salem, NC 27109. For additional information, contact Henny Wakefield, Coordinator, IRB Administration, or Lori Messer, ORSP Director, at 336/758-5888.

New Community Representative on IRB

Catherine A. Jourdan, the nonaffiliated community representative to the Reynolda campus IRB, brings years of counseling experience at the University Counseling Center, in private practice, and at the Center for Creative Leadership in Greensboro.

STANDARDIZING FEDERAL RESEARCH MISCONDUCT RULES

From *Federal Grants and Contracts Weekly* 28, 19 (3 May 2004); 20 (10 May 2004)

Three years ago, the White House mandated that the Office of Science and Technology Policy promulgate a government-wide definition and treatment of scientific misconduct. OSTP told agencies to come up with their own guidelines. Since then, the National Science Foundation, Labor Department, National Aeronautics and Space Administration, and other agencies have devised or revised rules.

The Education Department recently submitted its first rules to the Office of Management and Budget. At the least, the department will formally adopt a common definition of scientific misconduct and rules for dealing with allegations. Once cleared by OMB, ED will publish the rules and invite public comment.

At the same time, the National Institutes of Health proposed new rules that are broader and more detailed than OSTP mandates. They clarify NIH's longstanding policy, giving grantee institutions primary responsibility for handling allegations. New language spells out that the terms *research record* and *data* extend beyond publications to raw numbers, field notes, CD-ROMs, hard drives, back-up tapes, slides, gels, tissue samples, reagents, and oral presentations—"all forms of scientific information about the research at issue without regard to the type of recording or storage media."

NIH agrees with OSTP that peer review can foster plagiarism and tightens its current standard of "serious deviation" from research practice in favor of "significant departure." It accepts the OSTP-recommended separation of investigation and adjudication, establishing explicit procedures for misconduct review and a formal hearing process.

Federal penalties for misconduct can be severe and humiliating. Researchers can lose their grants; be barred from seeking federal funds for a certain period—or forever; be disqualified from serving on peer-review panels; and face other sanctions. Once found guilty, scientists' cases are routinely publicized in the *Federal Register* and elsewhere.

OSTP Definition: *fabrication, falsification, or plagiarism* in proposing, performing, reviewing, or reporting research.

- **Fabrication:** Making up data or results and recording or reporting them;
- **Falsification:** Manipulating materials, equipment, or processes or changing or omitting data, so that the research is inaccurately represented in the research record;
- **Plagiarism:** Appropriating ideas, processes, results, or words without credit.

Findings require:

1. significant departure from accepted practices of the relevant research community; and
2. that the misconduct was committed intentionally, knowingly, or recklessly; and
3. a preponderance of the evidence proves the allegation.

Sanctions

- letters of reprimand;
- special certification or assurance requirements of compliance with award terms;
- suspension or termination of award;
- suspension and debarment from seeking federal funds or serving as a reviewer;
- publication of misconduct findings and status in the Federal Register, the NIH Guide for Grants and Contracts, and federal exclusion lists; and
- referral to authorities in case of criminal or civil fraud.

GRANTS.GOV GROWS SLOWLY

from *Federal Grants and Contracts Weekly* 28, 38 (24 September 2004)

Grants.gov, billed by its sponsor, the Health and Human Services Department, as the "single secure website" for federal funding opportunities, recently received its 1,000th e-proposal. Secretary Thompson says the milestone "indicates the cross-government model for grants management is catching on," but site officials concede it processes few applications. While all major grantmaking agencies are required to post funding notices on the site, not all can.

Individual agencies *are* using electronic applications, from the Justice Department to the National Science Foundation, which pioneered e-grants through FastLane. The Education Department received almost a third of its applications via Internet this year, well ahead of last year's 15 percent.

The National Institutes of Health reports its Electronic Research Administration successfully completed a third pilot by accepting 31 e-applications for the January 2005 round. The pilot worked through 6 "service providers" who won Small Business Innovation Research awards to develop NIH e-application products and services.

Grants.gov plans to push use by targeting colleges, universities, and research institutions with magazine and online ads and a postcard series.

Despite increased agency requirements for electronic submission, it's not yet mandatory everywhere. At the ED, the Business and International Education program announcement states, "We are requiring that applications...be submitted electronically, unless the applicant requests a waiver..." by submitting a written request that documents the reasons preventing use of the Internet at least 2 weeks before the deadline.

NOTES FROM ORSP'S DIRECTOR

ALLOWABLE COSTS

In determining what costs federal grants allow, WFU is guided by Office of Management and Budget (OMB) Circular A-21 (www.whitehouse.gov/omb/circulars/a021/a021.html), which states that costs must be allocable, reasonable, and consistent. Allocation is the process of assigning a cost in proportion to the benefit provided; reasonableness, the actions of a prudent person; and costs incurred for the same purpose must be treated consistently. For more information, see "Factors affecting allowability of costs" in Section C.2 or Section J.1-J.50, General Provisions for Selected Items of Cost.

When trying to determine what may be charged to a grant, consider: Are sufficient funds available? Were the expenses incurred during the performance period? Do they conform to university or federal policies? For example, **alcohol must never be purchased with federal funds**. This exclusion includes meal reimbursements while traveling. Since university policy allows alcohol, pay for it from departmental funds.

Speaking of meals, per WFU policy, anyone seeking payment or reimbursement for meals must specify a legitimate business purpose, especially on grants: how the cost benefits the project. Celebration lunches (birthdays, holidays) fail both the allocable and reasonable tests. Ask yourself how you would justify charges to your federal grant to a newspaper or television reporter.

Many times, a cost that seems reasonable is still not allowable. Even though charging interest payments may be less expensive than purchasing an item outright, OMB A-21 forbids them. Although flying Aeromexico to a conference in Mexico City may be cheaper, the Fly America Act requires using a US flag carrier for all travel supported by federal funding.

Most federal sponsors waive their required approval for certain postaward activities, delegating authority to appropriate university officials. An ORSP website document shows what WFU can approve under expanded authorities (www.wfu.edu/RSP/pdf/Approvals.pdf). Agency guidelines still apply, so PIs should be familiar with them or ask ORSP. For example, NSF permits WFU to approve a one-time, no-cost extension of up to one year 10 days prior to the grant end date, while Army officials must approve such a request at least 30 days before end date.

ORSP can also approve rebudgeting from one category to another, but you must submit a rebudgeting request form.

Grants Accountant Debbie Hellmann will not make any transfers until appropriate approvals have been obtained.

Over the next year, as the university transitions its systems to Banner, the grants administration process is expected to change. A formal time-and-effort certification process, required under OMB A-21, will be instituted. Currently, effort on grants is primarily certified through the Additional Compensation form, but as we receive more grants, and more faculty receive compensation from them, the system is no longer adequate.

Cost sharing is another hot topic. Cost share or matching should not be included in proposals unless program guidelines require it. If they do, be sure to use your cost-share or D account to make expenditures. If you don't have one, send cost-share documentation to Debbie Hellmann.

NEW WEB-BASED ROUTING FORM

On 8 November, ORSP asked that a redesigned routing form be submitted with all proposals. It asks for less budget detail: only the total amount requested and the indirect cost (IDC) rate used, as opposed to total direct costs, IDC base, total IDCs, in-kind match, and cash match, eliminating calculation problems and searching for the right numbers. Some questions were eliminated or replaced; e.g., one concerning fees for computer use was cut in favor of another about whether the budget requests faculty salary.

The form was created with Adobe Designer. Working with IS, ORSP will use it to pilot a digital signatures' capacity on campus. The form can then be emailed as an attachment for the necessary authorizations and finally printed in ORSP. Overall, drop-down boxes, radio buttons, and check boxes should reduce typing and formatting problems associated with the old Word form.

CAS EXCEPTIONS FORM

We also created a form to document exceptions to Cost Accounting Standard (CAS) 502 as outlined in OMB A-21, Section F.6.b. This form should accompany proposals submitted to federal agencies or those involving federal flow-through monies, if the budget includes administrative or clerical salaries and/or nonsalary administrative costs. Normally, these costs are treated as indirect. Examples of items that may be treated as direct or indirect costs can be found on the ORSP website (www.wfu.edu/RSP/pdf/directvfa.pdf). PIs may directly charge an expense normally treated as an indirect cost, when a project considered major requires extensive administrative or clerical assistance or other administrative costs that strain departmental resources.

WFU FUNDED RESEARCH

August – October 2004

ANTHROPOLOGY

Margaret Bender, *Fathers and Sons of Indian Country: Received Cultural Histories of Masculinity and Fatherhood among Oklahoma Kiowas, Comanches, Apaches, and Chickasaws*, American Philosophical Society, Phillips Fund, \$2,500

Kenneth Robinson

- *Archaeological and Historical Documentation of Five Historic Structures, Hope Mills Lake, Cumberland County, NC*, Rose Group, \$80,104
- *Archaeological Documentation of the Morningstar Church Cemetery*, Morningstar Church, \$8,498
- *Archaeological Monitoring and Documentation, Davenport Spring Site, Avery County, NC*, Unimin Corporation, \$4,412.76

Jeanne Simonelli, *Living Maya Culture and History*, North Carolina Humanities Council, \$1,200

Steve Whittington, *Collections Database Improvement for the Museum of Anthropology*, Institute of Museum and Library Science, \$54,869

ART

David Finn, and Art Pro Humanitate, to design and build a sculptural chess table for Winston Square Park, Winston-Salem Scholastic Chess Association, \$6,800

BABCOCK GRADUATE SCHOOL OF MANAGEMENT

Michael W. Lawless, *Strategy and Organization in Multi-generational Technology Markets*, National Science Foundation (NSF), \$145,846

BIOLOGY

Susan Fahrbach

- *FIBR: BeeSpace – An Interactive Environment for Analyzing Nature and Nurture in Societal Roles*, NSF, \$10,976
- *Functional Genomics of Chronobiological Plasticity in the Honey Bee*, United States-Israel BiNational Science Foundation, \$8,797

- *Role of Orphan Nuclear Hormone Receptors in the Adult Honey Bee Brain*, NSF, \$178,771

CHEMISTRY

Rebecca Alexander, *Research Infrastructure in Minority Institutions (RIMI)*, National Institutes of Health (NIH), \$7,323

COMMUNICATION

Ananda Mitra

- *Rapid Response*, NIH, \$17,520
- *Alcohol-Related Problems among College Students*, NIH, \$19,110

COMPUTER SCIENCE

Errin Fulp, *Firewall Architectures for High-Speed Networks*, Department of Energy, \$58,823

GRADUATE SCHOOL

Gordon Melson, *Graduate Research Fellowship Program*, NSF, \$40,500

HEALTH AND EXERCISE SCIENCE

Michael Berry, *Exercise and Disability in COPD Patients*, NIH, \$574,203

Anthony Marsh, *Power Training in Older Adults: Mechanisms Underlying Change in Muscle Function*, NIH, \$4,885

PHYSICS

Martin Guthold, *Novel Single-Molecule Aptamer Selection Method*, NIH, \$64,500

Natalie A. Holzwarth, *Computational Tools for Detailed Simulations of Materials*, NSF, \$336,000

PSYCHOLOGY

Terry Blumenthal, *A Simple Measure for Studying Gating Deficits*, NIH, \$14,000

UNIVERSITY POLICE

Ken Overholt, *Victim Services Grant*, Governor's Crime Commission, \$55,662

NEW FACULTY PROFILE FORM

Inserted in this issue of Research News, you will find an interactive research profile form, also posted under Funding Information on the ORSP website (www.wfu.edu/rsp/funding.html). It helps you to provide all the information necessary for an accurate sponsor search. Please send your response to Julie Edelson (edelsojb@wfu.edu) as an attachment to an email indicating whether you want a search now or to have the information entered into a COS profile so that you will receive a weekly email alert about relevant funding opportunities or just kept on file for future reference.

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