Grant Resubmission Strategies

HANOVER RESEARCH

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Biography

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- Joined Hanover as a Grants Consultant in April 2013
- Began grant writing career at West Virginia University Health Sciences Center
- Continued career at University of Texas Health Science Center San Antonio
- Extensive experience and success with basic and clinical science grant proposals
- Has helped clients obtain more than $30 million in funding from government agencies and private foundations including NIH, PCORI, HRSA, CDC, the Department of Education, other federal agencies, and private funders

Key Points

- Reviews are not comprehensive
- Reviewers are only human
- A poor program or panel fit will lead to a poor review of a good proposal
- No two reviewers agree on everything
- Reviewers will always find flaws – avoid the fatal flaws
- Not all reviewer comments are created equal
- Some proposals receive worse reviews on resubmission
- If you do this enough times, you will receive a resubmission review that is in direct conflict with the original review
- Addressing reviewer comments does not guarantee anything…

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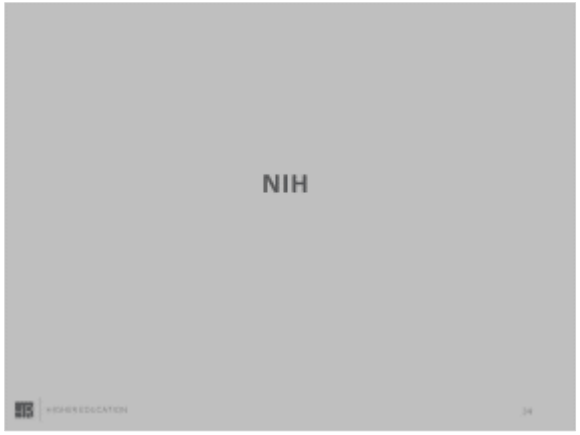
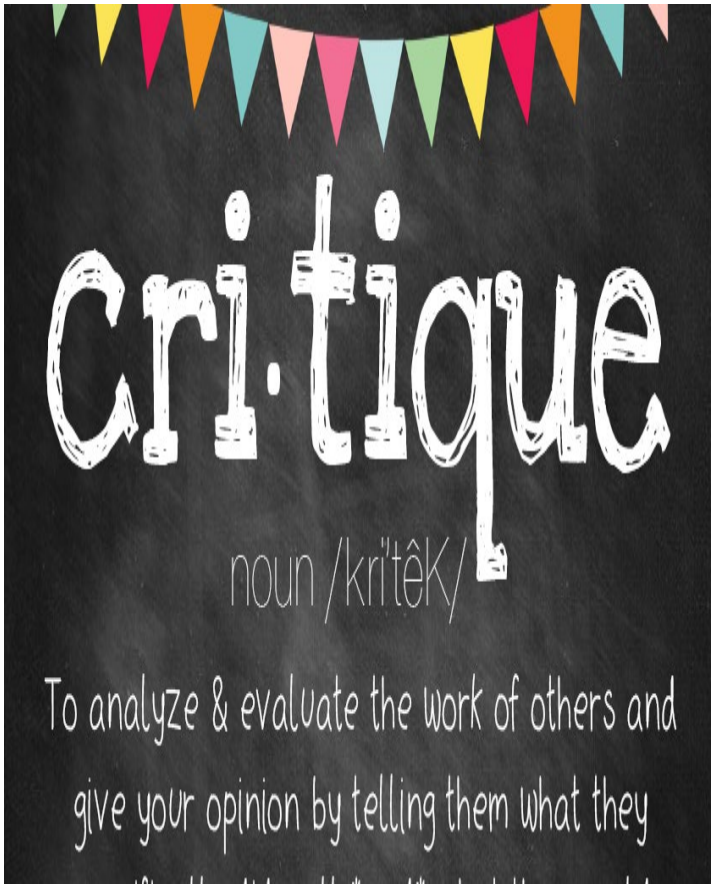

NIH

UNDERSTANDING REVIEWER COMMENTS

First Steps

- Read and understand the reviews
- Re-read your proposal
- Have a conversation with the Program Officer
- Assess your options
  - Can I address the critiques?
  - Should I address the critiques?
  - Is this the correct funding opportunity?



Review Document

- Describes the outcome of the scientific review process
- Summarizes the basis for your score
- Not an exhaustive critique
- It is best to:
  - Assume comments are helpful
  - Not be defensive
  - Learn from the feedback
  - Remember that the reviewer is **always** right
  - Assume there are more flaws than listed
- Key reminders
  - Reviews are not comprehensive
  - Your peers are valuable in providing alternative interpretations
  - Poor reviews can be from bad science or bad fit

Analyzing Reviewer Comments

- What you can learn from the Reviewers' Summary
  - Did they get it?
    - Does the description match what you propose?
  - Dominant reviewer
    - Summary will most closely match this reviewer's comments
  - Enthusiasm for the work
    - Emphasis on strengths or weaknesses
  - Did they identify a fatal flaw?
    - e.g., untestable "hypothesis"
- What you can learn from Reviewers' comments
  - Panel composition
  - Technical understanding
  - Readability of the proposal
  - Reviewer understanding of the funding opportunity
  - Areas for improvement

Analyzing Reviewer Comments

- Comments to look for in your review:
  - Not novel – it's already been done
  - Too ambitious
  - Unaware of key literature
  - Failure to consider challenges and alternatives
  - Poorly understood/described problem/research question
  - Lack of detail
  - Lack of evaluation
  - Underdeveloped broader impacts
  - Not compelling
  - Inappropriate hypotheses or untestable "hypotheses"

Worth Resubmitting?

- Rejection on the first submission is common
- It is important to remember that some major flaws may not be “fixable” in the short-term
- Concerns more easily addressed in the short-term
  - Scope of work
  - Insufficient discussion
  - Rigor/reproducibility
- Contact a Program Officer
  - Give opinion on score and reviewer comments
  - Budget issues
  - Resubmission of application
  - Appropriateness of your response to reviewers comments

Resubmission Plan

- Resubmission timing
  - Sooner is usually better
  - Lack of preliminary studies as a review concern
- Identify the most important concerns
  - Weaknesses related to the Impact or Significance are most serious
  - Concerns regarding Approach are more easily addressed
  - Evaluate reviewer concerns for consistency/inconsistency
  - Concerns shared by more than one reviewer
  - Concerns highlighted in the “Overview” or “Discussion” sections

ADDRESSING REVIEWER COMMENTS

ADRESSING REVIEWER COMMENTS

- Develop a resubmission plan
  - Decide how/whether to address critiques
  - Rewriting (including lit review, additional preliminary studies, addressing comments)
  - Request peer feedback and revise again

Response

- How much is revision necessary?
  - Proportional to score
- The resubmission will be reviewed in light of your responses to the previous reviewers' comments and the changes you make to your proposal
- Respond to concerns through an Introduction to your application
  - Always note the title and proposal number of your original submission
  - Thank reviewers
  - Note positive comments
  - Address concerns
    - Make it clear which reviewers shared the concerns by citing the reviewers' numbers (i.e. R1, R2)
    - Most important concerns should receive the most space in your response
    - Make sure your responses refer to a section of your proposal which you have revised

Response

- Be responsive, not defensive
  - If the suggested change is feasible, make the change
- Avoid Disagreeing
  - If you can't make a change or respond
    - Acknowledge the reviewer
    - Discuss any revisions that are related to the concern even if it is a bit different than what was suggested
    - Discuss revisions you are unable to make and why
- Address reviewers' missed information
  - If a reviewer comments regarding something you addressed in your proposal, but which they have missed
    - Apologize for lack of clarity
- Don't skip comments
  - At least summarize a response to all single reviewer comments

Example: Responsive not Defensive

Original Version

R1. Recommend the addition of a 6-month follow-up study to ascertain if the effect persists after the structured intervention.

We chose not to conduct a follow-up study as our primary focus in this application was to determine whether the intervention could be effective in real time.

Improved Version

R1. Recommend the addition of a 6-month follow-up study to ascertain if the effect persists after the structured intervention.

The reviewer raises an important point. Therefore, we have added a 3-month post-intervention focus group that will assess whether the family continues to dance together, how often, and in what format. We are unable to follow the participants for 6 months due to the fact that recruitment is rolling over the first 2 years of the grant, leaving insufficient time to follow the last recruited family. However, we will also perform a 6-month focus group in a subgroup of the first 50 recruited families.

Source: Writing Dissertation and Grant Proposals: Chapter 20, Resubmission of the Grant Proposal

Example: Reviewer Missed Information

Original Version

We already included age as a matching criteria as noted on page 18 of the original application.

Improved Version

We apologize for our lack of clarity in describing the study design. We will include age as a matching criteria. Specifically, cases and controls will be matched on age <18, age ≥ 18 (see Section C.4. Study Design).

Source: Writing Dissertation and Grant Proposals: Chapter 20, Resubmission of the Grant Proposal

Proposal Updates

- Reviewers identified lots of weaknesses
  - Indicator of enthusiasm for the idea and desire to help improve
- Reviewers missed information that was in the proposal
  - Grant writing issue – get help
  - Repetition, structuring, special formatting can help
  - Summarize important points

Addressing Grant Writing Concerns

- Tell a logical story
- Focus on making your proposal easy to read and technically flawless
- Formatting
- Spelling/Grammar
- Tables/Figures
- Goals, Objectives, and Expected Outcomes
- Define all technical terms
- Remember that most reviewers are not experts in your field

Addressing Significance and Expertise Weaknesses

- Weak Significance
  - Connect the work to the mission of funder
  - Connect the work to your field
  - Clearly show how your proposal addresses a critical need or gap in understanding
- Common Mistakes:
  - Delivering a dull science lecture without connecting the content
  - Assuming too much about the reviewers' background
  - Ignoring or misinterpreting the literature
  - Failing to make a step-by-step logical progression from broad context to specific problem
  - Failing to address the potential for other avenues of research that could address/answer the issue
- Poor Investigator(s) score or concerns about experience/expertise
  - Don't rely solely on biosketches to state experience/expertise
  - Recruit collaborators/consultants if needed

Addressing Methods Comments

- Update preliminary findings
- Add what is missing
- Revise and focus on providing sufficient detail
- Structure methods to match aims
- Point to common methods in the literature, but give at least broad outlines of the approach
- Explain design decisions – provide rationale, especially for unusual or potentially contentious choices
- Possible challenges and alternatives
  - Include this section for each aim/major method
  - Explain why you think challenges are possible but unlikely – or describe how you have or will address them
  - Offer alternative approaches

Submission Updates

- Solicit new Letters of Support
- Use any new templates and follow any new guidelines/requirements
- Update Biographical Sketches
- Do not obsess over prior critiques
- Ask for outside help and peer reviewers
- Don’t give up! (unless a Program Officer says you should)

NSF

NSF Proposal Review Process

- Reviewed on two NSB-approved merit review criteria: Intellectual Merit and Broader Impacts.
- Reviewers' information to the NSF Program Officer to make recommendation
- NSF Program Officer recommends to the cognizant Division Director whether the proposal should be awarded or declined
- Process can take up to six months
- Decline=the organization is notified and review information is available in the FastLane System
- Awarded= the recommendation is submitted to a Grants & Agreements Officer in the Division of Grants and Agreements (DGA)

Panel Summary

- Description of the Project
- Intellectual Merit
- Broader Impact
- Summary Statement
- Score
  - (E)xcellent, (V)ery Good, (G)ood, (F)air and (P)oor, and
  - Intermediate grades of E/V, G/F etc.
- Categorization
  - Not Competitive – will not be funded and probably should not consider resubmission
  - Low Competitive – will not be funded; resubmission possible with major overhaul
  - Competitive – may be funded but likely needs some attention and a resubmission
  - Highly Competitive – probably funded; if not, find out why before resubmitting

What can you learn from Summary?

- Did they get it? – does the description match what you propose
- Dominant reviewer – summary will most closely match this reviewer's comments
- Enthusiasm for the work – emphasis on strengths or weaknesses?
- Did they identify a fatal flaw? – e.g., untestable "hypothesis"

What can you learn from Summary?

- Reviewer Comments
  - Strengths/Weaknesses in Intellectual Merit
  - Strengths/Weaknesses in Broader Impacts
  - Score – Poor, Fair, Good, Very Good, Excellent
- Panel composition
- Technical understanding
- Readability of the proposal
- Reviewer understanding of the funding opportunity
- Areas for improvement

Things to look for in your review

- Not novel – it's already been done
- Too ambitious
- Unaware of key literature
- Failure to consider challenges and alternatives
- Poorly understood/described problem/research question
- Lack of detail
- Lack of evaluation
- Underdeveloped broader impacts
- Not compelling
- Inappropriate hypotheses or untestable "hypotheses"

NSF Review Example

- Comments from the cognizant Program Officer:
  - In the absence of strong support for this proposal in comparison with other proposals reviewed, a declination is recommended. The PI is advised to attend a grant-writing workshop and overhaul this proposal with clear hypotheses and connections between data collection methods, interpretation strategies, and expected outcomes. A better coverage of other methods from the literature is also welcome.

NSF Review Example

- In the context of the five review elements, please evaluate the strengths and weaknesses of the proposal with respect to intellectual merit.
- The specific project objectives and outcomes are not clearly articulated.
- The three directions stated on page 3 of the research plan need to be tightly connected to the milestones.
- It is unclear why the particular XXXXX was chosen and if there is prior evidence that XXX occur without XXX.
- Specific outcomes of this milestone are not clear and potential impact of studies is not clearly placed within the context of current knowledge.
- Based on some of the references that the investigator cites, there is little evidence that these XXXXs are particularly effective for XXXX compared other choices.
- While the proposal describes some interesting methods (XXXXX) it does not describe specifically what specific data will be obtained or how it will be interpreted. Indeed to the reader it sounds (perhaps inadvertently) as a bit of a fishing expedition.

NSF Review Example

- In the context of the five review elements, please evaluate the strengths and weaknesses of the proposal with respect to broader impacts.
- The investigator is attempting to shed insight on a very difficult problem: XXXXX. Because of the poorly articulated research methods and outcomes, it is doubtful that activities will produce transformative results.
- The plan to carry out most of the key experiments off site with undergraduate researchers has both positive and negative aspects. Certainly introducing undergraduates to the research environment at a larger institution may encourage them to pursue graduate studied and broaden their horizons overall. However there is a concern that the logisitics of transporting the students to (and housing them at?) these larger institutions could inhibit progress. How many visits would be necessary? How long would these visits have to be to obtain meaningful data?
- I am concerned that proposing the use of XXX will convey a message that it may be OK to pursue such a policy. I am conceptually opposed to this.

Should I Resubmit?

- Reviewer score
- Positive comments
- Negative comments

NSF Resubmission

- Agency specific
- Refer to the respective agency resubmission policies
- Treated as new submission
- Some panel members may be the same
- New panel members do not have access to previous proposal
- May want to include Introduction paragraph explaining changes (consult with PO)

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NIH Peer Review Model

- Prevalent scientific peer review model and review process
  - Dual peer review system
  - Adopted by several research-based funding agencies
  - First Level of Review
    - Scientific Review Group (SRG) composed primarily of non-federal scientists who have expertise in relevant scientific disciplines and current research areas
  - Scoring
  - Summary Statement
  - Appeals
  - Second Level Of Review - Advisory Council/Board
    - The second level of review is performed by Institute and Center (IC) National Advisory Councils or Boards. Councils are composed of both scientific and public representatives chosen for their expertise, interest, or activity in matters related to health and disease

NIH Review Criteria

CATEGORY	DEFINITION
Significance	Addresses an important problem or critical barrier to progress?
Investigator(s)	Appropriate experience and training? Well suited to the project?
Innovation	Novel theoretical concepts, approaches, methodologies, instrumentation, or interventions?
Approach	Appropriate to accomplish the project's specific aims?
Environment	Contributes to the probability of success? Adequate for the proposed project

NIH review criteria: Rigor and reproducibility

Element of Rigor	Section of Application	Criterion Score	Additional Review Consideration	Contribute to Overall Impact?
Scientific Premise	Research Strategy	Significance	NA	Yes
Scientific Rigor		Approach	NA	Yes
Consideration of Sex and Other Relevant Biological Variables		Approach	NA	Yes
Authentication of Key Biological and/or Chemical Resources	New Attachment	NA	Acceptable or unacceptable	No

NIH Scoring

Score	Descriptor	Additional Guidance on Strengths/Weaknesses
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses
4	Very Good	Strong but with numerous minor weaknesses
5	Good	Strong but with at least one moderate weakness
6	Satisfactory	Some strengths but also some moderate weaknesses
7	Fair	Some strengths but with at least one major weakness
8	Marginal	A few strengths and a few major weaknesses
9	Poor	Very few strengths and numerous major weaknesses

Minor Weakness: An easily addressable weakness that does not substantially lessen impact

Moderate Weakness: A weakness that lessens impact

Major Weakness: A weakness that severely limits impact

Overall impact/priority score is the average of scores of review panel members to one decimal point multiplied by ten. Scores range from 10-90 in whole numbers.

NIH Scoring

- Statement
  - Summary Impact Score
  - 10-30 likely to be funded
  - 31-45 occasionally funded
  - 46+ almost never funded
- Percentile
- Critique Sub-scores (1-9)
  - Significance
  - Investigator(s)
  - Innovation
  - Approach
  - Environment

Understanding NIH Reviewer Comments

- NIAID's website is a phenomenal resource for submission, resubmission, and other guidance:
  - http://www.niaid.nih.gov/researchfunding/grant/strategy/Pages/default.aspx
- You should also review the NIH Q&A (FAQs) on resubmissions:
  - http://grants.nih.gov/grants/policy/resubmission_q&a.htm
- These pages include much of the information presented in these slides

To Resubmit or Not? – NIH

Factor	Resubmit	New Submission	Something Else
Impact Score	<46	46+	Not Discussed
Enthusiasm	High	Moderate to High	Low
Weaknesses	Fixable	Fixable/Fatal	Fatal
Timing	< 1 year	> 1 year	N/A
Fit	Good panel fit	Poor panel fit	Good panel fit

NIH Resubmission Guidelines

- Resubmit after a new, renewal, or revision application, as specified by the funding opportunity announcement
- NIH permits one resubmission of an unfunded application (see NOT-OD-09-016).
- For all application due dates after April 16, 2014, following an unsuccessful resubmission (A1) application, applicants may submit the same idea as a new (A0) application for the next appropriate new application due date (see NOT-OD-14-074)
- Resubmissions (A1) must be submitted within 37 months of the new (A0) application (see NOT-OD-10-140)
  - Thereafter, the application must be submitted as a new application
- For more details on the Resubmission Policy, visit the Resubmissions webpage

Understanding Reviewer Comments – NIH

- Talk to the Program Officer
  - Successful investigators do this almost immediately
  - Ask about reviewer enthusiasm
  - Ask whether reviewers discussed things that were not reflected in the summary statement
  - Ask about fit
  - Ask for guidance on resubmission vs. new submission vs. different opportunity

- Important Note on Special Funding
  - If you are on the list for special funding (a tool for funding projects with additional funds later in the year if available), revise and resubmit immediately unless a Program Officer says to wait

Examples From Reviews – NIH

CRITIQUE 1:

Significance: 2
Investigator(s): 4
Innovation: 3
Approach: 6
Environment: 3

CRITIQUE 2:

Significance: 7
Investigator(s): 5
Innovation: 7
Approach: 7
Environment: 3

CRITIQUE 3:

Significance: 4
Investigator(s): 5
Innovation: 1
Approach: 7
Environment: 1

Sample Review

1. Significance:

Strengths

- Studies the feasibility and efficacy of a school-based intervention to reduce childhood obesity among young children.
- Study will be conducted in urban and rural schools in a very high risk population in a state with one of the highest rates of childhood overweight and obesity.
- The intervention being tested is based on children being agents of change in their homes.

Weaknesses

- None noted.

2. Investigator(s):

Strengths

- PI is a family nurse practitioner in a school-based health clinic.
- Dr. [redacted] is an established researcher, although she has a pharm D background.

Weaknesses

- PI has very limited research and publication track record.
- No nutritionist/dietician or physical activity expertise on the team.

3. Innovation:

Strengths

- Leveraging School Health Council in the design and implementation of the intervention provides a framework for statewide scalability.
- Train-the-trainer approach with children as the intended trainer.

Weaknesses

- None noted.

Sample Review

4. Approach:
Strengths

- Strong recruitment and implementation plan.
- Strong buy-in from study schools.
- Intervention will be integrated into the school curriculum and will be taught by school teachers throughout the school term.
- Multiple data collection points – baseline, end of intervention (end of school term), and 4-weeks post intervention.
- BMI will be measured.
- Use of existing health behavior surveys will allow comparability to other studies.

Weaknesses

- No control group (moderate). How will the study assess whether the changes observed are not time trends?
- Not much detail provided about the curriculum content. While I understand that it will be developed as part of the study, some examples of the types of things included in the curriculum would be useful to get a sense for how exactly training the child as trainer would work.

5. Environment:
Strengths

- good research environment and strong partnerships.

Weaknesses

- None noted

Sample Review

Weaknesses

- The approach for the changes in child behavior is based upon the Social Cognitive Theory. However, considering the study is using the community and leveraging stakeholders etc. it would seem that the approach should be based on a model such as the social ecological model.
- The timeline of 6-months for the development phase is very aggressive, especially considering the PI has little experience (i.e., early stage investigator) and working with school boards and school districts takes a significant amount of time. It is of particular concern that there is no mention of IRB approval in these first 6-months.
- The recruitment will take place through informational sessions for parents (e.g., open house, parent/teacher conferences, or the like). This is a moderate weakness of the study as parents that attend these school meetings are often the "low hanging fruit". How will the more unengaged parents be recruited?
- The implementation phase is also very aggressive and this is a moderate to major concern of the application as recruitment, implementation, and analysis of data in 6-months may be difficult. Additionally, a major concern is that the applicants expect no challenges with retention; this is especially concerning given the known retention rates in at-risk populations. The investigators justify their estimate of no challenges with retention based on one study in 2005 in an at risk population.
- The CATCH questionnaire for the measurement of health behaviors in 8-10 years olds is concerning and a moderate weakness. Children in this age group may not be able to recall the information and facilitation by an adult will not improve this. Additionally the tool has 95 questions. Qualitative data (e.g., focus groups) may be better suited or a shorter tool.
- The investigators are highly underestimating the challenges with their approach based on the literature in similar settings and populations and are a major weakness.

Preparing an Introduction – NIH

- One paragraph including
  - Gratitude for the previous review
  - List of strengths the reviewers identified
  - Description of how changes are marked (or explain that they are not marked)

- EXAMPLE: We appreciate the reviewers' recommendations regarding our original application and appreciate their recognition of the application's strengths including "an outstanding team," an "important target population," and "high dissemination potential." Here we provide a summary of our responses to the critiques. Changes within the proposal are indicated by a vertical line in the left margin.*

- *NOTE: You are no longer required to mark changes!

Preparing an Introduction – NIH

- Identify and respond to all critiques
- Group similar critiques and use an appropriate description
- Describe changes where appropriate, and point the reader to the relevant section(s) of the proposal for additional information
- Explain cases where you choose not to make changes
- Diplomatically point out any misunderstandings and either point to the corresponding information or explain how you have made it more clear
- Do not be hostile, and do not say the reviewers were wrong

Preparing an Introduction – NIH

EXAMPLE:

Topic 1. a) Some concern that the educational video alone may not be enough to change behavior and b) the difficulties in increasing knowledge vs. changing behavior are not discussed. We now include a review of literature in the Innovation Section on the effects of entertainment-education programming and behavior change. The proposed study will evaluate the addition of a home component to further augment changes found with our existing evidence-based school intervention. Our original trial of the school intervention demonstrated slower increase in BMI in intervention vs. control children at one and two years follow-up. *Our goal is to determine whether reinforcement with a home-based component yields a larger effect than the school intervention alone.* Based on a pilot study, we anticipate parental involvement with the DVDs will lead parents to be more supportive of their child's healthy food and activity choices. Pilot study results also showed that children requested fruits and vegetables with meals, asked parents to purchase fruits and vegetables, danced throughout the songs, watched the DVDs with the family more often than we requested, and understood the messages. *Please see Preliminary Studies.*

Sources Other than Funding Agencies

- Chasan-Taber, Lisa. Writing Dissertation and Grant Proposals: Epidemiology, Preventive Medicine and Biostatistics. Chapter 20, Resubmission of the Grant Proposal. CRC Press-Taylor &Francis, Boca Raton, FL; 2014.

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