**FRAMEWORK FOR REVIEW OF CRIS RESEARCH PROPOSALS**

The purpose of this document is to describe the process for reviewing research proposals that are submitted in response to a Request For Proposals (RFP) by the Center for Research on Ingredient Safety (CRIS) at Michigan State University (MSU).

The procedures identified in this framework follow the CRIS Director posting an advertisement for RFPs, and allow for the review of proposals that have been submitted by the closure date.

**I. Identifying Proposals that Should Be Reviewed**

The deadlines for RFPs shall be ‘hard’ deadlines, that is, no extensions or exceptions. This avoids a conflict where a proposal may be received after the RFP date, and the late proposal receive favorable funding over the proposals that met the deadline. There shall be no restriction to the number of RFP deadlines in any given year, and this determination is at the discretion of the Director ofCRIS.

Any proposal that meets the basic criteria stated in the RFP, as judged by the Director of CRIS, shall be considered for review by the CRIS Emerging Issues Committee (EIC).

**II. Handling the Proposals**

The CRIS Director will be responsible for receipt and administrative review of the proposals. Electronic copies will be sent from the CRIS Director’s office to the Chair and Vice Chair of the EIC within 1 week of the RFP deadline.

**III. EIC and Nomination of Reviewers**

**a)** There will be two external scientific reviewers (representing academic, government or non-government organizations from outside the EIC), who will be asked to review and score the proposal. Additionally, one internal reviewer from a non-industry sector of the EIC will be assigned to review each proposal. If no current member of the EIC has the technical background to review a proposal, then another member of the MSU faculty with the appropriate expertise will be asked to review the proposal. Finally, one industry member of the EIC will review each proposal to provide some context for the practicality or relevance of the proposal. The final reviewer will not be asked to score the proposal.

**b)** The EIC Chair and Vice Chair will send the proposals to the EIC members for their nomination of ‘scientific reviewers’, including the names of possible reviewers as identified in the proposal. The EIC Committee members will send the Chair and Vice Chair names of scientists with sufficient expertise to review and provide critique and appraisal of the proposals. This should be completed within 1 week of receiving the proposals.

**c)** A ‘proposal reviewer’ must meet the following criteria:
 1. Scientific reviewers should have scientific expertise in the general area of the proposal.
 2. Scientific reviewers must have professional affiliation with an academic, government or non-government organization. This criteria does not apply to the EIC industry reviewer, who shall be selected based on a consensus by the CRIS Director, the EIC Chair, and the EIC Vice Chair.
 3. A reviewer shall not have professional association with any of the proposal scientists, and shall not have published with any proposal members in the past 5 years.
 4. A reviewer shall not have any existing research or other funding from any of the supporting industry members of CRIS.
 5. A reviewer must be able to sign a conflict of interest statement.

**d)**  The Chair and Vice Chair of the EIC will compile a list of the submitted ‘proposal reviewers’, develop a priority list, and ensure that the nominees are contacted until two external scientific reviewers agree to provide a review.

**IV. Components of the Review**

**a)** The scientific reviewers will evaluate each proposal for strength in the following six evaluation areas (adapted from NIH guidelines for proposal review – see Appendix 1):

 1. Hypothesis (does the proposal have a hypothesis?; is the hypothesis testable?; is the hypothesis consistent with the CRIS strategic focus on the safety of ingredients?);

 2. Innovation (is the approach different, or new, in addressing the problem?);

 3. Significance (is the problem and its impact sufficiently described?);

 4. Experimental Design and Approach (will the proposed studies test the hypothesis and provide novel or further information pertinent to the safety of an ingredient?);

 5. Capability of the Investigator(s) and Environment (is the track record and experience of the investigator and sufficient to execute the experiments?; are the facilities adequate?).

 6. The evaluation should also take into consideration, and at least address:

 i. The inclusion of male and female derived cells, tissues or animals;

 ii. The need of addressing possible vulnerable populations (*in utero*, neonate, juvenile, elderly);

 iii. The integration of sufficient statistical power in study design and data analysis.

**b).** Each of the six evaluation areas will be scored from 1-5 based on the following guideline:

 1- insufficient

 2- weak

 3- average

 4- strong

 5- outstanding

**c)** The reviewers will also provide text describing the reasons for the scores, pointing out strengths and weaknesses of the proposal. There is no limit on the text, however, it is expected that the text will be brief, yet informative.

**d)** The reviews will be submitted to the Chair and Vice Chair of the EIC within 2 weeks of receipt. The Chair and Vice Chair will total the scores and evaluate the consistency of the scoring.

**V. Arbitration of Reviewer’s Recommendations**

The EIC Chair and Vice Chair will evaluate the totality of the reviewer’s scoring and comments for each proposal. If the reviewers are in general agreement regarding the scoring, an arbitrator will not be needed.

If *(i)* there are significant differences in the scoring for a proposal or *(ii)* the EIC Chair and Vice Chair interpret the reviews as ‘inadequate’, the EIC Chair and Vice Chair will determine which two of the three scores to consider for the proposal.

**VI. EIC Industry Member Review of Significance to Program**

Each proposal will be reviewed by an industry member of the EIC and evaluated for relevance to the mission of CRIS. The EIC member will be selected by the EIC Chair and Vice Chair. This evaluation will be based on the following five point analysis:

 1- no relevance

 2- weak relevance

 3- average relevance

 4- strong relevance

 5- outstanding relevance

The EIC member will have 1 week to provide the relevance of the proposal to the industry member needs and mission of CRIS.

**VII. Compilation of Results by EIC Chair and Vice Chair and communication with EIC**

**a)**  The EIC Chair and Vice Chair will communicate the results of the review to the EIC. Each review area (see **IV a.** above) will either receive average scores from the three scientific reviewers (two external reviewers and an internal EIC reviewer from a non-industry sector) and the total score, or the average scores from two of these three reviewers, and the total score, as described above in **Section V**. The communication will also contain the score for industry member relevance.

The EIC Chair and Vice Chair may choose to also communicate some narrative from the assessments by the reviewers.

**b)** The EIC members have **3 business days** to respond as follows:

 - agree with the reviews and to not request any further discussion

 - indicate that there is a need to have a conference call to discuss the results

**c)** If an EIC member indicates discussion is needed, a conference call will be arranged and the concerns of the EIC member will be presented and discussed. The concern and the results of the EIC call will be summarized by the EIC Chair and Vice Chair.

**VIII. Communication of Results to CRIS Director**

**a)**  The EIC Chair and Vice Chair will communicate the results of the review to the CRIS Director.

**b)** The communication will include:

 1. The average scores from either all three scientific reviewers or two scientific reviewers and the total score;

 2. The score for industrial relevance;

 3. Any concern from members of the EIC and summary of the call;

 4. Any narrative from the reviewer’s assessment that is informative;

 5. The EIC Chair and Vice Chair will recommend:

 i. funding with priority ranking;

 ii. not to fund with explanation.

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# APPENDIX 1

# NIH Scored Review Criteria

(from NIH at <http://grants.nih.gov/grants/peer/critiques/rpg_D.htm#rpg_01> )

**1. Significance**.
Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

**2. Investigator(s)**.
Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

**3. Innovation**.
Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

**4. Approach**.
Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (exclusion) of children, justified in terms of the scientific goals and research strategy proposed?

**5. Environment**.
Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?