August 24, 2007 CSR Integrated Biological I Open House Breakout Groups
Report Out Summary

The substantive focus of the August 24, 2007 CSR Integrated Biological I Open House was the breakout groups. These groups provided a forum for external participants to respond to two science-focused questions. Each breakout group was led by a Study Section chair and a Professional Society representative who co-facilitated the group as two Scientific Review Administrators (SRAs) recorded the discussion. At the conclusion of each breakout group session, participants reconvened in the auditorium, where each group reported the top consensus issues listed below. Post-meeting comments regarding these report-out issues can be e-mailed to CSRIB1oh@csr.nih.gov. The post-meeting comment period will close on October 6, 2007.

Question 1:

What will be the most important questions and/or enabling technologies you see forthcoming within the science of your discipline in the next 10 years?

Basic and Integrative Physiology/Technology and Bioengineering

1. *Phenotyping*:
    A. Concept of fingerprint: cell diversity and cell response, organ system network analysis.
    B. Integrative high resolution phenotyping: advanced functional technologies.

2. *Integrative Approaches*:
    A. Molecular to whole animal.
    B. Mathematical modeling as a means to integrate data and supply predictive power.
    C. Translate “omics” data into physiological context
    D. More effective use and production of model organisms.

3. *New Technologies*:
    A. Bioengineering: patterning of tissues, modify tissue environment, capacity to provide tools.
    B. Development of advanced cell culture models.
    C. In vivo imaging: higher resolution, real time, enhanced functional capabilities, application to animals and humans.
    D. Proteomic technology development.

4. *Questions:*
    A. Reproduction.
    B. Human Biomaterials interface, e.g., dialysis.

C. Matrix modification of broad importance across many systems.
D. Inflammation, injury, repair/regeneration, cell death, and fibrosis.
E. Impact of physical inactivity on development of disease.
F. Environmental and gene interactions across the lifespan.
G. Membrane protein structure function.

Molecular and Cellular Mechanisms

1. Integration of molecular and cellular information into systems biology and between scientific disciplines; developmental and integrative biology.

2. *Regulatory Mechanisms*: Genomics; epigenetics; individualized information at the protein, gene, RNA level; role of regulatory RNAs; disease biomarkers, metabolomics, bioengineering as a tool to understand cellular/molecular level, how genes coordinate development of various organs/tissues.

3. *Non-Invasive, Real-Time Measuring Tools in Living Cells/Organisms*: Biochemical events taking place within cells, dynamic structure of cells and tissues, cell-cell interaction, how cells interact with environment, how cells develop into tissues, structure-function measurements in real time; protein-protein interaction; non-invasive ways; computational biology. Micro RNAs.

Pathogenesis and Translational Research

1. Development of cell and animal models to study mechanisms and treatment of disease. Development of technologies in the diagnosis and treatment of disease, including imaging, nanotechnology and gene-based therapy.

2. Stem cell biology research in health and disease with emphasis on aging, chronic diseases, tissue engineering, regeneration and development.

3. Gene-environment interactions in health and disease. Integration of genomic/proteomics/metabolomics/epigenetics/biomarkers/clinical data.

4. Studies of multi-organ interactions in health and disease. Development, accessibility and integration of complex data sets to include bioinformatics, computational biology and systems biology.

Clinical

1. *Bioinformatics*: Protection, communication, training, usability for clinical trials, objective and subjective end points, consolidation, common language, integrating multidisciplinary clinical, behavioral and basic science.

2. Clinical trials and clinical investigations for understudied clinical issues, guidelines/registries, for evidence based treatments.

3. Communication with the population, accessing patient population for trials, standardization of criteria.

4. Enabling technologies for proven treatments for the general population. Advanced technologies assisted diagnosis and therapies.

Question 2:

Is the science of your discipline, in its present state, appropriately evaluated within the current study section alignment? Suggestions?

Basic and Integrative Physiology/Technology and Bioengineering

1. *Review Alignment*:
   A. Current Study Section alignment is appropriate but requires continual evolution; this will not happen spontaneously; overlapping Study Sections occasionally provide poor coverage.

   B. Cross-cutting areas are still problematic; multi-organ studies; multi-techniques; for example, physical activity/inactivity and chronic kidney disease affect many organs and tissues, does not fit into current alignment.

2. *Review Process*:
   A. Interdisciplinary applications need many different areas of expertise.
   B. Phone, mail and ad-hoc reviewers not the best.
   C. AED and VED are not good substitutes.
   D. Solutions: (1) two-stage review; (2) pool technical reviewers to serve many Study Sections to evaluate special techniques.
   E. Greater focus on the impact or importance of research.
   F. Member SEPs need to have a more stable set of reviewers to maintain continuity.

3. *Review Quality*:
   A. Best solution is reviewer quality; checkbox on awards to serve on Study Sections.
   B. NIH suggests to AAMC that medical schools give recognition for Study Section service; current management policies deter clinicians form serving on Study Section.

Molecular and Cellular Mechanisms

1. *Current Study Section*: Only funded investigators should be reviewers. Ad hoc reviewers should possess broad expertise and be taken from a pool of reviewers. Continuity of reviewers. Reviewers need to be reminded about review criteria re: R21, and hypothesis driven. "Reducing application size will increase reviewers' burden" vs. "shorter applications better." Triaged applications should get scores. Discrepancy between scores in CSR vs. IC review.

2. *Study Section Alignment*: Organ- or disease-specific Study Section alignment is good for some disciplines, but loses integration. Applications in particular disciplines, e.g., environmental science, therapeutics, are distributed among too many study sections thus losing integration. Modular design of Study Sections.

3. *Reviewer Recruitment Issues*: Video conferencing, reduce workload. Serving on Study Section may be made mandatory for funded investigators. Inducement of service may be provided. Training of reviewer and Chairs.

Pathogenesis and Translational Research

1. *Some disciplines not well served by the current review groups, including*: toxicology, study of alcohol-related diseases, urology, urogynecology and pain syndromes/visceral hypersensitivity.

2. *Potential Solutions*: Create (1) an Environmental Health Sciences IRG for the toxicology applications, which would also include a study section dealing with the effects of alcohol in health and disease, (2) a study section dealing with the study of urological sciences, and (3) an urogynecological study section.

3. *Potential New Mechanisms of Review*: (1) emphasis should be given to innovation and significance, (2) training and education of reviewers, particularly new ones, and (3) CSR should evaluate how to review appropriately applications involving analysis of large data sets.

Clinical

1. *Achievements*:
    A. Some study sections focused on multidisciplinary and clinical approaches.
    B. Face to face meetings.

2. *Challenges*:
    A. Lacking specific expertise on a study.
    B. More integrated approach is needed. Current study sections are not attuned to this or with high risk ideas.

C. Need a site where Principal Investigators can go to see where their application could go.
D. Translational approach to study sections vs. a more focused approach. Who should serve?
E. How do you integrate new investigators into the review process?
F. Where do the common ailments/issues, orphan areas that affect the general population go? For example, gynecological disorders, surgery, emergency medicine.

Conclusion

The Center for Scientific Review will carefully review these comments and suggestions and will consider appropriate steps to address concerns. For example, CSR plans to address the challenges facing review of translational and multidisciplinary applications. To ensure stakeholder participation and broad perspective, results from Open House deliberation will be presented to the NIH Peer Review Advisory Committee (PRAC) for its consideration before changes are implemented.

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