June 29, 2007 CSR Disease-based Open House Breakout Groups
Report Out Summary

The substantive focus of the June 29, 2007 CSR Disease-based 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 three consensus issues listed below. Post-meeting comments regarding these report-out issues can be e-mailed to CSRBSSRoh@csr.nih.gov. The post-meeting comment period will close on August 24, 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 Mechanisms

1. Imaging technologies. Major impact areas across Microbiology and Oncology.

2. Large scale analysis of cellular components. Advances in glycomics and proteomics. Development of new biomarkers for therapy and infectious diseases research.

3. Cell-environment interactions. Modeling in 3D. Impact of biophysics, statistics and structural biology. Single cell versus systems biology. How to look at complexity? Structure of the bacterial cell.

4. Small molecule screening becoming more accessible to academics.

5. Bioinformatics; pharmacogenomics; toxicogenomics; computational analysis; mathematical modeling; biomedical records; data integration.

Translational

1. Biomedical informatics: standardization, accessibility, handling and integrating large data sets including clinical trials.

2. Individualized risks and responses.
    A. Nanotechnologies (miniaturization).
    B. Biomedical imaging.
    C. Biomarkers (-omics)

3. Developing, optimizing, standardizing and validating model systems for translation to human diseases.
    A. Mathematical/biological.

4. Broad based multidisciplinary approaches.
    A. Integration of physics, math, chemistry, engineering and biology to address significant clinical problems.
    B. Training.

Molecular Mechanisms for Diagnosis and Therapy

1. Novel technologies for drug development (chemical biology & proteomics), screening (HTS), *in vivo* drug distribution (imaging, *in situ* sampling), individualized and general therapy and responses (point-of-care diagnostics, biomarkers, cell- and gene-based patient care, RNAi).

2. Computational methods for drug discovery, structural biology, and systems biology, and for analysis and sharing of increasingly complex data sets.

3. Integration of multi-disciplinary science (biomedical, physical, and social) for synergistic development of diagnosis, therapy, and prevention.

Pathogenesis

1. *Systems Integration and Large Scale Data Management*: Development of high through put data analysis and systems technology; improved sensitivity of integrated systems; improved protein based data; need for NIH to direct more coordination of data bases; development of data base for assessment tools for assays; Mathematical modeling.

2. *Development of animal models and establishing their relevance to human disease*: in vivo imaging analysis technology; tissue specific knockout of gene expression models; development of biomarkers – need for standardization and quantitation; coordination and validation of human and animal models; design of models, development of criteria for critical evaluation of models; need for coordination of evaluation.

3. *Multidisciplinary projects looking at systems and organisms as a whole and involving many different technologies*: look at disease state from different aspects; metagenomics; consensus needed in types of assays; central information source; need to be able to rapidly adjust to scientific paradigm shifts.

Technology, Computational Biology, and Bioengineering

1. Information and knowledge management – how to collect and share data and knowledge being collected form bench to bedside and the other way around.

2. Communication between disciplines – Common language – Shared hypotheses – Bridging the gap between disciplines to gain an understanding of major parameters important to each.

3. Personalized medicine-development of economically viable technologies that allow implementation of bedside to bench and back.

Clinical

1. Broad changes in the field.
    A. Increasing collaborative science – multidisciplinary.
    B. Increase in patient specificity affecting treatment such as cellular/molecular therapies.
    C. Science looking at follow through of interventions in the developing world, i.e., AIDS and opportunistic infection.

2. Technologies.
    A. Imaging, both anatomic and functional.
    B. High through input – genomic.
    C. Bioinformatics and processing.
    D. Diagnostic and theraperutic – virtual for emergency medicine, rural and urban.

Question 2:

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

Basic Mechanisms

1. Majority opinion is "Yes"; most science is appropriately evaluated under current alignment.

2. Emerging Technologies: Distinguish between persistent and transient trends. Incorporate into existing SRGs or set up a new SRG. More applications cut across disciplines and require reviewers with multiple expertise. Recruit more *ad hoc* reviewers – restrictions?

3. Certain disciplines absorbed into multiple SRGs, e.g., biochemistry, toxicology, gene therapy. SRAs competing for limited pool of reviewers; under-representation of experts?

4. Experts in some "neglected" diseases may be under-represented, e.g., melanoma. NIH should listen to suggestions from advocacy groups and scientific societies.

5. More clinician scientists needed on SRGs. How to preserve the quality of review of basic science in the context of more clinically oriented research?

6. SRAs should attend more scientific conferences to keep pace with emerging science and identify potential reviewers.

Translational

1. 90 – 95% are evaluated properly.

2. Examples of areas of concern (5-10%) include:
    A. Pain.
    B. Environmental toxicology.
    C. Sleep.
    D. Mitochondrial injuries.
    E. Multi-disciplinary nature of the applications.

3. Suggestion: Formalization of a transparent process to evaluate complaints.

4. Non-hypothesis driven applications:
    A. Infrastructure.
    B. Technology.
    C. Epidemiology.

Molecular Mechanisms for Diagnosis and Therapy

1. Balance of disease-based and basic science study sections works although there are still gaps, e.g., toxicology, ecology etc.

2. Integration of science at the review level.
    A. Interdisciplinary science.
    B. Across the translational continuum.

3. Greater appreciation of non-hypothesis driven science.
    A. Emphasize whether the science moves the field forward.
    B. Include discovery based scientists.

4. Specialized and broad expertise (academic, industry, and government reviewers) to rapidly address with flexibility multidisciplinary and emerging science.

Pathogenesis

1. Study sections where review appears to be appropriate: Virology, AIDS, Oncology IRG; Review based on specific pathways vs. specific organ sites; multidisciplinary study sections work well.

2. Matrix Biology not appropriately reviewed; reviewed by different study sections; could be resolved by recruiting appropriate reviewers; we need a basic biology study section for pathogenic microbes, opportunistic pathogens reviewed in AIDS study section should be reviewed in IDM.

3. Clustering of specific mechanisms in a particular study section works well, e.g., R01s, R03, R21; Need to shift mind set in moving from review of established investigators to young investigators.

4. Limited number of reviewers – how to get the best reviewers is still a concern; having right expertise is critical; question of level of how expertise, specific expertise vs. broad expertise.

5. How do you address review in rapidly emerging areas when the number of investigators in the field is very limited? (e.g., autophagy) a floating pool of shared expertise across study sections is suggested.

Technology, Computational Biology, and Bioengineering

1. Assignment to appropriate reviewers – add more ad hoc reviewers based on type of grant - interdisciplinary or translational reviewers?

2. Reviewer education and training – weighting different criteria.

3. Re-evaluate scoring system – technical merit and impact – score all criteria separately – and then depending on category – basic, hypothesis, mechanistic, translational, observational, clinical – give a final score.

4. Review process to assess past performance (senior investigators) – track record and impact factor, citations, productivity.

Clinical

1. Clinical trials:
    A. ONC – okay.
    B. AIDS – okay; R34 unknown.
    C. IDM – okay; R34 unknown.
    D. Surgery, issues (see below)

2. Clinical Studies:
    A. ONC – okay.
    B. AIDS - okay.
    C. IDM, Consider increasing study sections involved in clinical/human studies.
    D. Surgery, issues (see below)

3. Assignment and Expertise Issues:
    A. Surgery scattered applications being assigned to organ-based groups.

4. Clinical/human studies being scattered throughout IRGs:
    A. Possibly clustering would be beneficial and optimal use of resources.

5. New Need:
    A. Emergency and Disaster 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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