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The adolescent brain cognitive development study external advisory board

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"I get by with a little help from my friends" – *John Lennon and Paul McCartney*

Why should the Adolescent Brain Cognitive Development study (ABCD Study) have an External Advisory Board (EAB)? ABCD Study has approximately two-dozen principal investigators, all experts and leaders in the diverse fields of study required to accomplish ABCD Study's goals. Furthermore, as part of an NIH consortium, ABCD Study investigators work in close collaboration with scientific experts from multiple National Institutes of Health (NIH) Institutes and Offices (https://abcdstudy.org/nih-collaborators.html) and have ready access to their expertise. And NIH has constituted an Observational Study Management Board (OSMB) to offer oversight and counsel to ABCD Study regarding myriad ethical issues that might arise in the course of a 10-year longitudinal study of 10,000 children. So why also have an EAB? In a way, it is the organizational structure of ABCD Study, its cost, its complexity, its extraordinarily ambitious goals, and its importance to the scientific community and public health that together obligate oversight from an unbiased set of experts who can advise ABCD Study across a wide range of issues.

A nascent EAB for the ABCD Study existed before the ABCD Study was fully conceived or funded. On May 27–28, 2014, the Collaborative Research on Addiction at the NIH (CRAN), an initiative of the National Institute on Drug Abuse (NIDA), National Institute on Alcohol Abuse and Alcoholism (NIAAA), and National Cancer Institute (NCI), in collaboration with The Eunice Kennedy Shriver National Institute on Child Health and Development (NICHD), convened a public expert panel workshop (Table 1) to help envision the ABCD Study (https://addictionresearch.nih.gov/national-longitudinal-study-neurodevelopmental-consequences-substance-use-meeting-agenda) and to provide guidance on the development of a funding opportunity announcement (FOA). The goals of this public meeting were announced by NIH leadership in a public message on May 16, 2014 (https://www.niaaa.nih.gov/news-events/news-noteworthy/national-longitudinal-study-neurodevelopmental-consequences-substance). Working with NIH leadership and with input from the scientific community, the public expert panel considered general design parameters for a longitudinal study that)would deploy cutting-edge technologies in brain imaging, genetics, and neurocognitive assessment to characterize normal adolescent brain development and its modification by substance use, mild traumatic brain injury and other adolescent experiences. The work of the expert planning committee (https://addictionresearch.nih.gov/summary-expert-panel-meeting) shaped the broad outlines of the ABCD Study, and the study design and goals were further refined by the scientific community through a request for information (https://grants.nih.gov/grants/guide/notice-files/NOT-DA-14-014.html) and a second public meeting on November 17, 2014 at the Society for Neuroscience (https://addictionresearch.nih.gov/sfn-meeting-summary). Informed by this feedback, NIH released the FOA (https://grants.nih.gov/grants/guide/rfa-files/RFA-DA-15-016.html) that engendered the ABCD Study on February 4, 2015. While some members of the public expert panel were subsequently funded as ABCD Study investigators, others who chose not to submit applications became members of the EAB, carrying with them the memory of ABCD Study's origins and purpose.

1. Composition of the ABCD Study EAB

Membership of the EAB was determined by NIH program staff in conjunction with the Steering Committee and the EAB chair to provide a broad array of expertise that might inform every facet of the ABCD Study. The twelve members of the ABCD Study EAB (Table 2) are national and international experts in fields and scientific disciplines relevant to the design and implementation of the ABCD Study: child and adolescent development; prevention research and advocacy; mental health; education and education research; community outreach; cognitive development; neuroimaging; ethics; informatics; and data sharing. Importantly, the ABCD Study EAB also has community membership to represent the views of the community. Despite a broad representation of disciplines, *ad hoc* members may at any time augment the expertise of the EAB. Scientific and community members of the EAB are, to the extent possible, unaffiliated with ABCD Study investigators and their institutions, to preserve objectivity and to assure an unbiased review of ABCD Study plans and progress. A board with 12 members is slightly large for complex decision making but well sized to provide a broad array of scientific expertise. Scientific advising has been a far more important endeavor for the ABCD Study EAB than complex decision making.

2. Responsibilities of the ABCD Study EAB

The charge to the ABCD Study EAB was outlined in the FOA (https://grants.nih.gov/grants/guide/rfa-files/RFA-DA-15-016.html):

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Table 1
Members of the Public Expert Panel Workshop. Shown are their academic affiliations at the time of the meeting in May of 2014.

Louise Arseneault, Ph.D.;
Professor in Developmental Psychology
Institute of Psychiatry
King's College London

Frank M. Biro, M.D.
Director of Research, Adolescent and Transition Medicine
Professor, Department of Pediatrics
University of Cincinnati

BJ Casey, Ph.D.;
Professor of Psychology in Neuroscience, Brain and Mind Research Institute;
Professor of Psychology in Psychiatry;
The Sackler Professor of Developmental Psychobiology;
Weill Cornell Medical College

Linda Chang, M.D.;
Professor of Medicine
Program Director, Neuroscience and MR Research
Department of Medicine,
John A. Burns School of Medicine,
University of Hawaii

Michael E. Charness, M.D. (Chair);
Chief of Staff, VA Boston Healthcare System;
Professor of Neurology and Faculty Associate Dean, Harvard Medical School;
Professor of Neurology and Associate Dean, Boston University School of Medicine

Raquel Gur, M.D., Ph.D.;
Professor of Psychiatry, Neurology, and Radiology;
Director, Neuropsychiatry Section and the Schizophrenia Research Center;
Vice Chair, Research Development;
Department of Psychiatry;
University of Pennsylvania Perelman School of Medicine

Rolf Loeber, Ph.D.
Distinguished Emeritus Professor of Psychiatry and Psychology;
University of Pittsburgh

Robin Mermelstein, Ph.D.;
Professor of Psychology;
Distinguished Professor of the College of Liberal Arts and Sciences;
Director, Institute for Health Research and Policy;
University of Illinois (UIC) at Chicago;
Clinical Professor of Community Health Sciences in the UIC School of Public Health;
Assistant Dean, UIC College of Medicine;
Co-principal Director, UIC Center for Clinical and Translational Science
University of Illinois, Chicago

Adolf Pfefferbaum, M.D.
Senior Program Director and Distinguished Scientist,Neuroscience;
Center for Health Sciences;
SRI International

Table 2
The ABCD Study External Advisory Board.

Thomas Brock, Ph.D.;
Commissioner, National Center for Education Research;
Director, Institute of Educational Studies;
US Department of Education.

Michael E. Charness, M.D. (Chair);
Chief of Staff, VA Boston Healthcare System;
Professor of Neurology and Faculty Associate Dean, Harvard Medical School;
Professor of Neurology and Associate Dean, Boston University School of Medicine

Celia Fisher, Ph.D.;
Marie Ward Doty University Chair in Ethics;
Professor, Department of Psychology;
Director, Center for Ethics Education;
Fordham University.
Kathleen Mullan Harris, Ph.D.;
James Haar Distinguished Professor, Sociology;
Adjunct Professor, Public Policy;
University of North Carolina

Mimi Fleury;
President and Co-Founder;
Community of Concern

Russ Poldrack, Ph.D.;
Professor of Psychology,
Stanford University

Diana Fishbein, Ph.D.;
Director, Edna Bennett Pierce Prevention Research Center;
Professor of Human Development and Family Studies;
Pennsylvania State University

Raquel Gur, M.D., Ph.D.;
Professor of Psychiatry, Neurology, and Radiology;
Director, Neuropsychiatry Section and the Schizophrenia Research Center;
Vice Chair, Research Development;
Department of Psychiatry;
University of Pennsylvania Perelman School of Medicine

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Director, Institute for Health Research and Policy;
University of Illinois (UIC) at Chicago;
Clinical Professor of Community Health Sciences in the UIC School of Public Health;
Assistant Dean, UIC College of Medicine;
Co-principal Director, UIC Center for Clinical and Translational Science University of Illinois, Chicago

Larry Steinberg, Ph.D.;
Distinguishsed University Professor and Laura H. Carnell Professor of Psychology;
Temple University

Henning.W. Tiemeier, M.D., Ph.D.;
Professor of Psychiatric Epidemiology;
Departments of Epidemiology and
Child and Adolescent Psychiatry;
Erasmus Medical Center, Rotterdam, The Netherlands

David Van Essen, Ph.D.;
Alumni Endowed Professor of Neurobiology;
Department of Anatomy and Neurobiology;
Washington University School of Medicine;

"The consortium includes an external scientific advisory board whose purpose is to meet with the consortium coordinator and the Steering Committee to assess progress and provide feedback to the investigators and CRAN and other NIH ICs on proposed goals for the next year of support. The panel members are designated by CRAN and other NIH ICs in consultation with the Steering Committee, and consist of research scientists not actively involved with the consortia. The Scientific Advisory Board should meet with the consortium investigators after the release of the Notice of Award to review and revise the protocol before formal data collection activities begin. Thereafter, the Scientific Advisory Board should meet at least once a year immediately prior to the submission of the consortium annual progress report."

In effect, the ABCD Study EAB was tasked with providing scientific guidance throughout the course of the study. During the ABCD Study's first year of funding, much of that guidance centered on the design of protocols, recruitment plans, and contingency planning to assure that recruitment goals are met. Over the course of the study, the focus of the EAB will shift to subject retention, data analysis and sharing, and the ethical dilemmas that will arise as children become adolescents and some develop substance use disorders, experience traumatic stress, and suffer serious medical and mental health disorders. Finally, with a 10-year longitudinal study, the ABCD Study investigators and EAB will be challenged to integrate advances in neuroimaging, neurocognitive evaluation, genetics, mobile technology, and bioinformatics while maintaining the fidelity of the original experimental design. The members of the EAB are appointed to the EAB for renewable 2-year terms. As the study progresses over the coming decade, current members may cycle off the EAB and new members may be appointed to better address evolving needs for specific expertise.

3. Scientific advisory board governance for other studies on childhood development

The scientific literature is silent on the role of EABs in NIH-funded consortia and longitudinal studies of childhood development. Generation R has no scientific advisory board (SAB) or EAB (Henning W. Tiemeier, M.D., Ph.D., Erasmus Medical Center, personal communication). Methods papers outlining the study design for IMAGEN and PING make no mention of an SAB or EAB, although the IMAGEN methods paper briefly alludes to a multidisciplinary ethics group (Jernigan et al., 2016; Schumann et al., 2010). Likewise, there is no mention of an EAB or SAB on the websites of IMAGEN, the PING study, or Dunedin. The website for the Collaborative Initiative on Fetal Alcohol Spectrum Disorders (CIFASD) indicates that the SAB evaluates progress on each component of CIFASD as well as its overall mission. The NCANDA methods paper lists the SAB and acknowledges their role in the design and methods of NCANDA (Brown et al., 2015). The NCANDA grant application contains a much more detailed description of the role of the NCANDA SAB, which in many respects parallels that of the ABCD Study EAB. The NCANDA Administrative Resource, Steering Committee, and SAB are together responsible for "setting annual priorities and goals, evaluating progress, review of budgets and financial allocations, assurance of cross-site training and reliability, and facilitating retention efforts." (Sandra Brown, Ph.D. and Terry Jernigan, Ph.D., UCSD; personal communication).

4. Principles of board governance and function

There is little published literature to guide how a scientific advisory board should function; nonetheless, lessons from the corporate and healthcare sectors can be instructive. Chambers and colleagues (Chambers et al., 2013) reviewed the literature on board processes and governance in an effort to establish guidance for boards that advise the National Health Service in England. Most of the published literature concerned corporate boards, and there was insufficient data on business outcomes and board models to delineate ideal models. However, some of the outlined principles of board governance and function may be relevant for the external advisory boards of scientific enterprises, such as ABCD Study.

Boards have different roles and responsibilities across the business, healthcare, non-profit, and scientific sectors (Chambers et al., 2013). Accordingly, they are constituted differently and operate under different models and with different goals. A board structure and process that functions well in the corporate sector may not be effective in healthcare or science. Furthermore, the governance, culture, and function of a board might need to change as an organization evolves in size, complexity, and maturity. Board processes – how the board conducts business, gathers information, and makes decisions – may be more important than the composition of a board. Larger boards may provide a greater balance of views and expertise but are more costly and less efficient in decision making and communication (Chambers et al., 2013). High-performing boards tend to engage in self-evaluation and the development of skills for board members.

5. Models of board governance

Board models vary based on the priorities for organizational outcomes. Agency theory evolved to reconcile the conflicting interests of corporate shareholders (owners) and managers, mitigate financial risk to shareholders, and diminish the likelihood of poor corporate performance (Chambers et al., 2013). In this model, the board of directors has a responsibility to oversee and hold accountable the CEO. To do so, the board must monitor corporate performance and scrutinize and challenge the company's strategy and operations. It is difficult for a board that meets intermittently to accomplish all of these goals, and a strong focus on monitoring operations may distract from the review of strategic planning or risk mitigation.

Scientific advisory boards, such as the ABCD Study EAB, have a different relationship with organizational leadership. Both have a primary interest in the success of the scientific endeavor. The relationship of the board to the principal investigators (PI) is therefore collaborative, a model best described by stewardship theory. In this model, boards and managers work together on improving processes and strategies, and board members contribute to the desired outcome by tapping their expertise and experience to advise and guide the enterprise (Chambers et al., 2013). In the corporate sector, the stewardship model may compromise oversight of management by owners, but in scientific endeavors, the goals of the board and scientific leadership – the generation of valuable new knowledge – align closely. Although the relationship between boards and organizational leadership is collaborative, better outcomes may result when engaged boards build trust with, but also challenge, organizational leadership (Chambers et al., 2013), whether that organization is a corporation or an NIH-funded consortium. The ABCD Study EAB illustrates some of the attributes of the stewardship model.

6. ABCD Study EAB governance

The ABCD Study EAB advises two groups. ABCD Study is funded by NIH under a cooperative agreement and operates as a consortium that includes both field-based investigators and NIH scientists and program staff. In contrast to most NIH-funded research, the NIH scientists and program staff are active participants with the field-based investigators in the design and execution of the ABCD Study. Hence, the EAB provides advice to both field-based investigators and NIH staff.

The EAB meets in person annually and more frequently through online meetings. Ongoing communication between the EAB and the ABCD Study Coordinating Center is accomplished through attendance of the EAB chair at biweekly online meetings of the Council of Investigators, membership of the EAB chair on the ABCD Study Steering Committee, and *ad hoc* discussions between the EAB chair and ABCD Study's two principal investigators.

The EAB has no decision rights and no intrinsic power, short of the power of persuasion. It exists to evaluate and advise. However, when ABCD Study investigators and their NIH partners hold divergent views regarding direction or strategy, a strong recommendation from the EAB may help build consensus. ABCD Study investigators have been encouraged to contact members of the EAB for advice in their areas of expertise, and individual investigators have availed themselves of this opportunity in the areas of recruitment from schools, management of clinically significant imaging findings, the Human Connectome Project, and ethics. Regular meetings of the EAB provide a forum for more formal review and discussion. These principles of board governance and function can best be illustrated by considering how the EAB has engaged with ABCD Study leadership, NIH staff, and investigators in the areas of study design, strategic planning and risk management, crisis communication, ethics, and data sharing.

6.1. Study design

The full EAB met with the ABCD Study Steering Committee and NIH scientific and program staff for the first time in Bethesda, MD on January 14–15, 2016, nearly 10 months before ABCD Study formally began subject enrollment. This meeting focused on study design, recruitment strategy, imaging protocols, neurocognitive and behavioral assessment protocols, and pilot data. The EAB recommended that ABCD Study investigators reach consensus quickly on the target number of enrolled subjects, balancing the safety margin of higher numbers with the concomitant risk that with a fixed budget, lower per-subject funding might render recruitment goals unattainable. The EAB recommended a somewhat higher number than the planned recruitment goal of 11,111 subjects, as a reasonable balance between these risks and benefits.

Consequently, the ABCD Study investigators settled on a recruitment goal of 11,500 subjects.

In any study, there is a tension between the desire of investigators to learn as much as possible and the ability of subjects to withstand lengthy test batteries. The EAB expressed concern that implementation of the proposed test battery would lead to study fatigue and dropout. Since some of the test batteries were included to respond to requirements of the FOA, the EAB recommended that ABCD Study leadership negotiate with NIH program officers to reduce significantly the duration of the baseline neurocognitive evaluation, including allowing deviation from the FOA to increase the likelihood of test completion without burnout or challenges to retention. As a result of these recommendations, the cognitive and behavioral evaluation was shortened from 4 h to 3 h, allowing the total initial evaluation, including imaging, to be reduced from 8 h to 7 h. The EAB also recommended modifications to the assessment battery to include better capture of factors of risk, protection, and resilience, inclusion of education outcomes data, and the assessment of nutritional factors.

The EAB met again in person in San Diego, CA on November 18, 2016 in conjunction with the meeting of the Society for Neuroscience. The EAB again called attention to protocol length as a potential problem for the retention of adolescent subjects and research assistants. The EAB advised that should burnout of research assistants occur during the first year, steps should be taken to shorten the evaluation protocol or provisions be made for the completion of some questionnaires online using mobile or web-based technology. Any attempts to shorten the evaluation protocol should be strategic; i.e., reducing the lowest priority items from a list of all tests, rather than reducing a fixed percentage of items from each test. At that time, there were sites that differed in the average duration of time for completing test batteries. It was recommended that the high and low outlier sites be compared to identify and spread best practices for increasing the efficiency of the evaluations. The EAB also cautioned that PIs must balance for their staff the pressure of reaching targets for enrollment and testing with the need to run subjects in strict adherence with study protocols.

6.2. Strategic planning and risk management

One important role of the EAB has been to identify risks that would threaten the overall success of the ABCD Study. Among these, the most serious would be the failure to recruit a population of sufficient size, risk characteristics, and demographic diversity to accomplish the scientific goals of the ABCD Study. At its first full meeting, the EAB noted that with 19 original research sites, there was a significant risk that one or more sites would not succeed in reaching their recruitment targets, and there was a smaller risk of catastrophic failure at a single site due to equipment failure, natural disaster, or loss without replacement of the principal investigators. The EAB recommended the development of a risk management plan for recruitment in collaboration with the ABCD Study Council of Investigators and Steering Committee. The plan should include clearly delineated triggers and timelines for identifying challenged sites and the implementation of measures for site assistance. A transparent plan with predetermined triggers was felt to be essential in empowering ABCD Study leadership to reallocate resources quickly based on mutually agreed criteria.

The ABCD Study was designed to allow the shifting of recruitment goals and funding between hub and spoke sites through a U01 subcontracting mechanism. For freestanding sites without spoke sites, there were fewer opportunities to adjust funding and targets. The EAB recommended to NIH program staff that the Coordinating Center be provided with a flexible fund to enhance enrollment at sites that can expand subject capacity when other sites lag in their enrollment goals.

The EAB also discussed options for addressing catastrophic recruitment failure at one site or an aggregate recruitment shortfall across the 19 ABCD Study sites during the allotted two-year period of enrollment. One option would be an extension of the period of recruitment, which might significantly increase the costs of ABCD Study. A second option would be to align one or more reserve sites that could be stood up quickly as spoke sites to existing hubs. Concerns were raised about the costs to other ABCD Study sites to maintain readiness at one or more reserve sites, and consensus could not be reached on this plan, although the recommendation proved prescient.

By the time of the November, 2016 meeting, the ABCD Study had created strategies, protocols, policies, and procedures that led to the successful launch of subject enrollment in September of 2016. Recruitment remained a major focus of the EAB. Late starts at two sites had moved the ABCD Study towards a point where every site must meet its target goal for the ABCD Study to succeed in its overall enrollment goals.

The EAB requested that the ABCD Study Coordinating Center develop plans that could be implemented in a few months to address the further loss of enrollment capacity. At this meeting, more serious consideration was given to the standing up of reserve or new sites and to extending the period of enrollment for sites that go offline temporarily. The EAB's recommendation to augment enrollment capacity through the addition of reserve or new sites helped allay concerns among NIH staff regarding this approach and led to a critical expansion of enrollment capacity.

During an EAB teleconference meeting on April 19, 2017, the Coordinating Center indicated that its current rate of enrollment would achieve just 84% of its target goal. By this time, two new sites had been added to boost enrollment – University of Wisconsin, Milwaukee and Medical University of South Carolina – but it was too soon to gauge the impact of their inclusion. Optimism was expressed that the enrollment target could be reached by increasing enrollment above target levels at the higher-performing sites and sharing best practices to boost enrollment at the lower-performing sites. Efforts were underway to shift enrollment targets between hub and spokes sites funded by a common U01. Where this was not possible, additional funding flexibility would be required to provide incentives for sites to boost their enrollment above target levels. The EAB again endorsed the proposal to increase the budget of the common pool to allow the Coordinating Center to incentivize high-performing sites to recruit above their target levels of enrollments. The EAB also noted that a brief extension of the enrollment period (Sept 1, 2016 to August 31, 2018) would provide additional enrollment opportunities but might complicate the timetable for follow-up studies.

By the time the EAB reconvened by teleconference on August 11, 2017, a third new site, the University of Rochester, had been added. The activation of these three new sites and a surge in summer recruitment had changed the recruitment outlook. At the second annual face-to-face meeting of the EAB on November 8–9, 2017, investigators reported that the ABCD Study was on track to achieve its recruitment goals. At that meeting, the EAB recommended that investigators refine their retention strategies in advance of the first follow-up visits, modify testing schedules to accommodate a decrease in subject availability in the late afternoons as after-school schedules filled up, and plan for the tracking and follow-up of children who move after their initial evaluation.

6.3. Ethics, adverse events, and crisis communication plans

Brain imaging of children and adolescents in the NCANDA and Generation R studies revealed an 11.8–25.6% incidence of structural brain anomalies; less than 0.5% of these required clinical follow-up (Sullivan et al., 2017; Jansen et al., 2017). In early meetings, the EAB urged that ABCD Study investigators develop a risk management plan for the discovery and disclosure of incidental neuroimaging findings or the later release of baseline normal neuroimaging findings, as reflected in the informed consent form (ICF). The plan should be sensitive to the anxiety created by disclosure of clinically insignificant anomalies and the need to refer families to community providers to allay concerns and

provide appropriate follow-up. Likewise there should be timely disclosure of clinically significant brain abnormalities with appropriately rapid referral to community providers. The overlap of investigators between NCANDA and the ABCD Study facilitated the replication by the ABCD Study Coordinating Center of many of the processes for review and reporting of abnormal findings developed by NCANDA. By the time of the November 2017 annual ABCD Study meeting, this process had been successfully activated numerous times.

A second important risk for the ABCD Study is the occurrence of ethical lapses, data breaches, or the mismanagement of adverse events that might undercut support for the ABCD Study within NIH or Congress. The EAB advised the ABCD Study investigators to plan for the mitigation of risk for rare serious events, such as a subject overdose, suicide, or homicide. Personnel at all sites should be trained to a standardized plan for responding to the identification of risks to subjects and others based on clear, tiered definitions of risk. The plan should include a process for contacting local referral sites, emergency rooms, 911, and notification of the PI and Coordinating Center, as appropriate. Experience at individual sites should be shared broadly for quality improvement purposes, and a culture of just reporting of errors should be encouraged. There should be a clear plan for managing serious adverse events, such as injury to subjects or data breaches, including the prior development of a communications plan and the standing up of an incident command center to manage the flow of information. Members of the EAB offered to share the risk management plans from their own studies.

By the November 2017 annual meeting, the ABCD Study Coordinating Center had developed a meticulously detailed crisis management plan for coordinating the response to rare serious events, including personal harms and data breaches. The plan focused on central coordination and communication involving a joint ABCD Study and NIH leadership crisis management team. The EAB recommended the additional development of a separate crisis management plan for each study site, noting that “all politics is local” and that events resulting in subject harm would have important local ramifications. Site-specific plans should be developed proactively in conjunction with the site’s grantee institution and community stakeholders, taking into account the importance of a unified message and the possibility that the interests of the ABCD Study site and its grantee institution might diverge. The EAB emphasized the need for sites to establish a strong relationship with their grantee institution, local schools and school boards, and local, state, and national political representatives before any crisis occurs and the importance of coordinating crisis communication with these various entities.

The EAB noted that when the OSMB was fully constituted, the ABCD Study would benefit from ethical advice from three sources: the OSMB; the EAB; and an internal ABCD Study bioethics group. The optimal relationship of these to each other requires further consideration. The EAB highlighted several ethical topics that deserved close attention: release to families of neurocognitive data, as reflected in the informed consent form (ICF); data sharing, including levels of control on data release; management of genomic data; a potential role for community advisory boards; the need for full disclosure in the ICF of what fluids will be collected and how they will be used; and a plan for evaluating, managing, and paying children who are intoxicated or psychiatrically impaired when they present for testing.

6.4. Sharing of ABCD study data and resources

The November 2017 annual meeting highlighted the many early successes of the ABCD Study and heralded the upcoming first data release to the scientific community. This moment prompted consideration of the relationship of the ABCD Study with the general scientific community and its responsibility to quickly share its data and resources. The EAB recommended that ABCD Study investigators and NIH staff formulate a plan for the financing, storage, sharing, and analysis of the ABCD Study’s growing data repository to facilitate community access. Plans for financing this effort might involve government sources, private partnerships, and user fees. The EAB recommended the development of a coordinated approach with other large studies, such as the Human Connectome Project, to establish common standards and approaches for the storage, sharing, and analysis of complex datasets, such as brain images, in the National Institute on Mental Health Data Archive. Because of the complexity of the ABCD Data study set, it was recommended that the ABCD Study staff a listserve or chat room and provide a navigator to encourage and facilitate data mining by the scientific community. The EAB likewise recommended that a group convene to create a governance process for curating and distributing limited resources, such as biospecimens. Finally, the EAB advised that the ABCD Study publish a clear explanation of the scope of its research to encourage research in areas outside of the ABCD Study’s purview. This was considered necessary to allay concerns that grant review committees might undervalue grant proposals that were assumed incorrectly to overlap with research planned by the ABCD Study.

7. Conclusions

The ABCD Study EAB serves the mission of ABCD Study through a collaborative relationship with study investigators and NIH staff. As constituted, the EAB is well positioned to advise the ABCD Study across a broad range of issues. Like the ABCD Study, the membership and practices of the EAB will evolve over time to continue to support both field-based investigators and NIH scientists and staff in this extraordinary venture. The primary initial focus of the EAB has been risk management and study design. Once enrollment is complete, the EAB will shift its attention to subject retention, the monitoring of study results, data sharing, initiation of focused, pilot studies with internal and external investigators using ABCD Study infrastructure, succession planning, and ongoing self-assessment and improvement of its own effectiveness. The EAB has built a relationship of trust with the ABCD Study but has not hesitated to respectfully challenge ABCD Study leadership and NIH program staff. Recommendations of the EAB played a major role in the addition of new sites to augment the enrollment capacity of ABCD Study, and at the onset of the second and last year of enrollment, the ABCD Study is on target to meet its recruitment goals and release its first trove of data. This experience suggests that trust and challenge should be two important attributes of scientific advisory boards.

Conflicts of interest

The author has no conflicts of interest.

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