21st Century Cures Act: ACD Working Group Recommendations and Proposed Updates for Rigor

NIH Office of Extramural Research

April 16, 2018

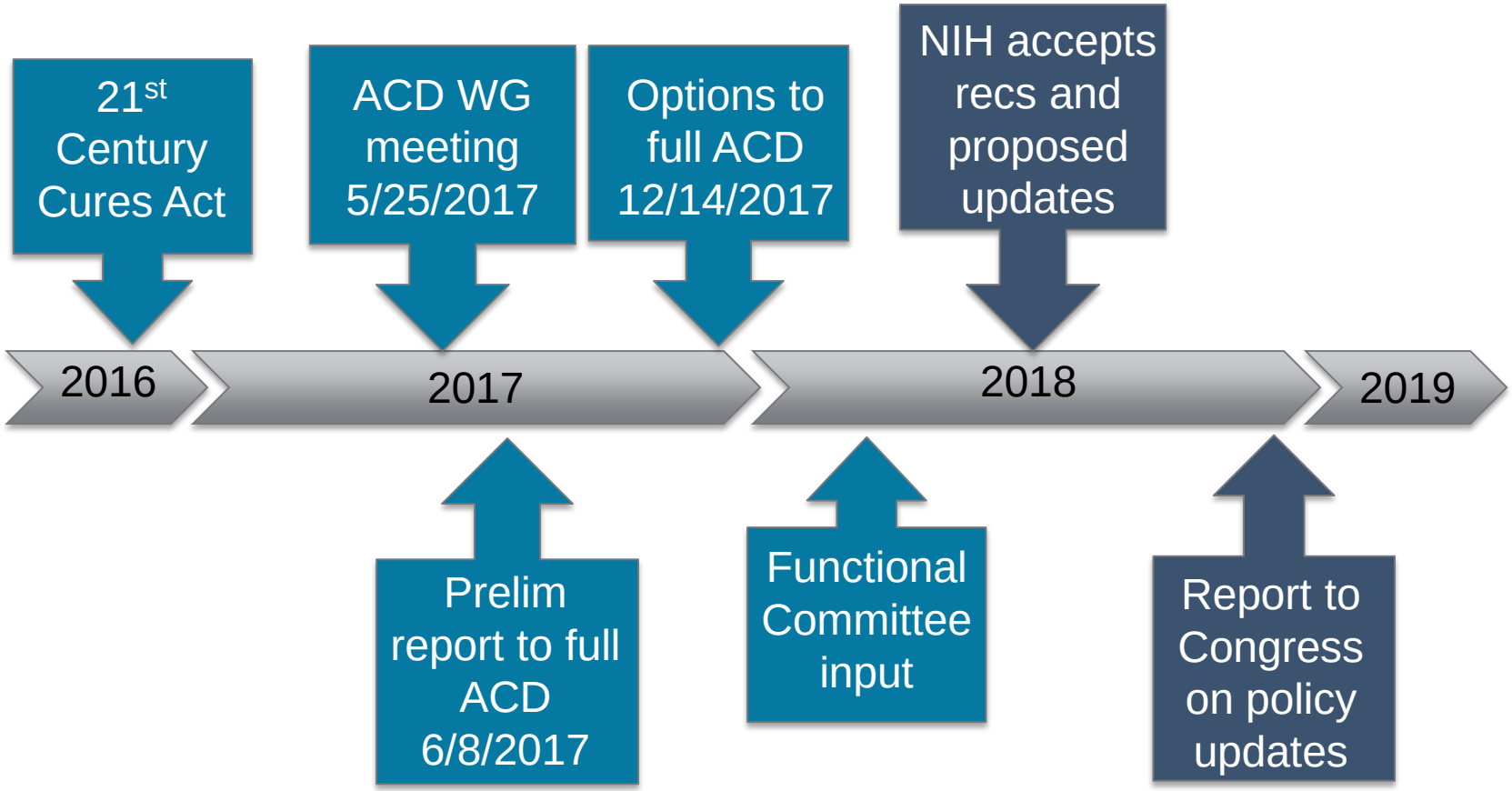
Statute

Section 2039 requires the NIH Director to convene a working group under the ACD to develop and issue recommendations through the ACD for a formal policy, which may incorporate or be informed by relevant existing and ongoing activities, **to enhance rigor and reproducibility of scientific research funded by NIH**.

ACD Working Group

- ACD
  - Russ Altman (Chair)
  - Mary Sue Coleman
  - Lisa Cooper
  - Jose Florez
  - Linda Griffith
  - Peter MacLeish
- NIH
  - Michael Lauer
  - Pritty Joshi
  - Jennifer Plank-Bazinet
  - Patricia Valdez

Timeline for Working Group



RPG Application and Review

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 Relevant Biological Variables Such as Sex		Approach	NA	Yes
Authentication of Key Biological and/or Chemical Resources	New Attachment	NA	Adequate or Inadequate	No

January 2016

ACD Recommendations

1) Resources on rigor
2) Clarify Scientific Premise
3) Examples of Authentication Plans
4) Training in Rigor scored
5) Outcomes evaluation

Resources on Rigor

Provide resource links in application instructions

- NIH-produced resources
  - OBSSR Training Resources
  - NIGMS Clearinghouse for Training Modules to Enhance Data Reproducibility
  - ODP Online Course for Designing and Analyzing Pragmatic and Group-Randomized Trials in Public Health and Medicine

Resources on Rigor

Provide resource links in application instructions

- Outside resources
  - Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Initiative
    - Minimum elements to be addressed in Clinical Trial protocols
  - National Centre for the Replacement, Refinement & Reduction of Animals in Research (NC3Rs) Experimental Design Assistant (EDA)
    - Guidance on experimental design for animal researchers, including support for randomization, blinding, sample size calculations, and statistical analyses

Clarify “Scientific Premise” in Instructions

Current Instructions (Scientific Premise)

Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.

Proposed Revision (Rigor of the Prior Research)

Describe the strengths and weaknesses in the rigor of the prior research (both published and unpublished) being cited as key support for your research question(s).

Clarify “Scientific Premise” in Review Criteria

Current Review Criteria (Scientific Premise)

Is there a strong scientific premise for the project?

Proposed Revision (Rigor of the Prior Research)

Does the application describe strengths and weaknesses in the rigor of the prior research being cited as key support for the proposed research question(s)? Has the applicant included a plan to address such rigor issues that potentially weaken the proposal?

Move “Rigor of the Prior Research” from Significance to Approach?

Significance

- Explain the importance of the problem or critical barrier to progress that the proposed project addresses.
- **Describe the strengths and weaknesses in the rigor of the prior research (both published and unpublished) being cited as key support for your research question(s).**
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.

Examples of Authentication Plans

- Provide examples of Authentication plans to the applicant community
  - Solicit examples of Authentication Plans from the Program Leadership Committee (PLC)
  - Post online for extramural communities

Training in Rigor Scored

- Integrate training in Rigor throughout training applications so that it contributes to score
  - PAR-17-341, NIGMS T32 pilot (1st due date May 25, 2018)
  - Will inform an eventual NIH-wide adoption in all training mechanisms

Outcomes Evaluation

- Continued outcomes evaluation to assess adherence to the policy by applicants and reviewers
  - IC evaluations (NINDS, CSR, others)
  - Ongoing OER evaluation

Discussion

Thank you!

Comments?