Limited Competition: Transformative Research to Address Health Disparities and Advance Health Equity at Minority Serving Institutions
(U01 Clinical Trial Optional)

Technical Assistance
Pre-Application Webinar
RFA-RM-22-001
This webinar is being recorded.

Please send your questions to
CFHealthDisparities@mail.nih.gov

NIH National Institutes of Health
Office of Strategic Coordination–The Common Fund

WELCOME

Transformative Research to Address Health Disparities and Advance Health Equity Initiative

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AGENDA

TIME	TOPIC	PRESENTER
2:00-2:05	Overview of the Transformative Health Disparities Research WG and the NIH Common Fund	Yvonne Ferguson, Program Leader
2:05-2:10	Purpose of the *Limited Competition: Transformative Research to Address Health Disparities and Advance Health Equity Initiative at Minority Serving Institutions (U01 Clinical Trial Optional),* Eligibility Information and Scientific Requirements	Alison Brown, WG Program Coordinator
2:10-2:15	Application Structure with a focus on Transformative Research (preliminary data not required) and Budget	Nathan Stinson, WG Program Coordinator
2:15-2:20	Cooperative Agreement (U01) Mechanism	April Harrison, Grants Management Specialist
2:20-2:25	Peer Review Information and Review Criteria	Aruna Behera, Scientific Review Officer
2:25-2:35	Advancing Health Equity Through Implementation Science	April Oh, Senior Advisor for Implementation Science & Health Equity
2:35	Question & Answer	Cheryl Anne Boyce, Program Leader and Panelists

What is the Common Fund?

- Funded by the Office of the Director, managed in partnership with the NIH Institutes and Centers

- Supports a set of trans-NIH scientific programs

- Fosters innovative ideas with the potential for transformative impact

- Intended to benefit the broad biomedical research community

The Common Fund Moves the NIH Mission Forward-Faster

- Supporting bold scientific programs that **catalyze discovery** across all biomedical and behavioral research

- Advances areas of biomedical and behavioral research important to the missions of multiple NIH Institutes and Centers

- Spurs subsequent biomedical advances that otherwise would not be possible without an initial strategic investment

Aligns with the NIH UNITE Initiative

NIH has launched the UNITE initiative to identify actions to end structural racism and racial inequities throughout the biomedical research enterprise.

In support of the UNITE initiative and health equity research, the Common Fund is supporting *transformative research to address health disparities and advance health equity.*

Ending Structural Racism

nih.gov/ending-structural-racism

National Institutes of Health
Office of Strategic Coordination−The Common Fund

Limited Competition: Transformative Research to Address Health Disparities and Advance Health Equity at Minority Serving Institutions (U01 Clinical Trial Optional)

Purpose:

- To support collaborative investigative teams or individual scientists who propose unusually innovative research projects, which would have a major impact in developing, implementing, or disseminating innovative and effective interventions to prevent, reduce, or eliminate health disparities and advance health equity.

Additional Information:

- No preliminary data required.

- Projects must clearly demonstrate, based on the strength of the logic, a compelling potential to produce a major impact in addressing health disparities and advancing health equity.

Eligibility

- Higher education institutions
  - Public/State Controlled Institutions of Higher Education
  - Private Institutions of Higher Education
- Following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:
  - Hispanic-serving Institutions
  - Historically Black Colleges and Universities (HBCUs)
  - Tribally Controlled Colleges and Universities (TCCUs)
  - Alaska Native and Native Hawaiian Serving Institutions
  - Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Eligibility (cont.)

- Applicant institution <u>must</u> be a domestic institution located in the U.S. and its territories which:
    - Received less than $25 million dollars per year (total costs) from NIH Research Project Grants (RPGs) in each of the preceding two fiscal years, calculated using NIH RePORTER; and
    - Award undergraduate (B.S. or B.A.) and/or graduate degrees in biomedical sciences; and
    - Have a historical and current mission to educate students from any of the populations identified as underrepresented in biomedical research as defined by the National Science Foundation (NSF), see http://www.nsf.gov/statistics/wmpd/) (i.e., African Americans or Blacks, Hispanic or Latino Americans, American Indians, Alaska Natives, Native Hawaiians, U.S. Pacific Islanders, and persons with disabilities) or has a documented record of:
        - (1) recruiting, training and/or educating, and graduating underrepresented students as defined by NSF (see above), which has resulted in increasing the institution's contribution to the national pool of graduates from underrepresented backgrounds who pursue biomedical research careers and,
        - (2) for institutions that deliver health care services, providing clinical services to medically underserved communities.

Scientific requirements

- All projects <u>must</u> include an **intervention component.**

  - Development/testing of a novel intervention

  - New implementation/dissemination strategies for evidence-based interventions

  - Novel examination of program/policy interventions that provide innovative insight into their effectiveness

- All projects <u>must</u> be **transformative** – projects should reflect ideas substantially different from mainstream concepts and have high potential to lead to major improvements in health.

- All projects <u>must</u> include a focus on **one or more NIH-designated populations that experience health disparities** in the U.S. – Blacks/African Americans, Hispanics/Latinos, American Indians and Alaska Natives, Asian-Americans, Native Hawaiians and Other Pacific Islanders, socioeconomically disadvantaged populations, underserved rural populations, and sexual and gender minorities (SGM).

- All projects <u>must</u> document or demonstrate **meaningful collaboration and partnership with local community-engaged leaders** that represent the communities/populations of focus.

This list is not exhaustive. Please read the RFA carefully for additional requirements and instructions.

Not required, but encouraged

- Community-prioritized research questions – what are the health conditions/topics most important to the communities involved in the project?

- Cross-cutting issues, such as social determinants of health across sectors

- Priority areas of multiple NIH Institutes and Centers

- Multi-level interventions that address two or more levels of influence of health and behavioral outcomes (interventions that go beyond the level of the individual)

- Transdisciplinary and intersectoral collaborations (e.g., transportation, housing, food systems)

This list is not exhaustive. Please read the RFA carefully for additional areas/topics that are encouraged.

Application structure

- Uses standard Research (R) application form (SF424 (R&R) Application Guide), but in an <u>unconventional way</u>

Specific Aims page	- Not used to list specific objectives of the research - Instead, used as a one-page distillation of the research and why it is well-aligned with the spirit of the RFA - Two sections: **"Significance, Innovation and Impact"** **"Insight and Rationale"**
Questions to consider	**"Significance, Innovation and Impact"** - What is the challenge or opportunity that is the focus of the proposed research? - Why is this significant? - What is the overall approach you are proposing? - What are the most original or innovative aspects of your application? - If successful, what would the impact be on our scientific understanding and (ultimately) health disparities and health equity? **"Insight and Rationale"** - What is the fundamental new insight that is motivating the proposed research? - What is the underlying logic or rationale that provides support for pursing this insight despite little or no preliminary data?

Application structure[2]

- Uses standard Research (R) application form (SF424 (R&R) Application Guide), but in an <u>unconventional way</u>

Research Strategy section	- Not used to provide substantial preliminary data and experimental details - Instead, used to address items of programmatic importance to this RFA **Overview** and importance of the research (set context for project) **Approach** (describe the underlying logic and ensure project's robustness/rigor) **Innovation** (explain why the research should be considered innovative) **Appropriateness for this RFA** (address why the research is well suited to the goals of this RFA and not a more traditional research grant program) **Timeline** (describe transformative impact within the project period, include critical decision points and possible alternative paths)

Budget

- Application budgets are not limited but need to reflect the actual needs of the proposed project. Large budgets must be well-justified.

- This is intended to provide flexibility for researchers – there is no requirement/expectation to have a large budget. Base your budget on the research needs.

- Requests in excess of $250,000 direct costs in any year require detailed (non-modular) budgets

- Prior approval from NIH is NOT required before submitting a budget exceeding $500,000 in annual direct costs

- The maximum project period is 5 years

Cooperative Agreement (U01) Mechanism

- A **Cooperative Agreement** is used when there will be substantial Federal scientific or programmatic involvement.

- Substantial involvement means that, after award, NIH scientific or program staff will assist, guide, coordinate, or participate in project activities.

- The NIH purpose is to support and stimulate the awardees' activities; it is NOT to assume direction, prime responsibility, or adopt a dominant role.

Terms and Conditions of Award

- <mark>**See Section VI in the RFA for the complete list of Terms and Conditions of Award**</mark>

PI(s)/PD(s)	Project Scientist (PS)	Program Official (PO)
• Provide scientific leadership for all aspects of the study • Finalize study design milestones, including a robust statistical plan for analysis, with NIH staff. Provide summaries of progress towards goals and milestones • Milestones will be reviewed at least annually; negotiate new milestones as appropriate, working with NIH staff	• Consult with the PI(s)/PD(s) regarding study design milestones prior to finalizing study design and as needed thereafter • Provide scientific and programmatic support (e.g. input on experimental/clinical approaches, study protocol, data analysis, etc.) • Review the progress of the study • The PS will not make decisions about the funding of this project	• Review activities to ensure objectives are being met and NIH guidelines are followed • Have the option to withhold support if technical performance requirements/milestones are not met • Conduct special reviews of the project as the PO deems necessary

Review Process

- NIH's Center for Scientific Review (CSR) will convene a Special Emphasis Panel to review applications. Applicants do not need to provide recommended study section assignment.

- All applications will be reviewed in a special emphasis panel, ZRG1 MOSS-T.

- You may identify three to four broad expertise areas in your application either in the cover letter or using the assignment request form while submitting your application.

- All applications will receive a written critique. Only those applications deemed to have the highest scientific and technical merit will be discussed and assigned an overall impact score.

- Summary statements will be provided for discussed applications in 30 days after the meeting completion.

Letter of Intent

Due Date: Approximately 30 days prior to application deadline.

- <u>Letter of intent is not required</u>. However, the information provided is very helpful and allows us to estimate potential review workload and plan for the review.

- To submit a letter of intent, include the following information:
  - ➢ **Descriptive title of the proposed activity**
  - ➢ Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
  - ➢ Names of other key personnel
  - ➢ Participating institution(s)
  - ➢ Number and title of this funding opportunity

The letter of intent should be sent to: Email: CFHealthDisparities@nih.gov

Review Criteria

This RFAs include unique review criteria. Please read *Section V. Application Review Information* carefully!

- Reviewers will emphasize the conceptual framework, the level of innovation, and the potential to significantly advance our knowledge, understanding, or capability

- Reviewers will be looking for the potential for **transformative impact**, not preliminary data

- Reviewers will evaluate five scored review criteria (Significance, Investigators, Innovation, approach, and environment) in the determination of scientific merit and give a score on a scale of 1-9.

Center for
Scientific Review

Review Criteria

Significance: Does the study have <u>clear transformative potential</u>? Is the prior research that serves as the key support for the proposed project rigorous? Does the project address issues that are critical and relevant to one or more populations experiencing health disparities? Does the project address issues related to sustainability and/or implications for implementing and/or disseminating the intervention, if successful, to other health disparity populations?

Investigators: Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? 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?

Innovation: Does the application provide novel or innovative insights into improving the health of one or more populations experiencing health disparities?

Approach: Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects? Does the research use a <u>community engaged approach or sociocultural constructs</u> that reflect the desires of the community and engage the community in research design and conduct?

Environment: Will the scientific environment in which the work will be done contribute to the probability of success? Does the project provide <u>evidence of community engagement</u> and support, as appropriate?

NIH | Center for Scientific Review

"PUBLICATION PATHWAY"   Balas & Boren, 2000

Original Research

18%   Negative results   Dickersin, 1987   variable

Submission

46%

databases

Inconsistent indexing   50%   Poynard, 1985   6 - 13 years   Antman, 1992

Reviews, guidelines, textbook

9.3 years

Implementation
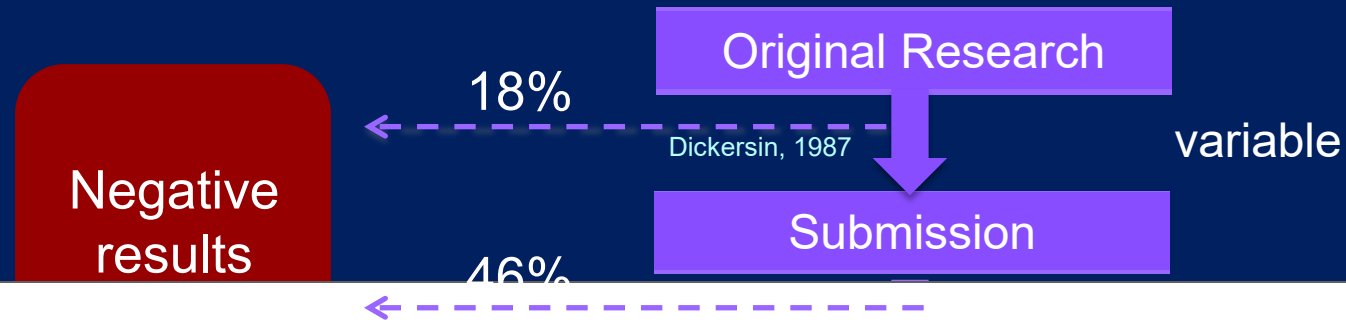
It takes 17 years to turn 14 percent of original research to the benefit of patient care
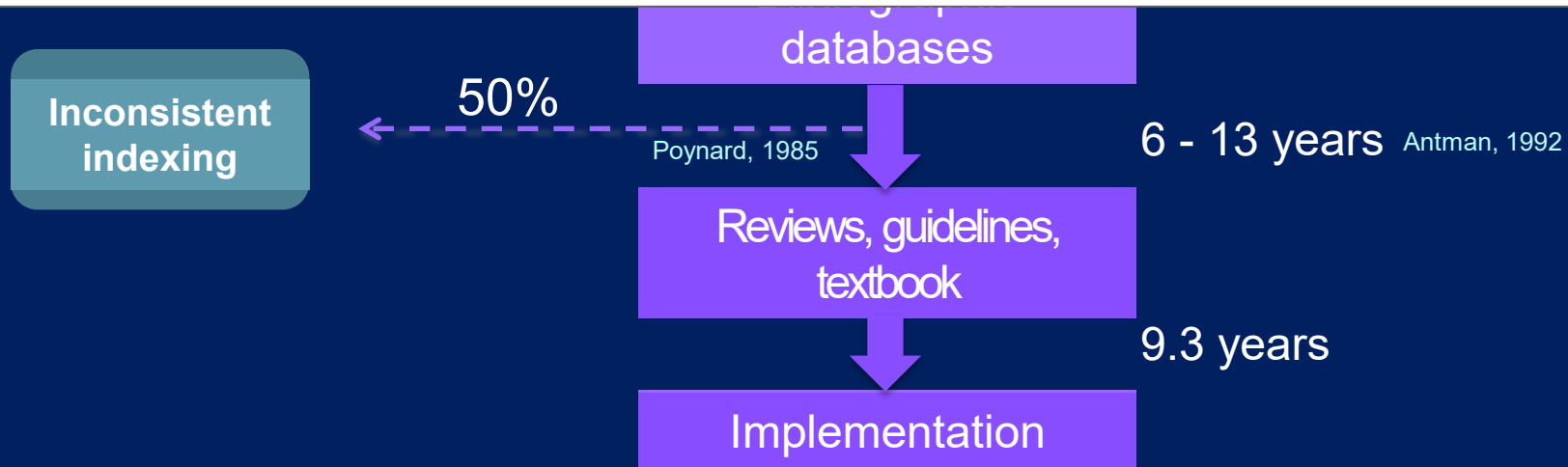
Beyond the evidence for efficacy/effectiveness…

Evidence-based interventions are only as good as how and whether…

- It is adopted?
- Practitioners and communities are trained to use it?
- Trained practitioners and communities choose to use it?
- Eligible populations/patients benefit from it?

If we assume 50% threshold for each step…

(even w/perfect access/adherence/dosage/maintenance)

Impact: .5*.5*.5*.5 = 6% benefit

NIH Definitions

Implementation Science intends to bridge the gap between research, practice, and policy by building a knowledge base about how health information, effective interventions, and new clinical practices, guidelines and policies are communicated and integrated for public health and health care service use.

- *Dissemination research* is the scientific study of targeted distribution of information and intervention materials to a specific public health or clinical practice audience. The intent is to understand how best to communicate and integrate knowledge and the associated evidence-based interventions.

- *Implementation research* is the scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings to improve individual outcomes and population health.

Implementation research

What?
Evidence-based
Interventions

How?
Strategies

Implementation Outcomes
Feasibility
Sustainability
Uptake
Costs

Service Outcomes*
Efficiency
Safety
Effectiveness
Patient-centeredness
Timeliness

Health Outcomes
Satisfaction
Function
Health status/
symptoms

*IOM Standards of Care

Implementation Research Methods
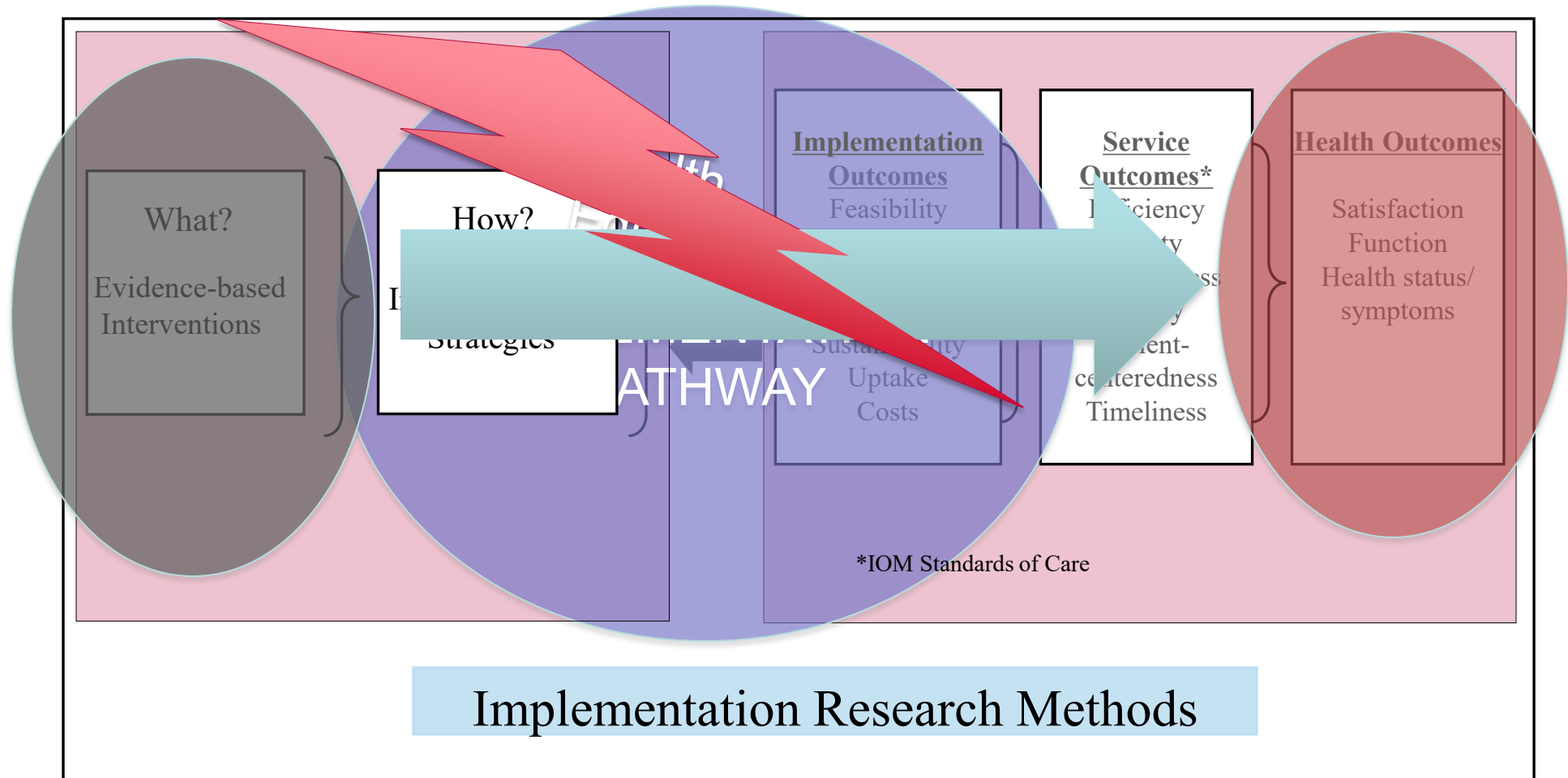
Proctor et al 2009 *Admin. & Pol. in Mental Health & Mental Health Services Research*

Why is an Equity lens important in Implementation Science?

- Our Evidence-Based Interventions (EBIs) may be inequitably applied to those with more resources

- Pragmatic approaches require an understanding of the "real-world" including history, local resources, and recognize local capacity that can impact disparities and sustainability

- Community (or "Stakeholder") engagement is an essential component of implementation models and frameworks

- Emphasis on context, multilevel approaches and intersecting systems which may be barriers or facilitators to implementation

Developing Your Implementation Research Proposal

Table 1 Ten key ingredients for implementation research proposals

Proposal ingredient	Key question	Review criteria	Check (yes/no)
1. The care gap or quality gap	The proposal has clear evidence that a gap in quality exists?	Significance Impact	
2. The evidence-based treatment to be implemented	Is the evidence for the program, treatment, or set of services to be implemented demonstrated?	Significance Innovation	
3. Conceptual model and theoretical justification	The proposal delineates a clear conceptual framework/theory/model that informs the design and variables being tested?	Approach Innovation	
4. Stakeholder priorities, engagement in change	Is there a clear engagement process of the stakeholders in place?	Significance Impact Approach Environment	
5. Setting's readiness to adopt new services/treatments/programs	Is there clear information that reflects the setting's readiness, capacity, or appetite for change, specifically around adoption of the proposed evidence-based treatment?	Impact Approach Environment	
6. Implementation strategy/process	Are the strategies to implement the intervention clearly defined, and justified conceptually?	Significance Impact Innovation	
7. Team experience with the setting, treatment, implementation process	Does the proposal detail the team's experience with the study setting, the treatment whose implementation is being studied, and implementation processes?	Approach Investigator team	
8. Feasibility of proposed research design and methods	Does the methods section contain as much detail as possible, as well as lay out possible choice junctures and contingencies, should methods not work as planned?	Approach Investigator team	
9. Measurement and analysis section	Does the proposal clarify the key constructs to be measured, corresponding to the overarching conceptual model or theory?	Approach Investigator team	
	Is a measurement plan clear for each construct?		
	Does the analysis section demonstrate how relationships between constructs will be tested?		
10. Policy/funding environment; leverage or support for sustaining change	Does the proposal address how the implementation initiative aligns with policy trends?	Impact Significance	

Resources

Proctor EK, Powell BJ, Baumann AA, Hamilton AM, Santens RL. Writing implementation research grant proposals: ten key ingredients. Implement Sci. 2012 Oct 12;7:96.

Brownson RC, Colditz GA, Dobbins M, Emmons KM, Kerner JF, Padek M, Proctor EK, Stange KC. Concocting that magic elixir: successful grant application writing in dissemination and implementation research. Clin Transl Sci. 2015 Dec;8(6):710-6.

Sample grants:
https://cancercontrol.cancer.gov/is
https://tracs.unc.edu/

Equity Considerations for Dissemination and Implementation Frameworks

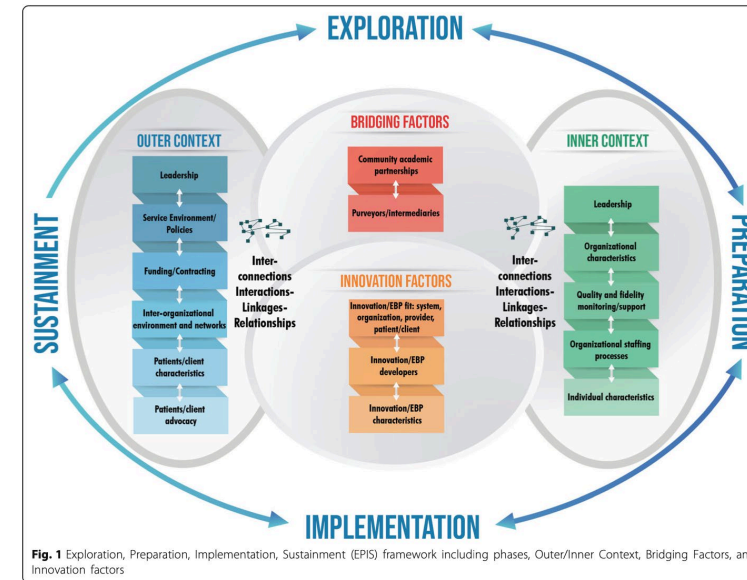http://dissemination-implementation.org

2/17/2022

- Examination of multiple levels and outer context, culture, and history
- Stakeholder or Community engagement
- Measure and examine the influence of equity-related contextual factors or determinants
- Consider how to operationalize health equity in the process and outcomes

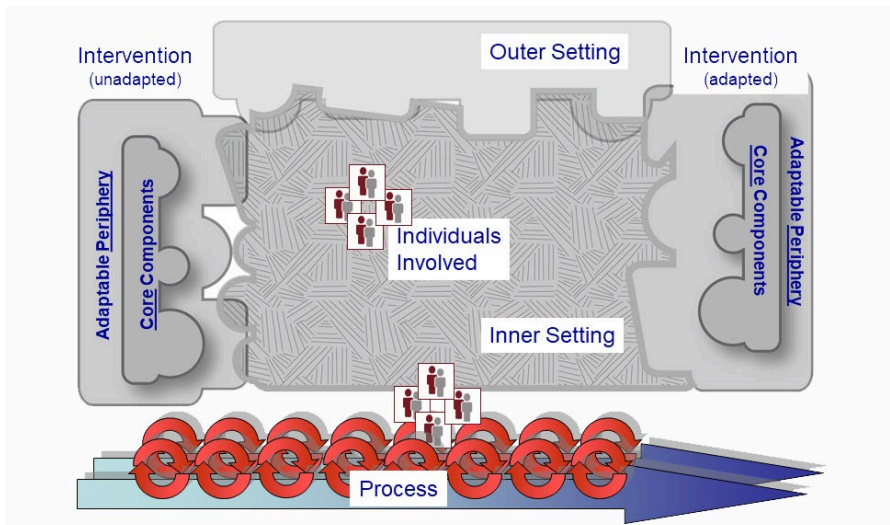- Consider: Usability, Testability, Applicability, and Acceptability (T-CaST) tool (Birkin, et al, 2018)
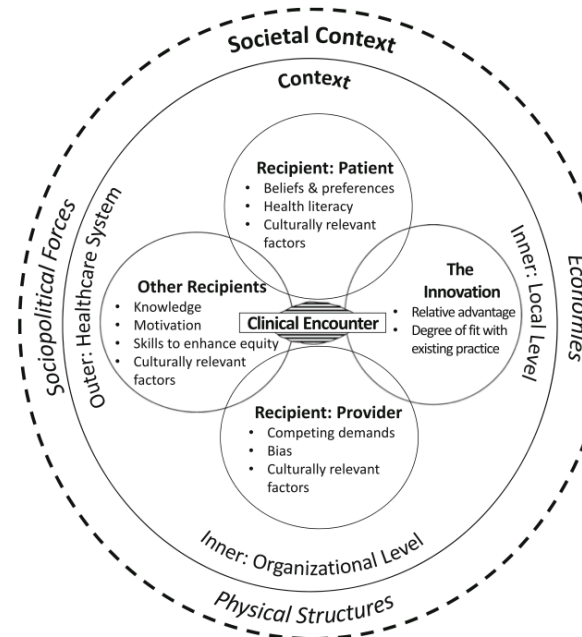
Example Theories, Models, and Frameworks
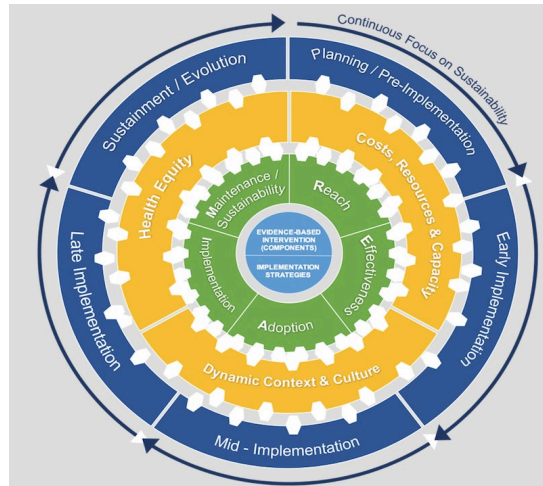
Re-AIM/Re-AIM Extension for Sustainability: Reach and Effectiveness, Adoption and Implementation, and Maintenance (Shelton, et al, 2020)

Fig. 1 Exploration, Preparation, Implementation, Sustainment (EPIS) framework including phases, Outer/Inner Context, Bridging Factors, and Innovation factors

Exploration, Adoption/Preparation, Implementation, Sustainment (EPIS) Model
(Aarons, et al 2011)

Consolidated Framework for Implementation Research (CIFR) https://cfirguide.org

Health Equity Implementation Framework (Determinant Framework)
Woodward, et al, 2021

Resources and Tools
please find these resources at:
https://commonfund.nih.gov/healthdisparitiestransformation/applicantresources
## Theories, Models, and Frameworks

- **REACH, EFFECTIVENESS, ADOPTION, IMPLEMENTATION, AND MAINTENANCE (RE-AIM) FRAMEWORK**
  http://www.re-aim.org

- **CONSOLIDATED FRAMEWORK FOR IMPLEMENTATION RESEARCH TECHNICAL ASSISTANCE WEBSITE:**
  http://cfirguide.org

- **NIH EVIDENCE-BASED PRACTICE AND PROGRAMS:** https://prevention.nih.gov/resources-for-researchers/dissemination-and-implementation- resources/evidence-based-programs-practices#topic-13

- **EXPANDNET/WHO SCALING-UP GUIDE:** http://expandnet.net/tools.htm

- **DISSEMINATION AND IMPLEMENTATION MODELS IN HEALTH RESEARCH AND PRACTICE:** http://dissemination-implementation.org

Open Access Resources for Training and Learning About Implementation Science

https://cancercontrol.cancer.gov/is/tools/
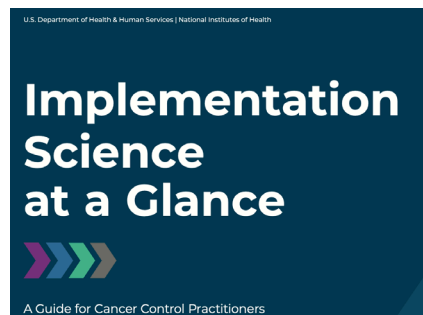
Training Institute in Dissemination and Implementation Research in Cancer (TIDIRC), NIH NCI (Open Access): https://cancercontrol.cancer.gov/is/training-education/training-in-cancer/TIDIRC-open-access
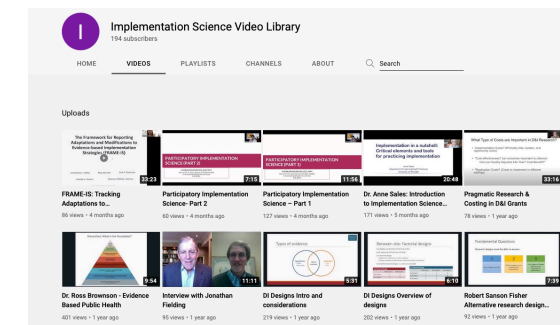
Implementation Science Video Library
Drs. Rachel Shelton, Rachel Tabak, Ross Brownson

Question & Answer

Please submit your questions to:
CFHealthDisparities@mail.nih.gov.

Please e-mail scientific inquires and plans for individual research projects to: **CFHealthDisparities@mail.nih.gov**

Slides and Frequently Asked Questions will be posted to our website: **https://commonfund.nih.gov/healthdisparitiestransformation/**

NIH National Institutes of Health
Office of Strategic Coordination–The Common Fund