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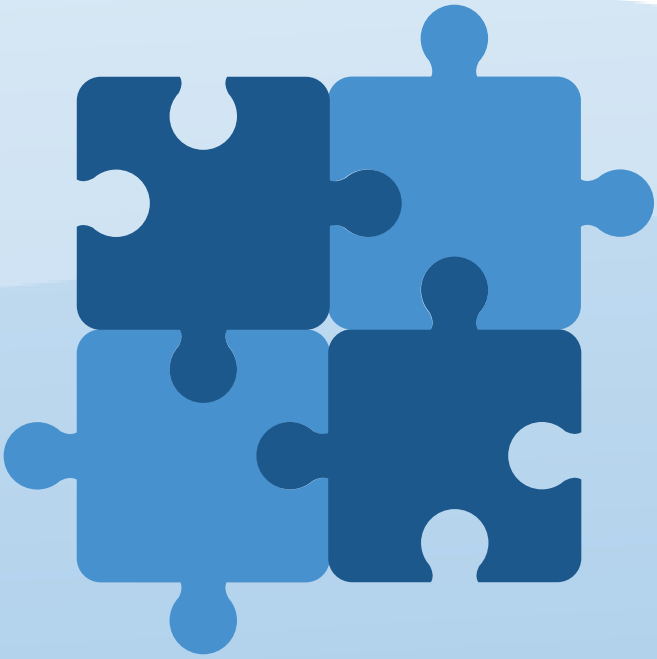
Tufts Clinical and Translational Science Institute

Dissemination and Implementation (D&I) Science Core

Guide for Getting Started in Implementation Science



Piecing Together the Implementation Science Puzzle

Request a D&I consult via **www.tuftsctsi.org**

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Last updated by Tufts CTSI D&I Core: June 27, 2024

This guide was supported by the National Center for Advancing Translational Sciences, National Institutes of Health, Award Number UM1TR004398. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

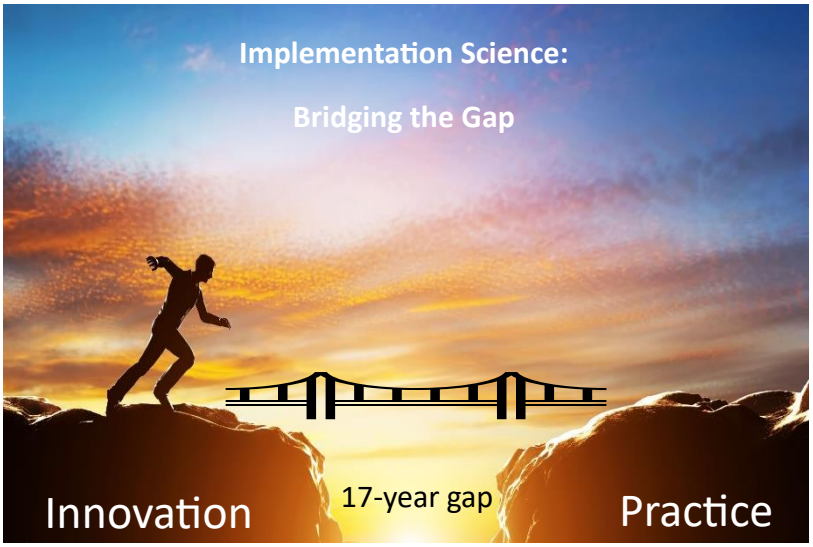
Using this guide

This guide is meant to be a starting place for researchers new to implementation science. It provides brief overviews of key topics and describes useful articles, online resources such as videos, presentations, and self-paced courses, and materials from Clinical and Translational Science Award (CTSA) institutions. It also lists training resources for those interested in broadening their background on the topic.

Why is implementation science important?

On average, most innovations and evidence-based practices do not make it into use; for those that do, the average time it takes to go into practice is 17 years.[1] Many innovations fail to make it into practice, or are delayed, because they did not sufficiently consider the environment in which the implementation would take place. Innovations or interventions are often tested in very controlled environments that do not reflect the real world in which they'll be implemented. Implementation science attempts to help researchers consider contextual factors to better prepare innovations for use in real world settings and optimize successful adoption.

We hope this guide will help you piece together the different elements of implementation science.



The Tufts CTSI Dissemination and Implementation (D&I) Science Core is here to support Implementation Science grant proposals or to discuss how you might incorporate implementation science in other types of research studies. To receive a D&I consultation, request services on the Tufts CTSI website.

Introduction to implementation science

Implementation science is the study of methods and strategies that help with the uptake of an innovation, intervention, or other evidence-based practice with the aim of improving healthcare quality and effectiveness. Implementation science works to try and close the gap between what we know and what is done in practice. Curran[2] provides some helpful, non-scientific language to help us think about the different parts of implementation science (Figure 1).

Figure 1. From Curran's "Implementation science made too simple: a teaching tool".[2]

The intervention/practice/innovation is **THE THING**

Effectiveness research looks at whether **THE THING** works

Implementation research looks at how best to help people and places **DO THE THING**

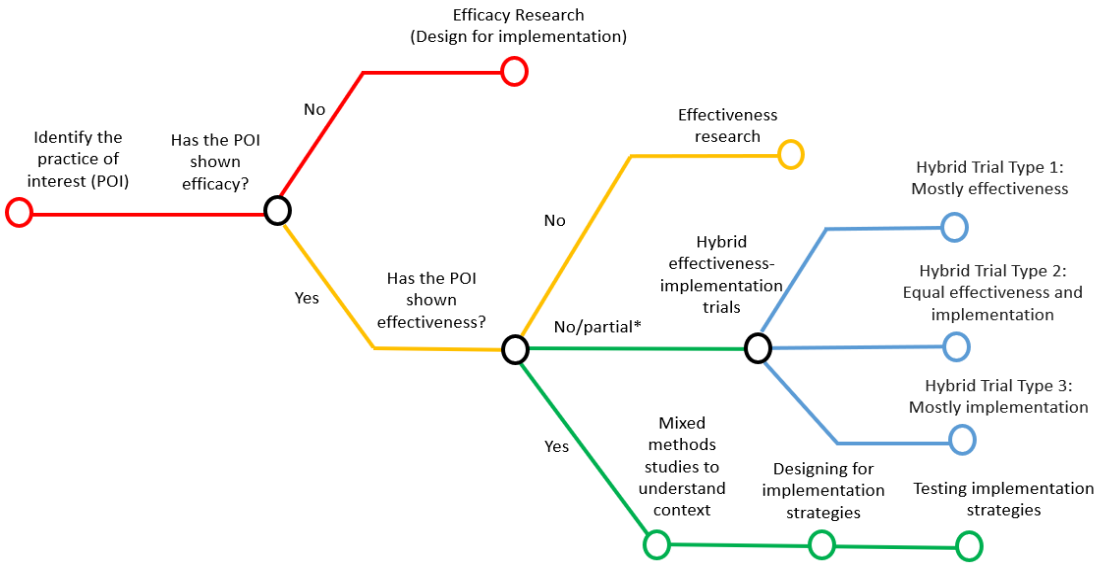
Implementation strategies are the stuff we do to try and help people/places **DO THE THING**

Main implementation outcomes are **HOW MUCH** and **HOW WELL** they **DO THE THING**

The resources in this section focus on introducing you to implementation science and how it can be used to address improving healthcare quality at the patient, provider, organization, and policy levels.

Effectiveness research and implementation research are closely related fields that often intersect in the evaluation and application of interventions. Hybrid effectiveness-implementation studies simultaneously address questions related to both the effectiveness of an intervention and the implementation strategies used to integrate that intervention into real-world practice. These studies are valuable for researchers and practitioners interested in understanding not only whether an intervention works but also how to effectively implement it in diverse settings. Figure 2 provides a schematic to guide researchers considering hybrid implementation studies.[3]

Figure 2. Adapted subway schematic for selection of study type.[3]



If the study is a hybrid implementation-effectiveness trial, the aims should clearly reflect whether it is a Type 1, 2, or 3 design.[4] Curran et al summarizes these as follows:

- Type 1
  - Primary question: Will a clinical treatment work in this setting/for these patients?
  - Secondary question: What are potential barriers/facilitators to a treatment's widespread implementation?

- Type 2
  - Coprimary question: Will a clinical treatment work in this setting/for these patients?
  - Coprimary question: Does the implementation method show promise (either alone or in comparison with another method) in facilitating the implementation of a clinical treatment?

- Type 3
  - Primary question: Which method works better in facilitating the implementation of a clinical treatment?
  - Secondary question: Are clinical outcomes acceptable?

In comparison, the overarching questions for effectiveness, efficacy, and pure implementation studies are listed below:

- Efficacy question: Does novel treatment work better than standard care?
- Effectiveness question: Does novel treatment work within a specified population in a specific setting?
- Implementation question: What implementation strategies most effectively support the uptake of a given clinical treatment?

Articles

A. Curran GM. Implementation science made too simple: a teaching tool. *Implementation Science Communications*. 2020/02/25 2020;1(1):27. doi:10.1186/s43058-020-00001-z

- Curran shares a visual teaching tool to help with the understanding of key concepts in implementation science using simple, non-scientific language.

B. Lane-Fall MB, Curran GM, Beidas RS. Scoping implementation science for the beginner: locating yourself on the "subway line" of translational research. *BMC Medical Research Methodology*. 2019/06/28 2019;19(1):133. doi:10.1186/s12874-019-0783-z

- In this article, the authors use a "subway model" to describe and illustrate the journey of implementation science. The "subway model" is helpful for envisioning where research falls on the implementation science spectrum.

C. Bauer MS, Damschroder L, Hagedorn H, Smith J, Kilbourne AM. An introduction to implementation science for the non-specialist. *BMC Psychology*. 2015/09/16 2015;3(1):32. doi:10.1186/s40359-015-0089-9

- Written for those new to implementation science, this article discusses how implementation science can help to move evidence-based practices (EBPS) into clinical use. It also provides

background information on what is implementation science and how it can be used in different types of research.

Other resources

A. Morshed, A., Tabak, R., Taranhike, I., Baumann, A., & Proctor, E. Intro to D&I. [Internet]. St. Louis, MO: Washington University; 2018 October. Eight toolkits related to Dissemination and Implementation. Available from https://implementationresearch.wustl.edu/support-your-research/toolkits/
   - These toolkits cover a range of topics from an introduction to D&I to translating your research for impact. They offer a more in-depth introduction to different elements of implementation science such as formulating aims, identifying research outcomes, and understanding organizational constructs and measures.

B. Orientation to the Science of Dissemination and Implementation (AcademyHealth, 2022)
   - This hour-long recording from the 15th Annual Conference on the Science of Dissemination and Implementation in Health provides an orientation to D&I. The presenters include Dr. Meghan Lane-Fall, Dr. Cara C. Lewis, Dr. Byron J. Powell, and Dr. Rinad S. Beidas.

Theories, models, and frameworks

Implementation science promotes the use of theories, models, and frameworks to systematically guide, and evaluate the adoption and integration of evidence-based practices and interventions into real world settings. Choosing from the numerous models and frameworks available can be challenging. According to Nilsen[5], there are three overarching goals for using theories, models and frameworks in implementation science: 1) describing and/or guiding the process of translating research into practice, 2) understanding and/or explaining what influences implementation outcomes and 3) evaluating implementation. It's helpful to have a general understanding of some of the more frequently used models and what to consider when choosing a model or framework for your research. The resources below provide a general understanding of some of the commonly used models and why they may be used over other alternatives.

A note on the term "stakeholder"

The term stakeholder is widely used in health research, but there is an ongoing discussion on its use and historical context. The Centers for Disease Control (CDC) notes that the word can have violent connotations for some groups and can group all parties under one name, which can fail to acknowledge the differences in power and resources between groups. While this word is still commonly used in healthcare-related research, including implementation science, the CDC has suggested a list of alternative words for the term stakeholder. [5]

In this guide, we use the CDC-suggested term "contributor" to acknowledge the differing perspectives that contribute to research.

As you think through what theory or model will work for your research, remember to engage your key contributors (stakeholders) to ensure you are capturing the perspectives of the end-user. You will also want to engage other contributors who may have influence in the setting where you intend to implement the innovation. Ensuring there is appropriate organizational readiness is a precursor to any implementation science project.[7]

Articles

A. Nilsen P. Making Sense of Implementation Theories, Models, and Frameworks. In: Albers B, Shlonsky A, Mildon R, eds. *Implementation Science 30*. Springer International Publishing; 2020:53-79.
   - This chapter focuses on defining the categories of theories, models and frameworks used in implementation science. It describes a range of theoretical approaches and their different aims in implementation science.

B. Weiner BJ. A theory of organizational readiness for change. *Implementation Science*. 2009/10/19 2009;4(1):67. doi:10.1186/1748-5908-4-67
   - This article defines organizational readiness and develops a theory for organizational readiness's determinants and outcomes.

C. Tabak RG, Khoong EC, Chambers DA, Brownson RC. Bridging research and practice: models for dissemination and implementation research. *American journal of preventive medicine*. 2012;43(3):337-350.
   - This article organizes and inventories theories and frameworks (referred to as models in the text) used in dissemination and implementation (D&I) research and provides guidance on how to select a theory or framework.

D. Pinto RM, Park S, Miles R, Ong PN. Community engagement in dissemination and implementation models: A narrative review. *Implementation Research and Practice*. 2021;2:2633489520985305. doi:10.1177/2633489520985305

- The review article identifies community-specific constructs that can help researchers to collaborate and engage with community partners in dissemination and implementation science research.

E. Peters DH, Tran NT, Adam T. Implementation research in health: a practical guide. Alliance for Health Policy and Systems Research, World Health Organization; 2013.
   - In this guide by the Alliance for Health Policy and Systems Research, authors introduce both what implementation research is and why stakeholder engagement is important in conducting implementation research.

Other resources

A. Pick a Theory, Model, or Framework (University of Washington, The UW Implementation Science Resource Hub)
   - In addition to an introduction to theories, models, and frameworks, this website offers a selection of articles based on the type of theory, model, or framework you are interested in using (example: process models, determinant frameworks, classic models, etc.).

B. Theories and Frameworks in Implementation Science (Video)
   - This series of short videos by Dr. Rachel Shelton provides information on theories and frameworks in implementation science.

C. Applying Implementation Science Frameworks to Your Research (Online module)
   - This short course, presented by Sara Folta, PhD, and Denise H. Daudelin, RN, MPH, provides an overview of two common implementation frameworks used in grant proposals, RE-AIM (the Reach, Effectiveness, Adoption, Implementation, and Maintenance Framework) and CFIR (the Consolidated Framework for Implementation Research), and how the CFIR framework, combined with ERIC (Expert Recommendations for Implementing Change) strategies, can be used in planning for protocol implementation or problem solving. You will learn what these frameworks are, when to use them, and how to best integrate them into a grant proposal or ongoing study.

D. Resources for Stakeholder and Community Engagement (Consortium for Cancer Implementation)
   - In this guide, there are a variety of resources includes readings, trainings, guidance, and tools to help researchers and community stakeholders with community engaged implementation science.

Implementation science questions, strategies, and mechanisms

A key ingredient in any implementation science proposal, is your research question. We have identified a few resources in this section that will help you to frame your implementation science question. This question will help you to identify your strategies and mechanisms.

In implementation science, implementation strategies are used to promote the adoption of an innovation, intervention, or best practice. These strategies focus on the "how"; how is the innovation, intervention, or best practice (the "what") going to be put into practice and used. Implementation mechanisms are the processes through which strategies work, essentially answering the "why" question.[8] The following resources offer a starting place for learning about implementation science strategies and mechanisms.

In Cara Lewis's 2020 talk on Implementation Mechanisms, she provides the following examples of how determinants, implementation strategies, mechanisms, and implementation outcomes fit together. [9]

Table 1. Relationship of key implementation science concepts.

Determinant	Implementation Strategy	Mechanism	Implementation Outcome
Provider knowledge deficit	Education (provision of information)	Awareness building, knowledge acquisition	Feasibility, acceptability, appropriateness, adoption
Provider view evidenced-based practice (EBP) unfavorably	Audit and feedback provision of descriptive social norms indicating peer use of the EBP	Social pressure, norms	Adoption
Provider habit (forgets to use EBP)	Audit and feedback provision of descriptive social norms indicating peer use of the EBP	Self-reflection, awareness	Penetration
Unclear integration of EBP; EBP perceived to be out of scope	Opinion leader targeted training	Clarifying workflow, exerting social influence	Adoption, cost, provider penetration
Unstandardized clinical care options	Guidelines	Clarifying priorities	Fidelity

Another emerging topic for implementation scientists is de-implementation. De-implementation seeks to remove practices that are harmful or ineffective in practice and that may be of low value.[10] Often a de-implementation study will use similar methods and frameworks as an implementation study, but focuses on the removal of practices.

Articles

A. Kirchner JE, Smith JL, Powell BJ, Waltz TJ, Proctor EK. Getting a clinical innovation into practice: an introduction to implementation strategies. *Psychiatry research*. 2020;283:112467.

- This article focuses on implementation strategies: what they are, how they are defined and applied, how they can be documented over the course of a study, and how you can test for their effectiveness.

B. Walsh-Bailey C, Tsai E, Tabak RG, et al. A scoping review of de-implementation frameworks and models. *Implementation Science*. 2021/11/24 2021;16(1):100. doi:10.1186/s13012-021-01173-5
   - This review article identifies frameworks and models that can be used in the study of de-implementation.

C. Powell BJ, Waltz TJ, Chinman MJ, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. *Implementation Science*. 2015/02/12 2015;10(1):21. doi:10.1186/s13012-015-0209-1
   - This article is an update on the Expert Recommendations for Implementing Change (ERIC) study. The ERIC strategies are a compilation of 73 implementation strategy terms and definitions.

D. Lewis CC, Klasnja P, Powell BJ, et al. From Classification to Causality: Advancing Understanding of Mechanisms of Change in Implementation Science. Perspective. *Frontiers in Public Health*. 2018-May-07 2018;6doi:10.3389/fpubh.2018.00136
   - This article describes a four-step approach to developing causal pathway models for implementation strategies.

E. MEASURE Evaluation Implementation Research Technical Working Group. Fundamentals of Implementation Research. U.S. Agency for International Development (USAID); 2012 (rev. 2015).
   - This resource offers an introduction to implementation science, including implementation science questions. It offers guidance on how to identify and formulate implementation science questions.

Other resources

A. Frame Your Question: What is an implementation science question? (University of Washington)
   - This webpage has general questions grouped by categories that may be of interest, such as: scaling up, sustainability, replication, program integration, equitability, and real-world effectiveness.

B. Implementation Strategies (Prajakta Adsul, University of New Mexico Cancer Center)
   - This module provides an overview of implementation strategies as well as additional readings and self-reflection questions to help guide your learning.

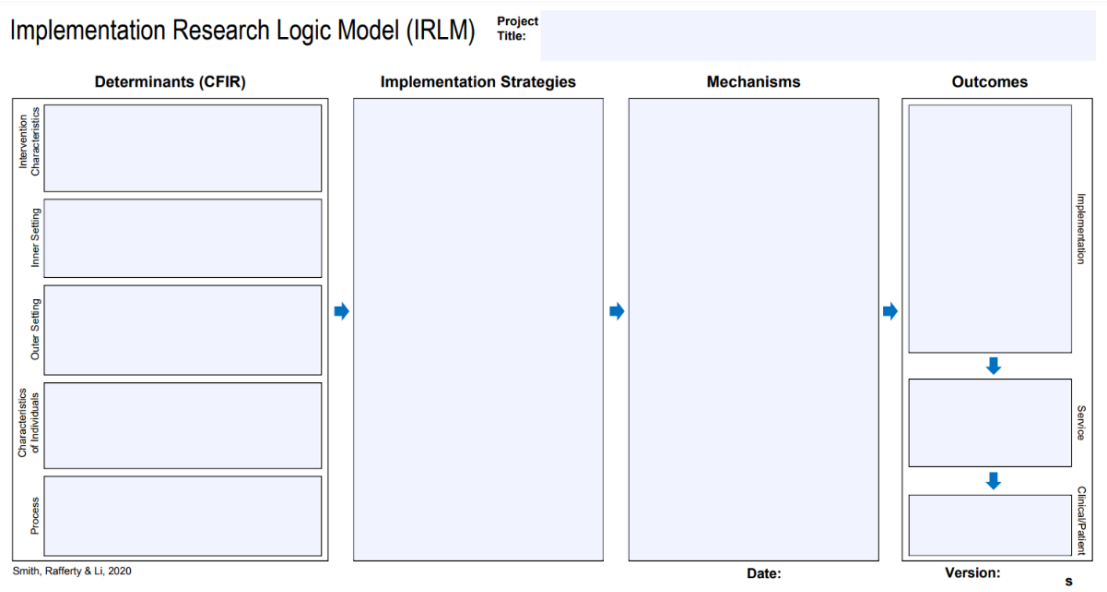
C. Implementation Mechanisms: The Next Frontier (Cara C. Lewis, Kaiser Permanente, Washington Health Research Institute)
   - This hour-long talk describes the current state of implementation mechanisms evaluation, an approach to articulating implementation mechanisms through causal pathway diagrams, and early learnings from an attempt to develop an implementation mechanisms research agenda.

D. CFIR-ERIC Implementation Strategy Matching Tool
   - This online tool helps you “match” strategies to barriers that were identified using the CFIR.

Using the Implementation Research Logic Model

The Implementation Research Logic Model (IRLM) is a tool that can be used to outline relationships between foundational elements of an implementation science study.[11] The IRLM typically outlines the determinants, strategies, mechanisms, and outcomes. It can be used in planning as well as evaluating implementation studies. If you are applying for a PCORI implementation grant, consider using the IRLM. This section of the toolkit focuses on resources specific to what the IRLM is and how the IRLM can be used in implementation science research.

Figure 4. Implementation Research Logic Model (IRLM) Standard Form. [11]



Articles

A. Smith JD, Li DH, Rafferty MR. The Implementation Research Logic Model: a method for planning, executing, reporting, and synthesizing implementation projects. *Implementation Science*. 2020/09/25 2020;15(1):84. doi:10.1186/s13012-020-01041-8
   - The Implementation Research Logic Model (IRLM) helps to illustrate the processes used in the implementation of an EBP. This article describes the design of the IRLM and how it can be used. The IRLM template can be found in the "supplementary information" of this article.

Other resources

A. Rigorous Implementation Research: The Implementation Research Logic Model and Key Design Considerations (J.D. Smith, University of Utah)
   - This slide deck from Dr. J.D. Smith provides more information on the IRLM, including examples and additional references.
B. Implementation Research Designs and Methods: Testing Implementation Strategies (J.D. Smith, University of Utah)
   - These slides describe different types of designs for implementation studies and the fundamentals of the Implementation Research Logic Model (IRLM).
C. Implementation Research Logic Model (The HIV Implementation Science Coordination Initiative)
   - This website provides templates and guides to using the IRLM.

Implementation outcomes and measures

Proctor defines implementation outcomes as "the effects of deliberate and purposive actions to implement new treatments, practices, and services."[12] Implementation outcomes have three important functions: 1) they are indicators of the implementation success; 2) they are proximal indicators of implementation processes; 3) they are key intermediate outcomes in relation to service system or clinical outcomes in treatment effectiveness and quality of care research.[12] There is currently work underway to evaluate several proposed implementation measures. Many measures are developed as single-use measures that are never repeated again in other studies. Efforts are underway to address this issue so that there can be future comparisons across studies.[13]

The resources in this section focus on introducing you to implementation outcomes, how they are used in implementation science research, and how they can be measured.

Articles

A. Proctor E, Silmere H, Raghavan R, et al. Outcomes for Implementation Research: Conceptual Distinctions, Measurement Challenges, and Research Agenda. *Administration and Policy in Mental Health and Mental Health Services Research*. 2011/03/01 2011;38(2):65-76. doi:10.1007/s10488-010-0319-7
   - This paper addresses eight distinct implementation outcomes—acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability—and provides their definitions.

B. Nilsen P, Bernhardsson S. Context matters in implementation science: a scoping review of determinant frameworks that describe contextual determinants for implementation outcomes. *BMC Health Services Research*. 2019/03/25 2019;19(1):189. doi:10.1186/s12913-019-4015-3
   - This review addresses how determinant frameworks were developed in implementation science, what terminology is used in implementation science for contextual determinants, and how context is conceptualized.

C. Damschroder LJ, Reardon CM, Opra Widerquist MA, Lowery J. Conceptualizing outcomes for use with the Consolidated Framework for Implementation Research (CFIR): the CFIR Outcomes Addendum. *Implementation Science*. 2022/01/22 2022;17(1):7. doi:10.1186/s13012-021-01181-5
   - The Consolidated Framework for Implementation Research (CFIR), first published in 2009, is one of the most used frameworks to help assess contextual determinants of implementation. This article addresses gaps in the CFIR that have been identified.

Other resources

A. Implementation outcomes: What are they? Why are they important? How are they measured? (The University of Texas Health)
   - This presentation by the University of Texas Health offers an introduction to the basics of implementation outcomes. It covers the functions of implementation outcomes, their role in research studies, and how to measure these outcomes.

Selecting a study design

When it comes to selecting a study design for an implementation science project, there are multiple options. Study designs for implementation science include randomized controlled trials, quasi-experimental designs, intervention optimization, and mixed methods. It is important to understand what different study designs can offer your research as well as when and how they can be used. This section provides a selection of articles and resources related to choosing a study design for implementation science studies.

In addition to thinking about a study design, your study may need to consider adapting an existing intervention to fit into a different context. Adaptation and modification are key areas in implementation science that may improve acceptability and feasibility of the targeted intervention.[14]

Articles

A. Brown CH, Curran G, Palinkas LA, et al. An Overview of Research and Evaluation Designs for Dissemination and Implementation. *Annual Review of Public Health*. 2017;38(1):1-22. doi:10.1146/annurev-publhealth-031816-044215
   - This article discusses randomized and nonrandomized designs for translational research, building on efficacy and effectiveness trials to look at how EBPs are implemented. It also describes other designs, including hybrid designs that combine effectiveness and implementation research, quality improvement designs for local knowledge, and designs that use simulation modeling.

B. Mazzucca S, Tabak RG, Pilar M, et al. Variation in Research Designs Used to Test the Effectiveness of Dissemination and Implementation Strategies: A Review. Review. *Frontiers in Public Health*. 2018-February-19 2018;6doi:10.3389/fpubh.2018.00032
   - This article reviews D&I study designs and methodologies and offers a guide for choosing a research design.

C. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care*. Mar 2012;50(3):217-26. doi:10.1097/MLR.0b013e3182408812
   - This article describes what "hybrid effectiveness-implementation" designs are and how they can be used in implementation science.

D. Wiltsey Stirman S, Baumann AA, Miller CJ. The FRAME: an expanded framework for reporting adaptations and modifications to evidence-based interventions. *Implementation Science*. 2019/06/06 2019;14(1):58. doi:10.1186/s13012-019-0898-y
   - This article provides an update on the FRAME (framework for reporting adaptions and modification to evidence-based interventions). This framework is designed to help characterize modifications to interventions.

Other resources

A. Select Study Designs (University of Washington, The UW Implementation Science Resource Hub)
   - The UW Implementation Science Resource Hub website provides information on study designs for implementation science and how to appropriately select a study design to meet the needs of your research.

B. Implementation Science Study Designs Overview (National Cancer Institute)
   - These slides provide a brief overview on implementation science study designs and address the concept of "equitable implementation" when discussing health equity.

C. An Overview of Hybrid Effectiveness Implementation Designs (Geoffrey M. Curran, University of Arkansas)
   - These slides cover the concept of "hybrid designs" in implementation science and provide examples of the different types of hybrid designs.

D. Adaptation & Fidelity of Interventions in Implementation Science (National Cancer Institute)
   - This talk is presented by Dr. Ana Baumann (Washington University in St. Louis) and Dr. Shannon Wiltsey Stirman (Stanford University) discuss adaption and fidelity in implementation science. Their talk includes a discussion on the tension between adaption and fidelity, how to address this tension, and how to conceptualize the relationship between the two.

E. Balancing Fidelity and Adaption: A guide for evidence-based program implementation (Washington State University)
   - This worksheet introduces the debate between fidelity and adaption and presents best practices to help balance adaption and fidelity to meet the needs of the community in which the innovation is being implemented.

Writing implementation science grant proposals

Writing implementation science grant proposals includes considerations and additional elements that are specific to implementation science. Proctor's article on ten ingredients for writing implementation science grant proposals has become foundational in the field.[15] The article addresses some of the challenges in writing implementation science grant proposals and suggests ten elements that should be included. In this section, we provide resources for developing implementation science aims and grant proposals and a link to sample applications from the National Cancer Institute.

Table 2. Key proposal ingredients checklist. From Proctor, Powell, Naumann, Hamilton, and Santen's "Ten key ingredients for implementation research proposals." [15]

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? Is a measurement plan clear for each construct? Does the analysis section demonstrate how relationships between constructs will be tested?	Approach Investigator team	
10. Policy/funding environment; leverage or support for sustaining change	Does the proposal address how the implementation initiative aligns with policy trends?	Impact Significance	

Articles

A. Proctor EK, Powell BJ, Baumann AA, Hamilton AM, Santens RL. Writing implementation research grant proposals: ten key ingredients. *Implementation Science*. 2012/10/12 2012;7(1):96. doi:10.1186/1748-5908-7-96
   - This article addresses the challenges faced when submitting an implementation science grant application and summarizes ten ingredients that are important in implementation research grants.

Other resources

A. D&I Aims Toolkit (Washington University in St. Louis)
   - This toolkit introduces scientists to the formulation of D&I research aims and provides guidance on how to effectively write such aims.
B. Implementation Science Grant Writing Resource (University of Washington)
   - The UW Implementation Science Resource Hub website provides information on the specific elements required in an implementation science grant proposal that are not common in other types of grants. This webpage includes a section on key considerations for writing implementation science grants, webinars on grant development and funding, and implementation science funding announcements.
C. 10 Key Ingredients for D&I Research Proposals (Video)
   - This short video by the University of Colorado Anschutz Medical Campus provides a minute and a half introduction to what should be included in a D&I research proposal.
D. Tufts CTSI D&I Interest Group Meeting with Dr. Rachel Gold: Writing implementation science grant proposals (Recording)
   - In this September 2023 talk, Dr. Rachel Gold discussed the ten key ingredients for writing implementation science grant proposals and shared examples from her own work.
E. Sample Grant Applications (The National Cancer Institute (NCI))
   - On the National Cancer Institute (NCI) webpage, there are examples of several dissemination and implementation grant applications that their investigators and their organizations have agreed to share online.

Guidance around research aims and research strategy

With the help and support of Kaiser Permanente, the Tufts CTSI D&I Core further developed guidance on writing implementation science grant proposals. The purpose of this additional section is to share lessons learned with those intending to conduct research trials with an implementation science focus.

Specific aims

- General guidance for writing an implementation Aim.
  - **Language and terms.** Be clear and consistent with the terms used to describe *what is being tested* and *what outcomes it seeks to impact*. The *evidence-based clinical practice* that should be more widely adopted than it is at present may also be called the targeted 'clinical innovation' or 'clinical intervention'. The *implementation strategy* hypothesized to potentially increase the adoption of that clinical practice may also be called the 'implementation intervention' or 'intervention'. Do not use 'intervention' to describe both the targeted practice and the method being tested. Consider that the term 'implementation strategy' may be used to describe a method used to support increased use of a given clinical practice, and 'implementation support strategy' to describe a method used to support use of the implementation strategy. For example, provider training may be considered an *implementation support strategy*; this training might be provided to enhance use of a clinical decision support tool that may be considered an *implementation strategy*; and the tool may be designed to remind users about new prescribing guidelines, which are the *clinical practice* of interest.
  - **Purpose and reasoning.** Explain why it is hypothesized that a given implementation strategy will be effective in the context of interest, and thus why the proposed research is needed. Has the strategy proven effective in another care setting, or effective at improving adoption of a different clinical practice, but not been tested in the context of interest and/or to support adoption of the targeted practice? Has prior research identified barriers to the adoption of a given practice, and the proposed work seeks to test strategies specific to those barriers?
  - **Order and content of aims.** There are many ways to organize aims in D&I studies. Some approaches are described below. These examples refer to non-hybrid D&I studies where the term "intervention" references the implementation strategy:

    Approach 1

    Aim 1: Test the intervention's impact on adoption using quantitative methods; list hypothesized outcomes.
    Aim 2: Learn more about why the quantitative results were found using qualitative methods.
    Aim 3: Assess maintenance of adoption outcomes over a longer period.

    Approach 2

    Aim 1: Test the intervention's impact on adoption using quantitative methods; list hypothesized outcomes.
    Aim 2: Learn more about why the quantitative results were found using qualitative methods and adapt the initial intervention accordingly.
    Aim 3: Test the adoption impact of the revised intervention.

    Approach 3

    Aim 1: Engage potential future users of the intervention in a development process.
    Aim 2: Pilot test the intervention, revise.

Aim 3: Test the adoption impact of the revised intervention.

Approach 4
Aim 1: Engage potential future users of the intervention in a development process; pilot and revise.
Aim 2: Test impact on primary outcomes, e.g., adoption of the intervention.
Aim 3: Assess impact on secondary outcomes, e.g., biological impact; specifics of how the adopted intervention was used; patient / user perceptions of the intervention.

Approach 5
Aim 1: Implement the intervention.
Aim 2: Quantitatively assess its effectiveness.
Aim 3: Qualitatively assess how it was perceived / should be modified.

- **Model(s).** In most cases, the study concept should be informed by a conceptual model or a logic model, implementation outcomes should be informed by an implementation measurement framework, potential barriers should be described according to established terms/frameworks, etc. There will likely not be room in the aims to explain how all of these will be applied but try to include a mention of them in the aims page, e.g., "Outcome measurement is guided by the RE-AIM framework."
- **Biomarkers.** In most cases, NIH and other funders will want the study to include an assessment of patient health outcomes. In implementation science studies (especially Type 3 hybrid studies) this does not always make sense, because the studies are premised on the fact that a given clinical practice is evidence-based, so if it were adopted more widely the health impacts should occur. One way to address this is to (1) have the biomarker impact be a secondary outcome, and (2) emphasize the point that the clinical practice is evidence-based and expected to have the assessed outcomes, and this is why that impact is a secondary outcome.

Research strategy

Consider the following points when developing your Research Strategy.

- **Language matters.** As noted in the Specific aims section, carefully select the terms used to describe the clinical practice whose adoption is targeted, and the implementation strategy and/or implementation support strategy being tested. Clearly define each one the first time it is used in the proposal and use that term consistently throughout the proposal.
- **Formative step.** Many implementation science trials will benefit from including a formative period in which potential future users of the intervention under study weigh in on the intervention. It can be beneficial to modify the intervention in response to feedback, to the extent possible. Getting this feedback can be one of the study aims, or part of an Aim. Make sure to include adequate time for both obtaining and applying feedback from this phase. In addition, reviewers will need to understand both why there is a need to refine the intervention, and what those refinements might involve. Consider giving an example of the type of refinement that might be made and note that they will be made as feasible given budget and time constraints.
- **Mixed methods.** Qualitative data are essential to understanding why and how quantitative results are achieved. Though mixed methods studies require team members with qualitative expertise and qualitative data collection and analysis is resource-intensive, it is worth the effort to include them.

- **Models and frameworks.** It is highly recommended that proposals include a conceptual model that lays out the anticipated path of influence of the intervention on the outcome. In some cases, a logic model may be used in addition or instead of a conceptual model. Many conceptual models have already been created; we recommend using an existing model rather than creating one. Though the selection of commonly used models for this purpose can be easier to explain, it is more important to use a model that is a good fit for the proposed work. It is critical to explain why you selected a given model (i.e., why it explains the proposed path of influence). It can be acceptable to note that only some elements of a given model apply to your study. It is also critical to be very clear about how that model influences the study design throughout the proposal. For example, the elements of the model might drive which data are collected, how the intervention is structured, etc. It is also recommended that the study's measures of adoption follow an implementation measurement framework. Several exist; modifying an existing framework is acceptable if the need to do so is well-explained.

Disseminating innovations

Dissemination plays a role in ensuring uptake in evidence-based practices. Many of the resources included in this guide touch on dissemination as well as implementation. You can also check out Tufts CTSI D&I Core's Dissemination Planning Template to help you get started with planning the dissemination of your next innovation or intervention.

Dissemination resources

A. Ross-Hellauer T, Tennant JP, Banelytė V, et al. Ten simple rules for innovative dissemination of research. *PLoS Comput Biol*. Apr 2020;16(4):e1007704. doi:10.1371/journal.pcbi.1007704

- This article outlines 10 steps researchers can take to disseminate their work to help ensure that their work engages their target audience and therefore increases its' impact.

B. Eagleman DM. Why Public Dissemination of Science Matters: A Manifesto. *The Journal of Neuroscience*. 2013;33(30):12147-12149. doi:10.1523/jneurosci.2556-13.2013

- This short article offers six reasons why researchers should take time to disseminate this work to the public.

C. Tufts CTSI D&I Core Dissemination Planning Worksheet

- Planning for dissemination is essential in all stages of research. By answering the questions posed in the worksheet, you will have all 10 essential elements of dissemination in your plan. You can access the Dissemination Planning Worksheet on the Tufts CTSI D&I Core page under "D&I Resources."

Training resources

If you are looking for more opportunities to develop your implementation skills, additional training and education might be the next step in your journey. Please find some additional training opportunities listed below, including online and in-person training.

Online training opportunities

Training Institute for Dissemination and Implementation Research in Cancer (TIDIRC) Open Access

- The eight modules included in this free online course make up the TIDIRC Open Access course. These modules can be viewed together as a whole or individually by section and include videos, readings, and self-reflection questions. Accessible anytime.

Introduction to Implementation Research: Designing & Evaluating Interventions

- This online course outlines qualitative, quantitative, and mixed research methods that address the facilitators and barriers to the translation of evidence into practice in healthcare. It is designed to be an introduction to the theory and methods of implementation research. General timeline: Apply by early summer, participate in course in late summer/early fall.

Washington University in St. Louis: Implementation Science Video Library

- A collection of short videos on key theories, models, and frameworks in the field of dissemination and implementation science. Accessible anytime.

In-person training opportunities

The Penn Implementation Science Certificate Program at the Perelman School of Medicine at the University of Pennsylvania

- This program is designed for those in mind who are interested in developing their competencies in implementation science to be used in future research, such as seeking NIH K award or equivalent funding. The certificate is intended for people who are implementation practitioners, including improvement scientists. This is a credit-based course that takes place over the academic year. General timeline: Courses take place over the academic calendar year.

The University of Pennsylvania Implementation Science Institute

- The Implementation Science Institute aims to provide participants with the skills to design and execute implementation science research. Students will be introduced to the foundations of implementation science as well as an overview of advanced topics including implementation strategies and sustainability. The course includes tips for grant writing, skill development and time will be spent writing specific aims for Implementation Science grants. This is a 4-day course. General timeline: Course takes place over the summer.

Implementation Science in Global Health Summer Institute at the University of Washington

- The Implementation Science in Global Health Summer Institute is a one-week course that provides participants with an in-depth look into implementation science. The Institute covers interdisciplinary framework of methods for improving implementation and scaling-up health programs as well as examples from global health leaders. General timeline: Course takes place in late summer.

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Appendix 1. Considerations for writing implementation science grant proposals

Writing implementation science grant proposals includes considerations around recruitment and retention, letters of support, staffing, budgeting, and human subjects. While these are elements that are also considered in other proposal applications, in implementation science grant proposals their specific content can vary from what is usual in other types of studies. The following section details and provides examples of what to include in these sections when writing an implementation science grant proposal.

Challenges for recruitment and retention

Implementation trials have unique recruitment and retention challenges:

- Recruitment can take longer than anticipated given that commitment is required at the group level (e.g., clinic or organization). Account for longer than typical recruitment period in the timeline (e.g., extra time for organizations to consider invitations given the potential complexity of participation) and be prepared to spend extra time communicating about the study (e.g., scheduling multiple meetings for Q&A with different organization contributors, responding to questions via email).
- Enrollment may be more difficult than anticipated given that many clinics/organizations have competing priorities. Even if they can see the value in the study, participation may be perceived as too burdensome.
- Retention can also be an issue. Once enrolled, leadership can change multiple times over the course of a multi-year study. With new leadership may come a shift in priorities.

Letters of support

Ensure that the language used in all letters of support (LOS) aligns with the language used in the proposal. If an implementation strategy is being tested, the LOS should reinforce that you are testing its implementation impact, and why. If appropriate, the LOS should also make clear that leaders at the clinic (or other setting) in which the strategy will be tested are supportive of this approach, understand the need for the evidence to be generated, and want to improve adoption rates for the targeted clinical practice.

Staffing

Ensure that your co-I team includes someone with implementation science experience, and not just experience with intervention development and testing. Their biosketch should highlight this experience.

Budgeting

Contributor engagement (i.e., focus groups, advisory panels, etc.) is often key in implementation science studies. In many cases, conducting engagement activities requires adequately compensating participants; the funds to do so should be included in the proposal budget, as doing so shows reviewers that the process is being designed appropriately.

Human subjects

Implementation studies may have multiple participant groups (e.g., organizations/clinics, staff, patients). When completing the Human Subjects section of a proposal, it is important to identify each group of participants described in the research plan.

Example: Eligibility criteria

This example describes eligibility criteria for an implementation trial that is recruiting clinics and clinic staff.

In this study, individual patients are not being enrolled into this clinic-randomized trial. The interventions under study will be provided at the clinic level and will target clinic processes that are part of routine patient care. However, clinic staff will be surveyed and interviewed as part of the qualitative component of this study. This data collection will focus on assessing perceptions of the clinical decision support (CDS) tools under study, including positive/negative impacts on care quality and patient-provider interaction. Example eligibility criteria language for a recruitment and retention plan, and example of a planned enrollment report are detailed below.

Community Clinics

Inclusion Criteria:

- Performed >100 social risk screenings in the previous 12 months at the time of recruitment
- Provides primary care

Exclusion Criteria:

- Participated in the pilot phase study
- School-based health center
- Provides care to prison population

Clinic Staff (survey and interviews)

Inclusion Criteria:

- Experience using CDS tools during patient encounters
- Age ≥ 18 years

Exclusion Criteria:

- Non-English or Non-Spanish speaker

Example: Recruitment and retention

This example describes the recruitment and retention process for an implementation trial that is recruiting clinics and clinic staff.

Community Clinics

- *Recruitment.* All study clinics will be recruited by [insert organization and research team role], with support as needed from the [insert sites as appropriate] research teams. [Insert organization]'s clinical leadership may also help with recruitment, as needed. Recruitment will be targeted to optimize diversity in clinic baseline characteristics. [Organization] utilizes a variety of recruitment methods when inviting community clinics to participate in research studies. Recruitment activities for this study may include: (1) verbal conversations, in-person or by phone; (2) sending an introductory recruitment email that allows clinics to opt in to the study, with study-related attachments; and (3) a presentation of recruitment materials at [organization] Grand Rounds meetings/webinars, or at other standing meetings of [organization] members, such as [insert relevant committees or groups]. Any interested clinics will be encouraged to contact study staff to discuss potential participation. Materials used for the recruitment of study

clinics will include a participation information sheet, a slide deck with information about study participation, and a recruitment card with a brief description of what study clinics can expect and what will be expected of them.

- *Retention.* We anticipate that clinics will want to participate in this study, both to learn how to use the social risk data they collect and to have a voice in developing the social risk CDS tools. Clinics that take part in the study will receive an impact fee to compensate them for the time spent engaging in qualitative data collection activities. Since the CDS tools will simply be turned on at the study sites, clinic participation in the study is not expected to be burdensome, so drop-out rates should be minimal. We have also powered the study to allow for the loss of one clinic per arm.

Clinic Staff

- *Recruitment.* The research team, working by email and phone with clinic contacts identified during the recruitment process, will identify and recruit staff members who have experience using the CDS tools for phone interviews. Clinics will be asked to agree to allow these interviews when they are recruited for the study.
- *Retention.* Interviews will be one-time only and will not require follow-up.

Example: Study timeline for implementation science project with a formative phase

The example below is a project with a formative phase that is *not* considered human subjects research, which can be covered by a JIT letter, followed by study activities that are considered human subjects research. Further IRB review and approval is required prior to starting any research activities involving human subjects. The following table is an example of how you might divide up your timeline by non-research activities and human subjects research activities to clearly delineate what does not require IRB approval and what does.

		Year 01	Year 02	Year 03	Year 04	Year 05
		2020	2020-2021	2021-2022	2022-2023	2023-2024
		F M A M J J A S O N	D J F M A M J J A S O N	D J F M A M J J A S O N	D J F M A M J J A S O N	D J F M A M J J A S O N
Non-Research	**Aim 1a - Identify potential care plan suggestions for the CDS tool**					
	Identify potential care plan adaptation suggestions for CDS tool (based on team's pilot work, lit review)					
	Obtain stakeholder input on care plan adaptation suggestions for the CDS tool (stakeholder committee vignette-based interviews)					
	Continue stakeholder engagement activities to obtain further input on *content* of CDS tool (stakeholder committee meetings, PEP engagement)					
	Rapid qualitative analysis of stakeholder input					
	Obtain stakeholder input on the *form/structure* of the CDS tool (CORC meetings)					
	Aim 1b - Develop an EHR-based CDS tool					
	Develop and iterate an EHR-based CDS tool that presents patient-centered suggestions for social risk-informed care, based on results from Aim 1a					
Human Subjects Research Activities	**Aim 1c - Pilot test the tool in 3 CHCs**					
	Recruit CHCs to participate in pilot					
	Pilot test CDS tool in 3 CHCs					
	Semi-structured interviews with providers and other staff					
	Aim 2 - Conduct trial					
	Randomize clinics to control/intervention pools					
	Recruit 6 clinics to participate in intervention					
	Follow clinics to assess impact of CDS tool in the study CHCs					
	Aim 3- Conduct a realist evaluation to assess impact of the CDS tool					
	Collect data on user perceptions of the CDS tools (interview with study staff)					
	Analyze data					
	National dissemination					

Example: Completing the planned enrollment table

It can be difficult to complete the Planned Enrollment table when it is not yet known which organizations/clinics will participate. We have addressed this in the past by explaining this issue in the "Comments" section and providing a proxy for the target population.

Example planned enrollment table 1

Comments: This table provides patient data (1/1/2017-12/31/2017) for the 80 community clinics currently eligible for the study (>100 social risk screenings). We note that randomization and intervention will be at the clinic level; individual patients will not be randomized. This report shows the diversity within these clinics as a proxy for to-be-recruited study clinics. We cannot anticipate how many or which patients will receive the intervention, nor which of the eligible clinics will opt to join the study.

Racial Categories	Not Hispanic or Latino		Hispanic or Latino		Total
	Female	Male	Female	Male	N
American Indian/Alaskan Native	810	670	730	600	2810
Asian	10100	7700	200	160	18160
Native Hawaiian or Other Pacific Islander	740	590	990	730	3050
Black or African American	41600	34200	4970	3480	84250
White	54900	45500	52000	33900	186300
More than one race	1280	950	400	250	2880
Total	109430	89610	59290	39120	297450

Example planned enrollment table 2

Comments: In this cluster randomized trial, patients are not individually recruited and assigned to an intervention. Instead, randomization and intervention occur at the clinic level. The shared decision making (SDM) interventions in this trial will target adults with high CVD risk. The estimated numbers in the planned enrollment table below represent adult patients (40-75 years old) with a hypertension flag or diabetes diagnosis seen between 11/01/2019 and 10/31/2020. These estimates reflect the number of potential patients that may be exposed to one of the intervention arms. NOTE: While clinic staff will be notified when the SDM tool is recommended for a particular patient, it is up to the discretion of clinic staff and/or the provider to (1) run the tool, (2) consider its recommendations, and (3) decide whether to discuss them with the patient during the encounter.

Race	Male (N)	Female (N)	Total (N)
American Indian/Alaska Native	1,247	1,377	2,624
Asian	10,557	13,643	24,200
Black/African American	33,384	41,021	74,405
Hawaiian/Pacific Islander	1,126	1,271	2,397
White	90,272	98,409	188,701
Multirace	867	1,071	1,938
Unknown	14,653	15,298	29,951
Ethnicity	**Male (N)**	**Female (N)**	**Total (N)**
Hispanic (Latino/Latina/Latinx)	42,147	54,100	96,247
Non-Hispanic	101,649	110,367	212,036
Unknown	8,310	7,623	15,933

Appendix 2. Pre- and post-award considerations

IRB considerations during the pre-award period

Implementation science studies can differ from classic research studies by having a formative phase that is not human subjects research. A formative phase in an implementation science study may include identifying potential adaptions to what is being implemented and obtaining contributor input on different elements of the project prior to starting the human-subjects research phase of the study.

If the project involves a formative phase, consider submitting a "Just in Time" (JIT) or similar request rather than a full IRB application in the pre-award phase. Please note that the Tufts Health Sciences IRB and NIH refer to these requests as JIT requests, but your local IRB may refer to them as something else. At Kaiser, they refer to them as "approval in principle" requests.

- Funding agencies often require IRB approval for awards involving human subjects research *before* grant funds are released.
- However, studies involving implementation science often have a formative phase where various contributors are engaged to provide feedback that informs intervention development and/or the implementation process before the pilot study and/or formal trial begins. In these cases, human subjects research occurs later in the project, and the JIT approval process may be a useful option.
    - The JIT approval process allows investigators to describe the design and development phase of the proposed work where human subjects are not involved yet in research. The IRB will then review/accept the general plan described in the grant application and provide documentation for the funding agency acknowledging this process has been completed. Typically, both the IRB documentation and the funding agency's award language will note that full IRB approval is required before any human subjects research begins.
    - JIT process limitations: (1) submissions do not allow for the access, use, distribution, or analysis of private, identifiable data nor do they allow for contact or enrollment of study participants, and (2) IRB approval of the detailed procedures for the specific study or sub-studies that include private identifiable data or interaction with subjects must be submitted to the IRB for review and approval *before* they are initiated.

The JIT template Letter of Understanding from the Tufts HS IRB:

800 Washington Street, Box 817
Boston, MA 02111
Tel. 617.636.7512
IRBoffice@tuftsmedicalcenter.org
https://viceprovost.tufts.edu/HSIRB

Tufts | Health Sciences IRB

Tufts Health Sciences Institutional Review Board

MaryAnn Volpe, MD
Chair

Date

PI Name
Tufts Medical Center/Tufts University
Boston, MA 02111

Re: Letter of Understanding

Dr. PI Name has received a request for Just In Time (JIT) Information from the FUNDING SOURCE relating to the grant application entitled "*TITLE*."

Background: Dr. PI Name has planned a project timeline which illustrates a planning period for the above referenced grant. The planning period provides for [development and creation of study documents, staff hiring and training, etc.] before any human subjects involvement will take place.

Project Timeline *[Revise entire table as needed]*	**Year 1**				**Year 2**				**Year 3**			
	1	2	3	4	1	2	3	4	1	2	3	4
Development of study documents	X	X										
Hiring and Staff Training	X	X										
Advertising and recruitment		X	X									
Conduct of the clinical trial			X	X	X	X	X	X				
Baseline Assessments			X	X	X	X	X					
12 Weeks of Interventions				X	X	X	X	X	X			
12-Week Assessments				X	X	X	X	X	X			
Data Processing and Analysis			X	X	X	X	X	X	X	X		
Manuscript Preparation							X	X	X	X		
Dissemination of findings										X	X	X

In reviewing the documents that Dr. PI Name has submitted to the Tufts Health Sciences IRB, the IRB Chair has noted that Dr. PI Name's plan for human subjects involvement requires further development. It is further agreed that no research funded by this project may involve human subjects until a protocol fully describing the research has been reviewed and approved by the IRB in accordance with 45 CFR 46.118.

Agreed to by and among Dr. PI Name and the Tufts Health Sciences IRB.

Dr. PI Name

Chair, Tufts Health Sciences IRB

An example of an Approval in Principle letter from Kaiser Permanente - Northwest Region IRB:

ACTION:	ACKNOWLEDGED
REVIEW TYPE:	Administrative Review
EFFECTIVE DATE:	December 4, 2019
EXPIRATION DATE:	May 4, 2020
FUNDING:	NIH/NIMHD
REVIEW CATEGORY:	Approval in Principle for Activities Preparatory to Research
DOCUMENTS REVIEWED:	• COHERE Approval in Principle Form • COHERE_ResearchPlan_FromProposal_2019-10-10

On December 4, 2019, the Kaiser Permanente - Northwest Region IRB reviewed the above-named submission and noted that the study activities and materials pertaining to human subjects research are not yet fully developed. In accordance with the US Department of Health and Human Services (DHHS) 45 CFR 46.118, the IRB does not need to review this study prior to an award being made. However, the Kaiser Permanente - Northwest Region IRB has granted an Approval in Principle for the design and development phase of this project which involves only activities preparatory to research.

The limits of this Approval in Principle are as follows:

- **Before beginning any activities with human subjects, a separate IRB application including relevant materials and procedures (including analysis of private, identifiable data) must be submitted for review and approval by the Kaiser Permanente - Northwest Region IRB.**
- Approval of activities described in this application will expire no more than one year from the date of IRB approval.
- Prior to the expiration date, a continuing review submission is required to confirm that the project remains in design and development OR to request closure of this file if all activities involving human subjects are covered in one or more separate IRB submissions.

Guidance if using the Tufts Health Sciences (HS) IRB

To obtain a JIT approval, email IRBOffice@tuftsmedicalcenter.org with the reason for your request. If a JIT is appropriate, the IRB Office will ask for the following:

1. A cover letter (briefly introducing the submission of a JIT request for a grant - NIH, USAID, etc.), which conveys the urgency of the submission and states by when you need the IRB letter

2. A copy of the Grant

3. Any other study documents including drafts (such as a draft protocol for the human subjects component, *if* you have this ready)

4. The JIT Template Letter of Understanding shown on page 8, modified to apply to your study. The IRB Office will send you this template in a MS Word format.

After review, the IRB office will provide you with an executed Letter of Understanding and an NHSR Determination Letter that state the following:

The IRB made the following determinations:

1. The study is currently in the developmental phase and does not constitute human subject research.

2.Research activities approved at this time are limited to [e.g. development of the study documents, hiring and training of staff].

3.The Principal Investigator must submit the study for IRB review and approval before proceeding to human subject research activities.

Example: Note documenting a formative phase of the project in the study protocol

The study may include components that are not considered research (e.g., a formative phase that includes engagement with contributors intended to inform the intervention). We recommend adding a note to the study protocol to document this aspect of the project (see example below).

II. Objectives

A. Overview

This study was designed to develop and test clinical decision support (CDS) tools that present clinical care team members with a given patient's social risk information and recommended care plan adaptations based on those risks. This study will test the hypothesis that providing CDS that alerts care team members to patients' known social risks, and recommends relevant care plan adaptations, will result in improved patient health outcomes. This study's focus is on hypertension and diabetes control, but the results will have implications for a wide range of morbidities.

B. Specific Aims

1. **Aim 1. (1a)** Identify potential care plan adaptations that might be used to contextualize care and mitigate the impact of social risks on patients' health by (a) iteratively engaging and obtaining input from diverse CHC staff and patient stakeholders and (b) drawing on our team's prior research. **(1b)** Develop an EHR-based CDS tool that offers social risk-informed care plan adaptations identified in Aim 1a and iterate the tool's form and content based on further stakeholder input. Through this process, determine which social risks the CDS tool will cover, including patient-reported and community-level factors; the preferred content of this CDS; and the preferred form of the CDS in the EHR. **(1c)** Pilot test the tool in three community health centers (CHCs) and further refine the tool based on extensive user feedback.

2. **Aim 2.** Implement a randomized quasi-experimental design to assess the impact of the CDS tool developed in Aim 1. **Primary Outcomes**: Assess the tool's impact on two Clinical Quality Measures (CQMs) among patients in intervention vs. control CHCs: (a) blood pressure control and (b) HbA1c control. **Secondary Outcomes**: (a) Assess the tool's impact on additional CQMs (e.g., BMI, lipid control) and (b) determine whether the suggested care plan adaptations were enacted (using EHR data).

3. **Aim 3.** In secondary analyses, assess care team perceptions of the tool's usability and impacts on care quality and patient-provider interactions (using data collected via staff interviews).

NOTE: Per consultation with the Kaiser Permanente Northwest (KPNW) IRB, Aims 1a and 1b do *not* involve research and are considered quality improvement (QI) activities. Aims 1c (pilot testing), 2 (cluster-randomized trial, quantitative assessment of tool impact) and 3 (mixed-methods assessment of tool impact) *do* involve human subjects and are described in this protocol. See project timeline in Section XVII for non-research/ research categorization of study activities.

Example: Note regarding clinic randomization rather than individual randomization

The note in the example below explains that clinics are being randomized rather than individual participants (something that should be reiterated throughout protocol in sections where a reminder would be helpful for the reader, e.g. study population; inclusion/exclusion criteria). It's also important to use language describing what *may* happen rather than what will happen (to account for parts of intervention or implementation support that are offered but not utilized by clinics, e.g. webinars, trainings, use of guides/implementation support materials).

NOTE: *Individual patients are not being enrolled for this study.* Recruitment, randomization, and intervention implementation will occur at the clinic/organization level, and the intervention under study will target clinic processes that are part of routine patient care. The CDS tools are intended to supply point-of-care information about social risks that may affect provider decisions or lead to provider-patient discussions. While we will ultimately compare patient health outcomes in intervention and control clinics to assess impact of the intervention, use of the CDS tools will be at the discretion of the providers in the participating clinics.

Example: Rationale for including or excluding certain vulnerable populations

Vulnerable Populations

1. **Pilot/Main Trial Clinics Using CDS Tools** (Study Aims 1c and 2). While individual patients are not being recruited/enrolled in this study, the CDS tools may be used by providers as part of routine patient care. The table below lists the vulnerable population categories and whether we anticipate that providers will include/exclude them when using the CDS tools, which in turn will result in their data being used in study analyses.

Vulnerable Populations (VPs)	Include/ Exclude	Rationale
Pregnant women	Include	May be incidentally included, but not in a focused or targeted manner; will depend on whether provider chooses to use the CDS tools.
Children	Exclude	CDS tools will only fire for patients 18 years and older.
Neonates of uncertain viability or nonviable neonates	Exclude	CDS tool recommendations not applicable for this population.
Prisoners	Exclude	This study will actively exclude clinics that serve the prison population.
Decisionally impaired adults	Include	May be incidentally included, but not in a focused or targeted manner; will depend on whether provider chooses to use the CDS tools.

Post-award considerations: Reporting to funders

Separate inclusion enrollment reports will need to be provided to funders for each group of participants (individuals in participating clinics that meet criteria; individuals participating in qualitative data collection efforts, e.g., clinic staff).

Example: Inclusion enrollment report for clinics

Two examples of clinic-level inclusion enrollment reports are presented below.

Example actual enrollment table 1

Comments: In this clinic-randomized trial, patients are not recruited (i.e., randomization and intervention occur at the clinic level). The intervention targets adults with high CVD risk. The

numbers below reflect adult patients (40-75 years old) seen in the 70 study clinics, with a hypertension flag, between 09/21/18 and 11/15/19. Note: Per organization policy, values ≤ 10 are not displayed. Therefore, 1 = any value between 1 and 10.

Racial Categories	Not Hispanic or Latino		Hispanic or Latino		Unknown Ethnicity		Total
	Female	Male	Female	Male	Female	Male	N
American Indian/Alaskan Native	140	120	80	70	15	1	426
Asian	1030	720	1	1	70	40	1862
Native Hawaiian or Other Pacific Islander	100	80	20	20	1	1	222
Black or African American	5080	4050	170	130	120	90	9640
White	11200	10600	4040	3120	350	350	29660
More than one race	160	130	30	20	20	20	380
Unknown	250	230	850	770	420	340	2860
Total	17960	15930	5191	4131	996	842	45050

* numbers have been changed

Example actual enrollment table 2

Comments: The numbers below represent patients who met tool alert criteria in the 6 main trial clinics from 02/09/23-08/31/23. Per organization policy, cells with counts <11 cannot be reported; therefore, the number 0 may represent a value of 0-10. For this reason, the tabulated total is less than our cumulative enrollment total of 4425. NOTE: For this study, CDS tools are enabled for use and staff receive an alert when a patient meets criteria; whether the tools are used is at the discretion of clinic staff.

Racial Categories	Not Hispanic or Latino		Hispanic or Latino		Unknown Ethnicity		Total
	Female	Male	Female	Male	Female	Male	N
American Indian/Alaskan Native	0	0	50	40	0	0	90
Asian	60	70	0	0	0	0	130
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0
Black or African American	390	240	110	80	20	10	850
White	860	820	540	420	60	40	2740
More than one race	20	0	0	0	0	0	20
Unknown	70	50	130	110	80	100	540
Total	1400	1180	830	650	160	150	4425

* numbers have been changed

Example: Inclusion enrollment report for clinic staff

An example inclusion enrollment report for clinic staff is presented below.

Comments: In this clinic-randomized trial, individual patients are not recruited. In Aim 1, to identify patterns of SDH data collection in diverse CHCs and factors associated with variation in SDH data collection rates, we conducted a formative evaluation through qualitative interviews with 45 CHC staff from 9/1/17-8/1/18.

Racial Categories	Not Hispanic or Latino		Hispanic or Latino		Unknown Ethnicity		Total
	Female	Male	Female	Male	Female	Male	N
American Indian/Alaskan Native	0	0	0	0	0	0	0
Asian	0	3	0	0	0	0	3
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0
Black or African American	6	3	0	0	0	0	9
White	11	7	0	0	3	0	21
More than one race	0	3	0	0	0	0	3
Unknown	0	0	6	3	0	0	9
Total	17	16	6	3	3	0	45

* numbers have been changed