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Institute of Clinical and Translational Sciences

DIRC

D&I Aims Toolkit

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Overview

This toolkit provides Dissemination and Implementation (D&I) scientists with tools to write effective aims for D&I research. According to the NIH, dissemination research is "the scientific study of targeted distribution of information and intervention materials to a specific public health or clinical practice audience" and implementation research is "the scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings in order to improve patient outcomes and benefit population health" (NIH PAR 16-236).

Objectives

- To help the researcher to become familiar with formulation of D&I research aims by research phase and design type.
- To enable the researcher to locate examples of funded D&I research online.

What's Inside?

This toolkit includes guidance on writing study aims for NIH grants, describes how D&I aims differ from other kinds of research, provides example D&I research aims for the three main objectives of research (explore, describe and test) and for hybrid studies, provides examples of different aim structures used in funded grants, and includes links to repositories of funded D&I grant proposals.

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How to Write an Aims Page

Importance:

- Reviewers read the aims page first and it influences the reviewers' disposition regarding the entire grant. It should be as clear as possible and frame the grant proposal well.
- Sometimes the aims page is the only part of the grant proposal that a reviewer reads. Most reviewer feedback will be based on the aims page.

Structure:

- ***Establish the problem area***: Include 1-3 sentences that state the problem and D&I knowledge gap your grant proposal addresses and relate it to the funding agency priorities. Make sure to differentiate clearly between implementation and clinical/disease-related phenomena, questions, outcomes, and later aims and methods.
  - Optional: Include 2-4 sentences on preliminary studies.
- ***Specific aims***: List 2-4 short aims for your study, each starting with a strong action verb.
  - The aims should be thematically and logically related to each other, but you should be able to carry out each independent of the others.
  - Be realistic and avoid promising what cannot be delivered as part of the grant.
- ***Methods***: Briefly explain how the aims will be achieved.
  - Include one paragraph on the methods following the aims section.
  - Alternatively, you can include a sentence after each aim with a general description of how that aim will be accomplished. Be careful to separate the aims from study activities.
- ***Importance/Impact***: Include one paragraph on the importance of the study or what the study will lead to.
- ***Optional components***:
  - If useful, you may include a brief rationale for each aim.
  - For large grants (e.g., R01), it is useful to include a clear hypothesis for each aim. Do not include these if the proposed study is exploratory or if the hypotheses are not self-evident.

Useful hints:

- Make the work as easy as possible for reviewers: Use clear and concise language. Pay attention to the formatting of the aims page, by including white space and bolding/italicizing important pieces.
- Seek plenty of feedback on the aims page to understand whether you accomplished what you set out to do.

Sources:
The above recommendations were adapted from:

- Brownson RC, Colditz GA, Dobbins M, et al. Concocting that magic elixir: successful grant application writing in dissemination and implementation research. *Clinical and Translational Science*, 2015, 710-716.
- Mittman BS. Drafting a compelling aims page in IS grants: style and substance. Presentation, Implementation Research Institute, Washington University in St. Louis. June 2016.
- Stange KC, Kreuter M, Brownson RC. How to write a specific aims page (and other essential life lessons). Webinar, Mentored Training for Dissemination and Implementation Research in Cancer (MT-DIRC). January 2016.
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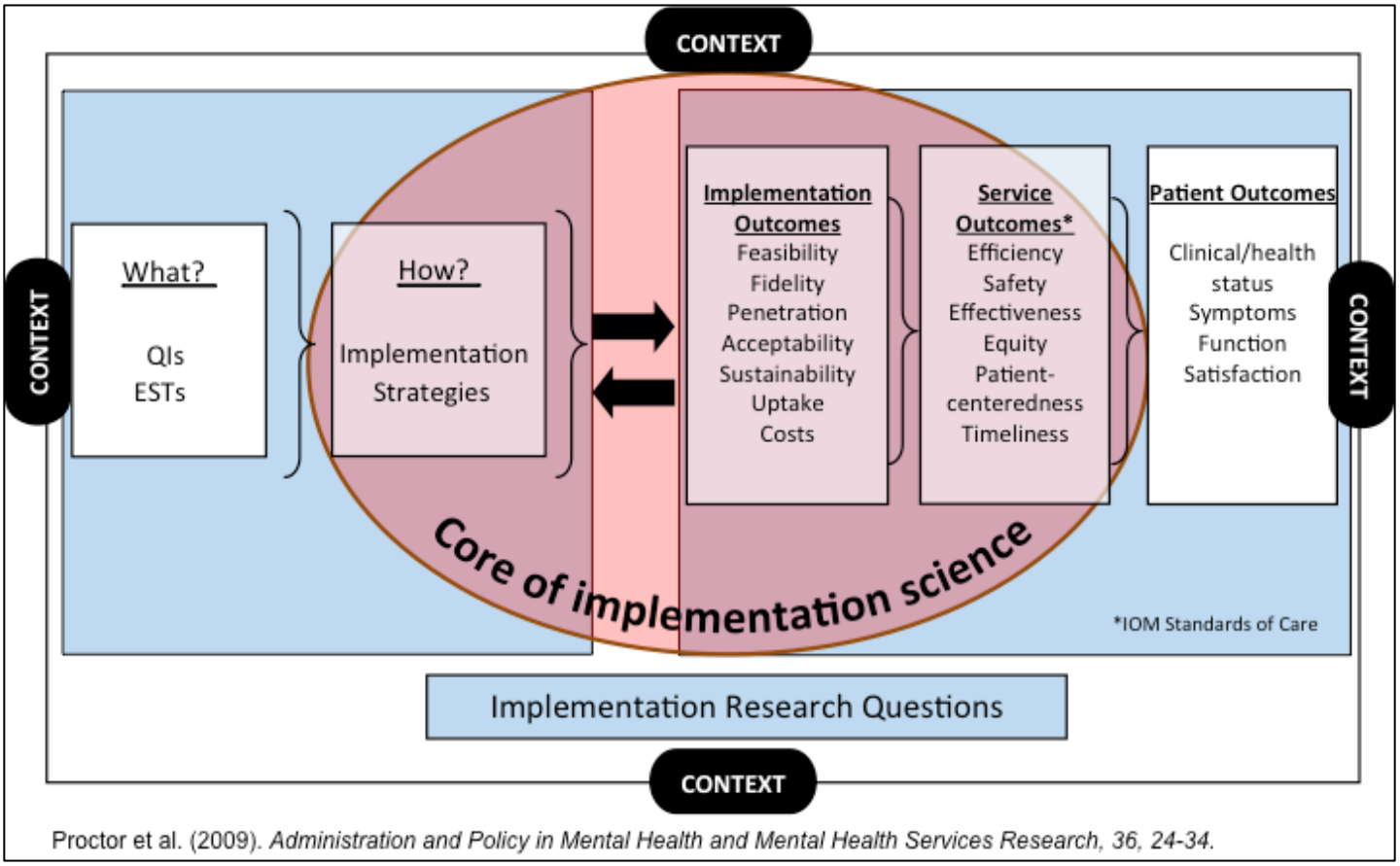
How Are D&I Research Questions Different?

The below figure (Figure 1) closely adapts Proctor (2016)'s conceptual model of implementation research which is useful for understanding how D&I research differs from usual research activities. Usual research questions focus on what innovations or practices have impact on patient or client outcomes, in other words innovation development, efficacy, and effectiveness. Implementation science examines the space in between, focusing on how interventions can be put into place (implementation strategies), how interventions or implementation strategies affect implementation and service outcomes, and how this all is informed by the implementation context.

Figure 1. Conceptual Model of Implementation Research



Source: Proctor, EK. 2016. Implementation science: conceptual and methodological foundations. Presentation, Grand Rounds Series, Department of Psychiatry and Human Behavior, The Warren Alpert Medical School, Brown University.

Table 1 takes three major general objectives of research (explore, describe, test) and provides general D&I questions for each, adapting the work of Peters et al. (2013). In addition, examples of specific aims from NIH-funded grants for each research objective are included to illustrate what is currently done in the field of D&I research.

Table 1. D&I research questions organized by study objective type with examples of specific aims adapted from funded D&I grants (NIH Reporter and UNC D&I Portal).

Objective	Description	D&I Question	Aims Examples
Explore	Explore an idea or phenomenon to make hypotheses or generalizations from specific examples.	What are the possible factors and agents responsible for good implementation of a health intervention? For enhancing or expanding a health intervention?	• Assess the contextual factors of the intervention settings (e.g., policies, organizational characteristics) that may influence utilization of evidence-based treatments and inform necessary modifications to proposed implementation strategies. • Develop a framework for disseminating an evidence-based intervention to a particular type of provider.
Describe	Identify and describe the phenomenon and its correlates or possible causes.	What describes the context in which implementation occurs? What are the main factors influencing implementation in a given context?	• Examine the relationship between organizational factors (e.g., leadership support, motivation practices) and evidence-based practice competencies. • Determine the importance of social interactions in the spread of evidence-based practices in a target population. • Evaluate the social, behavioral and cultural factors that impact the uptake of an evidence-based service. • Evaluate the barriers and facilitators for implementation of an evidence-based intervention in a novel setting.
Test	Test whether a D&I strategy produces the intended outcome.	What effect does the D&I strategy have on the implementation outcomes? How successful is the D&I effort?	
Testing by implementation stage		Adoption	• Determine which dissemination strategy most effectively increases adoption of an evidence-based approach for management of a particular disease. • Evaluate the acceptability of an evidence-based practice in a given setting.
		Early implementation	• Develop and pilot an implementation strategy to increase the uptake of an evidence-based services. • Determine the feasibility of expanding an evidence-based practice online education program to other settings/professions and exploring its effectiveness under the R01 mechanism.
		Ongoing implementation	• Examine the effect of an online education program on the attitudes, skills and use of evidence-based practices in a sample of clinicians. • Compare the effectiveness and cost effectiveness of two implementation strategies for implementing an evidence-based treatment guidelines.
		Sustainability and scale-up	• Project the impact and cost-effectiveness of strategies for scaling up an evidence-based intervention: A. To estimate disease incidence and mortality after scale-up of existing and newly proposed evidence-based intervention. B. To estimate discounted costs and incremental cost-effectiveness of different scale-up strategies. C. To evaluate the relationship of scale-up versus cost, cost-effectiveness and impact.
		Deadoption	• Determine whether a novel strategy is more effective for de-implementation of an intervention in comparison with passive dissemination of evidence.

Adapted from Peters, et al., 2013. Other sources: Landsverk et al., 2012; Proctor et al., 2011; NIH Reporter; UNC D&I Portal.

Somewhere in Between: Hybrid Designs

Hybrid study designs comprise a special case of D&I studies that assess both clinical effectiveness of an intervention and its implementation outcomes (Curran et al., 2012). There are three types of hybrid study designs and they place varying priority on intervention effectiveness and implementation outcomes (Table 2). Hybrid 1 designs place primary study focus on assessing the effectiveness of an intervention, while assessment of implementation outcomes is secondary. In a hybrid 2 design, both types of outcomes have equal focus. Hybrid 3 studies focus on testing how implementation strategy(ies) affect implementation outcomes, while also gathering information on effectiveness as a secondary focus.

Table 2. Varying priority on intervention effectiveness and implementation outcomes by hybrid design type.

Hybrid design type	Intervention effectiveness focus	Implementation outcomes focus
Hybrid 1	Primary	Secondary
Hybrid 2	Equal focus	Equal focus
Hybrid 3	Secondary	Primary

Source: Proctor, EK. 2016. Implementation science: conceptual and methodological foundations. Presentation, Grand Rounds Series, Department of Psychiatry and Human Behavior, The Warren Alpert Medical School, Brown University**.**

For more on utilizing hybrid designs in efficacy research, see the **Designs Toolkit**.

Examples of Hybrid Study Design Aims

The following specific aims of funded hybrid studies have been collected from study protocols published in *Implementation Science* :

- Evaluate the effectiveness of bCBT (intervention) for patient outcomes related to depression, anxiety, and physical health, and also to pilot test the acceptability, feasibility, and preliminary outcomes of a multifaceted implementation strategy to enhance patient engagement and clinician adoption and fidelity.

  Source: Cully, J. A., Armento, M. E., Mott, J., et al. (2012). Brief cognitive behavioral therapy in primary care: a hybrid type 2 patient-randomized effectiveness implementation design. *Implement Sci*, *7*(1), 64.

- Simultaneously evaluate the effectiveness of an evidence-based intervention and an implementation strategy on clinical and implementation outcomes using a factorial design by:
  - Evaluating the effect of the intervention implementation on participant health outcomes.
  - Assessing acceptability of the intervention, and barriers and facilitators to its implementation.
  - Assessing the fidelity of implementation.
  - Determining how the project's implementation strategy affects adoption, fidelity, and effectiveness.

  Adapted from: Hamilton, A. B., Mittman, B. S., Williams, J. K., et al. (2014). Community-based implementation and effectiveness in a randomized trial of a risk reduction intervention for HIV-serodiscordant couples: study protocol. *Implementation Science*, 9(1), 79.

- Primary: Determine if an implementation model can achieve high levels of intervention fidelity and provider competency in the context of a large-scale implementation effort; to characterize the relationship between individual provider characteristics and organizational factors and determine their impact on the implementation of of the intervention using a mixed-methods (quantitative and qualitative) approach.

  Secondary: Determine whether the implementation is associated with a change in health behaviors and disease incidence and to determine whether improvements in health behaviors an disease incidence are associated with variations in intervention fidelity and provider competency.

  Source: Patterson, T. L., Semple, S. J., Chavarin, C. V., Mendoza, D. V., Santos, L. E., Chaffin, M., ... & Aarons, G. A. (2012). Implementation of an efficacious intervention for high risk women in Mexico: protocol for a multi-site randomized trial with a parallel study of organizational factors. Implementation Science, 7(1), 105.

How to Structure Your Specific Aims: Examples

To following may be used to introduce your specific aims.

The **long-term goal** of the proposed research is to understand the [insert statement on how this piece of research fits into your future plans or other research that is currently under way; e.g., mechanism of action behind a phenomenon]. The **objective** is to [insert an overview of what this research will accomplish; e.g., explore two potential pathways in the mechanism]. The **central hypothesis** is that [insert an educated prediction of an answer to your research question, it should be testable]. The **rationale** for the proposed research is [summarize what led up to this research].

The **specific aims** for this research project are: *The following are examples aims from funded D&I studies.*

Example 1

1. Develop a model of disease diagnosis.
    a. Compile and review the key parameters needed for a useful model of diagnosis.
    b. Create a dynamic transmission model of a generalized epidemic, with focus on diagnostic process and incorporating operational realities.
    c. Create an iterative framework whereby descriptions of disease epidemiology and operational processes are translated into model inputs.
2. Project the impact and cost-effectiveness of strategies for scaling up the diagnosis.
    a. Estimate 10-year disease incidence and mortality after scale-up.
    b. Estimate cost and cost-effectiveness of different strategies.
    c. Evaluate the relationship of scale-up speed versus cost, cost-effectiveness, and impact.

Example 2

1. Pilot a preliminary toolkit for [insert toolkit purpose] in three primary care sites for feasibility and acceptability.
   We will use the mixed-methods approach to obtain provider and staff evaluations of the toolkit. An expert facilitator will assist the implementation team in creating a plan and implement the toolkit in the primary care sites. Evaluation will be carried out with [insert method].
2. Evaluate the reach and effectiveness of the toolkit.
   Electronic health records will be used to report study outcomes and assess indicators such as treatment initiation and appointment wait time. Measures will be compared across patients receiving services at baseline and 12 months follow-up.

Example 3

1. Examine the relationship between organizational factors and clinician competence.
   Hypothesis 1a: We hypothesize that an autonomy-supporting environment (e.g., clinicians perceive that leadership cares about them) will be directly related to higher levels of clinician competence as measured by [insert measure].
   Hypothesis 1b: The relationship between autonomy-supporting environment and competence will be moderated by other organizational factors (organizational climate, training resources) where positive perceived climate and increased resources strengthen the relationship between the environment and competence.
2. Examine the relationship between clinician attributes and competence.
   Hypothesis 2: We hypothesize that positive attitudes regarding the clinical procedure and higher self-efficacy will be related to higher competence.

Searching Funded D&I Grants and Aims Pages

1. NIH RePORTER

Website: http://projectreporter.nih.gov

About: RePORTER is an electronic tool that allows users to search a repository of both intramural and extramural NIH-funded research projects from the past 25 years and access publications since 1980.

In addition to NIH-funded research, the system provides access to research supported by Administration for Children and Families (ACF), Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), Food and Drug Administration (FDA), Department of Veterans Affairs (VA).

Pros and cons: NIH RePORTER allows for a comprehensive search that yields a large number of hits. The interface of the website also allows searching for funded projects using many categories, including a string of words. A weakness is that only grant abstracts are uploaded on the NIH RePORTER, which may or may not contain explicit aims (though most abstracts do contain the aims or a broader goal of the research).

Use:

- Go to the RePORTER website at http://projectreporter.nih.gov .
- Under 'Study Section' (see #1 below), uncheck all and select the 'Dissemination and Implementation Research in Health Study Section [DIRH]'.
- Notice that under 'Fiscal Year' (see #2 below) the database automatically selects 'Active Projects.' If you would like to search inactive grants as well, select the fiscal years of interest.
- The 'Text Search' section (see #3 below) is useful in that you can specify a search string to be found, e.g., obesity prevention, or cancer screening.
- Under 'Activity Code' (see #4 below), you can specify the type of grants that will be found (e.g., R01, R03, R21). Uncheck all and select the types of grant that are of interest.
- When you have specified all the options of interest, click on 'Submit' (see #5 below) to search the database.
- More information on using the NIH RePORTER can be found here: http://projectreporter.nih.gov/RePORTER_Manual_files/RePORTERManual.pdf.

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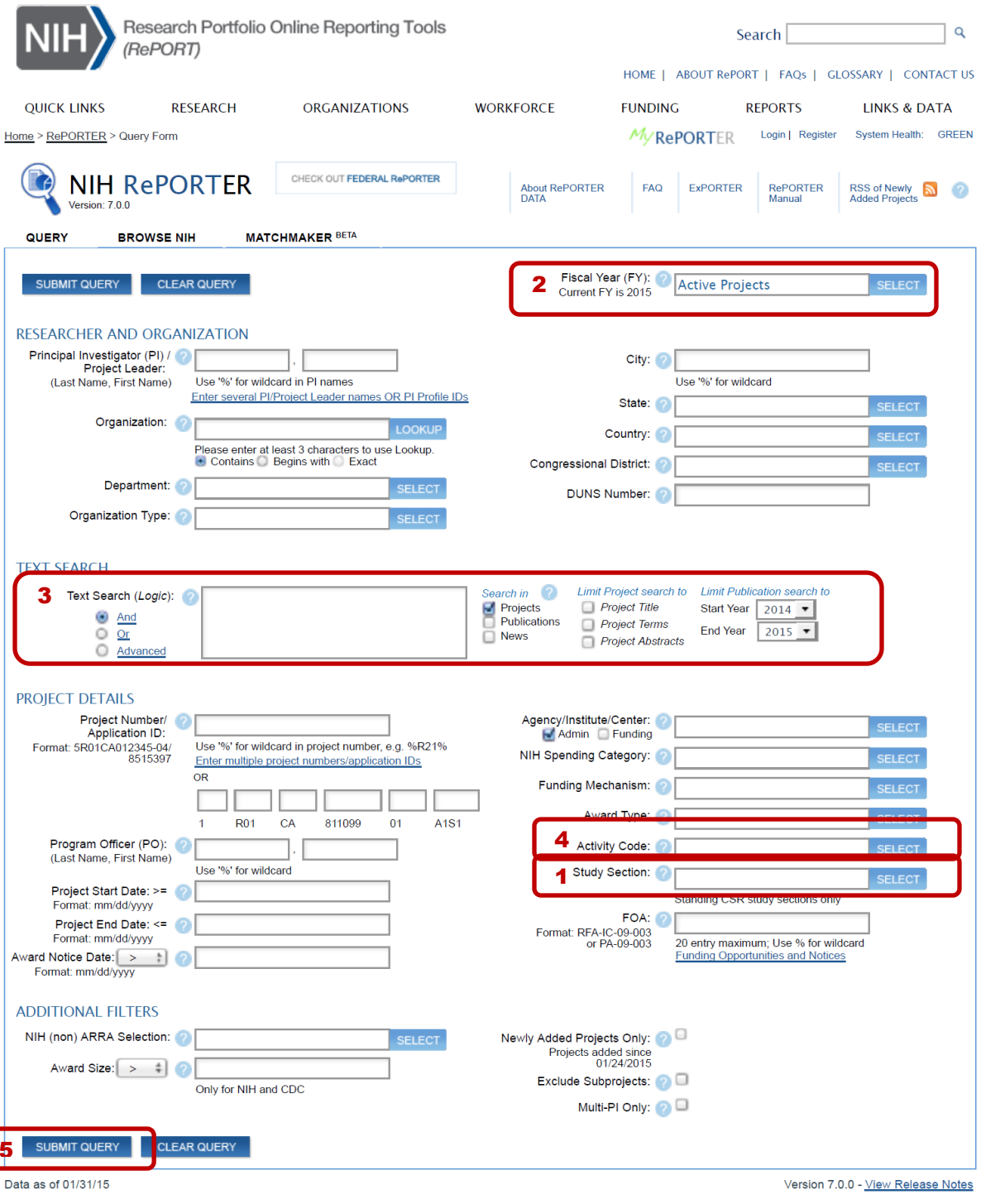

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2. University of North Carolina's Dissemination & Implementation Portal

Website: http://portals.tracs.unc.edu/index.php/d-iportal/grants/sample-grants

About: The UNC D&I Portal contains a repository of grant proposals that were funded through NIH's Dissemination and Implementation Research in Health (DIRH) Study Section and through other funding agencies and mechanisms.

Pros and cons: This repository contains full grant proposal examples that contain specific aims and other details, while other repositories usually only contains a grant abstract/description. But although this repository is organized by study section and year, the grants (except for the titles) are not searchable by anything else.

3. NIH OBSSR Dissemination & Implementation Grant Repository

Website: http://obssr.od.nih.gov/scientific_areas/translation/dissemination_and_implementation/

About: The NIH OBSSR (Office of Behavioral and Social Science Research) website has a section where D&I research resources are uploaded including sample D&I project descriptions (under 'Funded Projects in Dissemination and Implementation Research in Health'). These are organized by the type of award – R01, R03 and R21 – and their PAR numbers.

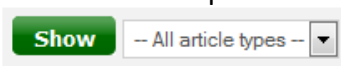
Pros and cons: The organization by award type makes it easy to locate the research type of interest. Also, the descriptions are searchable by words or phrases as they are all laid out on the same webpage (but more complex searches are not possible). However, only grant abstracts (or descriptions) are uploaded, which may or may not contain explicit aims (though most abstracts do contain the aims or a broader goal of the research). This repository only includes a limited number of examples, and in comparison to the NIH RePORTER is much less comprehensive.

4. *Implementation Science* Journal

Website: www.implementationscience.com

About: The *Implementation Science* journal publishes articles describing study protocols, which usually include study research questions, objectives, aims and hypotheses, among other study details and procedures.

Pros and cons: The *Implementation Science* website allows for a comprehensive search of submitted protocol articles using several categories and combinations of strings of words. In addition, since the entire protocols are included, they can serve as great examples of study design, measurement and analysis in funded D&I projects. A small weakness is that there may be selection bias in who chooses to submit protocols to the journal. Also, most of the protocol articles are not peer-reviewed.

Use: To browse protocol articles, go to http://www.implementationscience.com/content and under 

select "Study Protocols."

To search protocol articles, go to http://www.implementationscience.com/search and in the first field select "Article type" and type protocol in the search field. In the following fields specify your search terms, and hit 'Search.

Supporting Literature

The Center for Research in Implementation Science and Prevention (CRISP). Dissemination & Implementation Models in Health Research & Practice. http://www.dissemination-implementation.org/index.aspx. Accessed on March 18, 2015.

Cully JA, Armento ME, Mott J, et al. (2012). Brief cognitive behavioral therapy in primary care: a hybrid type 2 patient-randomized effectiveness implementation design. *Implement Sci*, *7*(1), 64.

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