Back to Search Results

Description

Details

Sub-Projects

Publications

Patents

Outcomes

Clinical Studies

News and More

History

Similar Projects

A Novel Wireless Ingestible Sensor System for Measurement of Medication Adherence in HIV Treatment and Prevention

Project Number	Former Number	Contact PI/Project Leader	Awardee Organization
5R01MH110057-05	1R01AI122307-01	BROWNE, SARA H.Other PIs	UNIVERSITY OF CALIFORNIA, SAN DIEGO

Description

Abstract Text

DESCRIPTION (provided by applicant): Advances in the last decade have transformed HIV-1 infection into a chronic disease through the use of highly active antiretroviral (ARV) therapy. Recent studies suggest the ARVs used as pre-exposure prophylaxis (PrEP) to prevent HIV infection have the potential to transform the HIV **pandemic**. However, the success of ARVs in both the treatment and prevention of HIV is critically dependent on taking medications exactly as prescribed (adherence). To date, no reliable, accurate measurement for ARV adherence exists. This proposal will evaluate the use of a novel sensor platform termed the Digital Health Feedback System (DHFS) for real- time adherence monitoring in HIV-infected persons starting ARVs and in persons at high risk for HIV infection starting PrEP. Aim 1: Develop selected digitized ARVs for use within the DHFS. We will combine an edible sensor with commonly used ARVs within a gelcap to allow the DHFS to detect when a person takes their medication. Outcomes will include successful development of a `digitized' panel of ARVs to use with the DHFS, which are tested against USP guidelines and safe for use in clinical settings. Aim 2: Evaluate the use, acceptability, validity, and utility of the DHFS for longitudinal monitoring of adherence during initial ARV therapy. We will assess if the DHFS is acceptable to persons living with HIV that are initiating ARV treatment for the first time. Outcomes include acceptabilit as measured through validated questionnaires and persistence of use by participants, positive detection accuracy of the DHFS as measured by directly observed ingestions at study visits, and medication adherence as measured by DHFS. Aim 3: Evaluate the acceptability, validity, and utility of the DHFS for longitudinal monitoring of ARVs used in HIV pre-exposure prophylaxis (PrEP). We will assess if the DHFS is acceptable to persons at high risk for HIV infection that are initiating PrEP. Outcomes include acceptability as measured through validated questionnaires and persistence of use by participants, positive detection accuracy of the DHFS as measured by directly observed ingestions at study visits, and medication adherence as measured by DHFS.

Public Health Relevance Statement

PUBLIC HEALTH RELEVANCE: Adherence to antiretroviral therapy is critical to the successful management of HIV and to the efficacy of pre-exposure prophylaxis (PrEP) in the prevention of HIV infection. This project investigates a novel medication adherence monitoring tool, the Digital Health Feedback System (DHFS), in HIV-infected persons initiating antiretroviral therapy and in persons at high risk for HIV infection initiating PrEP. The overarching goals of this proposal include evaluation of the use, validity, and acceptability of the DHFS.

NIH Spending Category

Behavioral and Social Science | Bioengineering | Clinical Research | Clinical Trials and Supportive Activities | HIV/AIDS | Infectious Diseases | Pediatric | Pediatric AIDS | Prevention | Women's Health

Project Terms

AIDS prevention | Adherence | Anti-Retroviral Agents | Behavior | Chronic Disease | Cities | Clinical | Detection | Development | Directly Observed Therapy | Dose | Drug Exposure | Drug Kinetics | Ensure | Evaluation | FDA approved | Feasibility Studies | Feedback | Future | Goals | Gold | Guidelines | HIV | HIV Infections | HIV-1 | Health | Highly Active Antiretroviral Therapy | Individual | Infection | Ingestion | Intervention | Intervention Studies | Measurement | Measures | Medication Systems | Monitor | Oral Ingestion | Outcome | Participant | Patients | Pattern | Performance | Persons | Pharmaceutical Preparations | Physiological | Pilot Projects | Plasma | Prevention | Proteus | Questionnaires

Read More

Details

Contact PI/ Project Leader

Name
BROWNE, SARA H.

Other PIs

Name
BENSON, CONSTANCE ANN

Program Official

Name
STIRRATT, MICHAEL J

Thank you for your feedback!

Back to Search Results

Description

Details

Sub-Projects

Publications

Patents

Outcomes

Clinical Studies

News and More

History

Similar Projects

A Novel Wireless Ingestible Sensor System for Measurement of Medication Adherence in HIV Treatment and Prevention

Project Number
5R01MH110057-05

Former Number
1R01AI122307-01

Contact PI/Project Leader
BROWNE, SARA H.Other PIs

Awardee Organization
UNIVERSITY OF CALIFORNIA, SAN DIEGO

UNIVERSITY OF CALIFORNIA, SAN DIEGO

City
LA JOLLA

Country
UNITED STATES (US)

INTERNAL MEDICINE/MEDICINE

Organization Type
SCHOOLS OF MEDICINE

CA

Congressional District
52

Other Information

FOA
RFA-AI-14-071

Study Section
ZAI1-UKS-A(S1)

Fiscal Year
2019

Award Notice Date
07-August-2019

Administering Institutes or Centers
NATIONAL INSTITUTE OF MENTAL HEALTH

DUNS Number
804355790

CFDA Code
242

Project Start Date
20-September-2015

Project End Date
31-July-2022

Budget Start Date
01-August-2019

Budget End Date
31-July-2022

Project Funding Information for 2019

Total Funding
$688,267

Direct Costs
$444,043

Indirect Costs
$244,224

Year	Funding IC	FY Total Cost by IC
2019	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$688,267

NIH Categorical Spending

Click here for more information on NIH Categorical Spending

Funding IC	FY Total Cost by IC	NIH Spending Category
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$34,413	Pediatric; Pediatric AIDS;
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$96,357	Women's Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$688,267	Behavioral and Social Science; Bioengineering; Clinical Research; Clinical Trials and Supportive Activities; HIV/AIDS; Infectious Diseases; Prevention;

Sub Projects

No Sub Projects information available for 5R01MH110057-05

Publications

No Publications available for 5R01MH110057-05

Patents

No Patents information available for 5R01MH110057-05

Outcomes

The Project Outcomes shown here are displayed verbatim as submitted by the Principal Investigator (PI) for this award. Any opinions, findings, and conclusions or recommendations expressed are those of the PI and do not necessarily reflect the views of the National Institutes of Health. NIH has not endorsed the content below.

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Back to Search Results

Description

Details

Sub-Projects

Publications

Patents

Outcomes

Clinical Studies

News and More

History

Similar Projects

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No Clinical Studies information available for 5R01MH110057-05

News and More

Related News Releases

No news release information available for 5R01MH110057-05

History

No Historical information available for 5R01MH110057-05

Similar Projects

No Similar Projects information available for 5R01MH110057-05