



BMI RAP Subsystem Overview

Thursday, April 18th, 2024

Recently updated Clinical Research SOPs:

- **UCH-OCR-REV-SOP-002**-Submission Process for UC Health Research Approval
- **UCH-OCR-OPS-SOP-018**-Coverage Analysis and Research Encounter Form Submission Process for Human Subjects Research at UC Health

**All OCR SOPs are accessible at the following link.
And from the UC Health intranet home page utilizing the Policy Portal Search function
or reach out to the Office of Clinical Research with any questions or concerns.**

Virtual UC RPAC Researcher Info Session

Come learn about the newly forming UC Research Participant Advisory Council (UC RPAC)! The UC RPAC will serve as a free (through the CCTST) tool for researchers to receive invaluable participant/community feedback about their research – from design to dissemination. At the info session, we'll discuss:

- What is a Research Participant Advisory Council (RPAC)?
- How would it benefit your research?
- How can you get involved?

The info session will be on **April 22, 2024 from 3 - 4pm on Microsoft Teams.**

RSVP: <https://forms.gle/Cb4UoV25XPS5vQ2w8>

Teams link: [Join the meeting now](#)

Meeting ID: 243 794 393 310

Passcode: xy5dxc

Contact Mo Kelly for more information: Kelly3mu@ucmail.uc.edu or (513) 400-4024



CANCELLED

The May 2024 First Friday is Cancelled

First Friday will Resume for June 2024

**UC / UC Health
Clinical Research Orientation and Training
(CRO&T)**

Thursday, June 13th, 2024

9:00 am - 3:00 pm

IN PERSON presentation

MSB Room 6051

The last day of registration is

Friday, June 7th, 2024

Register [Here](#)

**Please reach out to Nate Harris,
harrisnl@ucmail.uc.edu for any questions**

UC/UCH Clinical Research Professional

HAPPY HOUR

OTR Stillhouse

2017 Branch St, Cincinnati, OH 45214

Thursday, June 13th, 2024

5:00pm – 8:00pm

**next
lives
here**

University of
CINCINNATI





Today's Presentation:

BMI RAP Subsystem Overview

Discover how the BMI RAP Subsystem bridges the gap between the UC IRB RAP system and the UC Health Clinical Trials website. With this tool, accessing and managing your study details becomes easier and more user-friendly. You can also easily publish or unpublish your study with just a few clicks.

Jason Keller, MS

Associate Director, Data Services
UC Center for Health Informatics
Department of Biomedical Informatics

BMI RAP Subsystem - Overview -

Jason Keller, MS
Associate Director, Informatics Services

UC Center for Health Informatics

Jason.Keller@uc.edu

April 18, 2024

abin Way, Cincinnati, OH 45219, hereinafter "CHI". Each of ACE
as a "Party" and collectively, as the "Parties".

S, the ACE is a covered entity, as defined in HIPAA, which uses and maintains a
Medical Record ("EMR") and related information systems (e.g. scheduling systems,
y referred to as Health Information Systems ("HIS"), as described in Exhibit A:

WHEREAS, in order to effectively carry out certain of the healthcare operations and
missions of the ACE's participants and of the University of Cincinnati, the ACE desires to
o an agreement with CHI to help the ACE manage the uses and disclosures of data that
es protected health information ("PHI") from the HIS, exclusively for furthering certain of the
s clinical, operations, research and public health purposes as more fully described in this
reement (and any amendments thereto); and

WHEREAS, the ACE and CHI agree that any uses or disclosures of ACE PHI or de-
identified information accessed from UC Health will comply with all applicable privacy and
security requirements of federal and state law including HIPAA.

NOW, THEREFORE, the Parties agree as follows:

SECTION I. GENERAL PROVISIONS AND DUTIES OF THE PARTIES.

Throughout this Agreement, the term "Participants" is used to refer to the members of t
h whom the CHI is joining in this Agreement. "DR" refers to Data Reposi
extract data and create DRs from the HIS data as necessary under this Agre
ent. the Participants authorize the use and disclosure of their da

The CHI is the designated Honest Broker
for the
University of Cincinnati and affiliates





CHI Services

ABOUT OUR SERVICES

- Consultations/Grant Development
- Data from Epic
- Research Recruitment
- Data Collection using REDCap
- Data Exploration/Visualization
- Custom Software Development

 [CHI Terms of Service](#)

 [CHI Data Use Agreement](#)

Need *UC Health patient data* or *custom IT solutions* for your research data?

Whether you're looking to collect it, clean it, query it, visualize it, explore it, analyze it or mine it - CHI's team of IT professionals and data scientists can help.

Use the menu to the left to browse our services, or [request a general consultation](#) if you're not sure what you need.

POPULAR SERVICES



**TriNetX
User
Account
Creation**

TriNetX is an intuitive, elegant, and fast system for querying UC Health's Epic data holdings. TriNetX can define approximate patient cohort availability defined by clinical criteria such as diagnoses, demographics, clinical procedures, lab results, and medications. These queries can be used for feasibility, participant accrual, hypothesis generation, or defining a clinical data extract. TriNetX queries can be mediated by CHI or, with training, conducted directly by investigators. If TriNetX does not have the detailed elements required, we will escalate the request to a search within Epic. (See 'Study Feasibility directly from Epic')



**General
Consult**

Discuss with CHI about your data, technology development, or data analysis needs. We have Epic-certified analysts, application developers and data scientists on staff, along with closely aligned data science faculty. From study design, to designing ways for more effective utilization of biohealth data, to enhancing your grant submissions, our integrated group in Biomedical Informatics can help enhancing your biohealth data science. If you are a student, we can provide certain subsidized services, see Terms of Service.



**Study
Feasibility
using
TriNetX**

TriNetX is an intuitive, elegant, and fast system for querying UC Health's Epic data holdings. TriNetX can define approximate patient cohort availability defined by clinical criteria such as diagnoses, demographics, clinical procedures, lab results, and medications. These queries can be used for feasibility, participant accrual, hypothesis generation, or defining a clinical data extract. TriNetX queries can be mediated by CHI or, with training, conducted directly by investigators. If TriNetX does not have the detailed elements required, we will escalate the request to a search within Epic. (See 'Study Feasibility directly from Epic')



**Clinical
Data
Extractions:
FULLY
Identified
Data Sets**

CHI can provide fully identified data sets from UC Health's Epic Electronic Health System and other clinical systems for research use. Fully identified data sets can include HIPAA identifiers that requires an approved IRB protocol.



Data for

Data-intensive grants increasingly require demonstrated expertise in data science and robust data analysis plans. CHI can increase competitiveness of

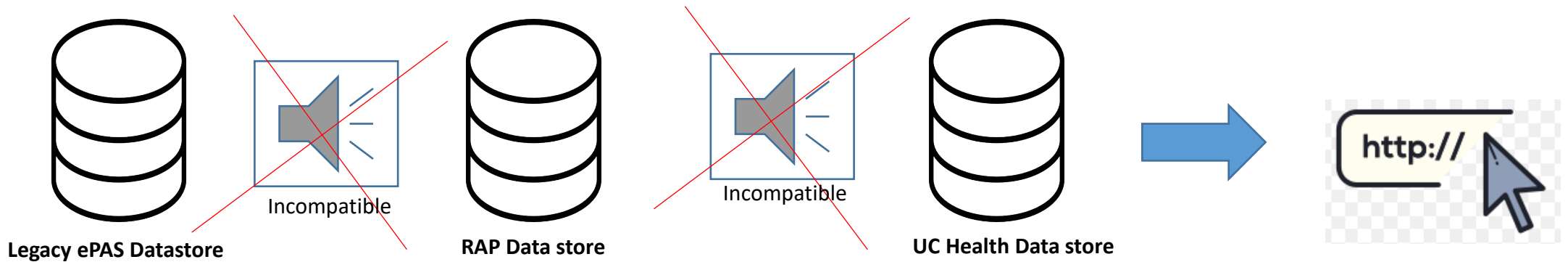


1. DESIGN

DESIGN

Design Problem

- The new IRB RAP system (~2018) does not have the capability to process and display studies on the public website for participant recruitment and informational purposes.
- Very limited fields in RAP data export
- Study teams need access to manage their studies
- Studies need to be categorized to improve findability on the public website.
- Different systems with different login credentials

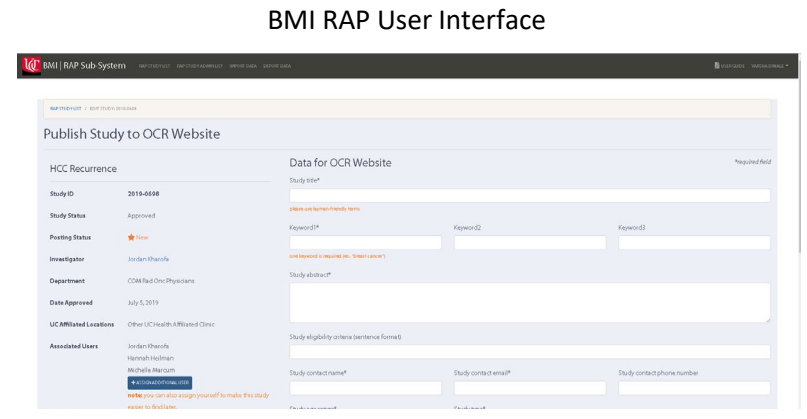
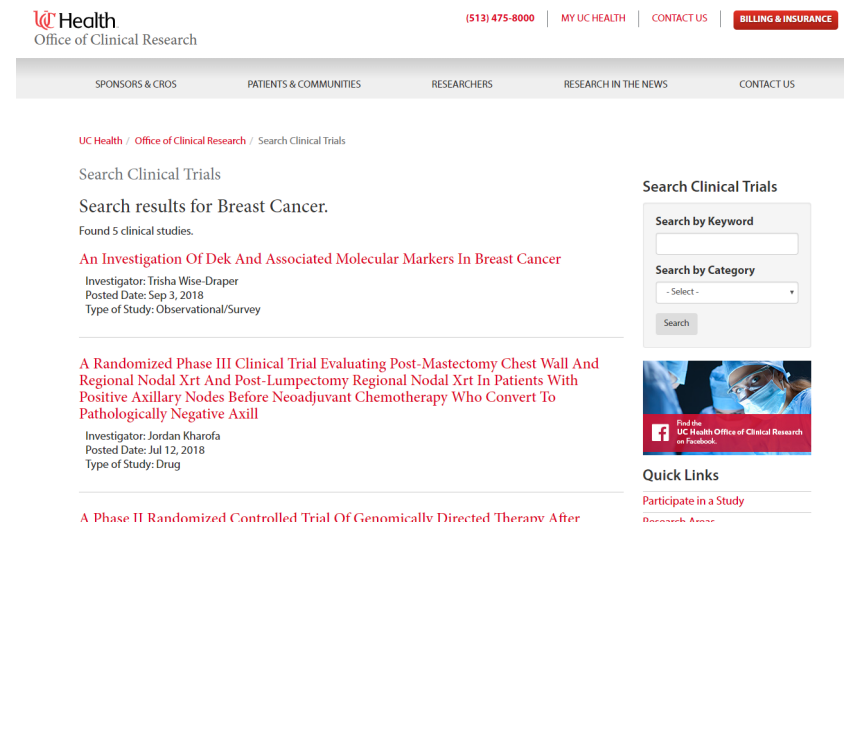
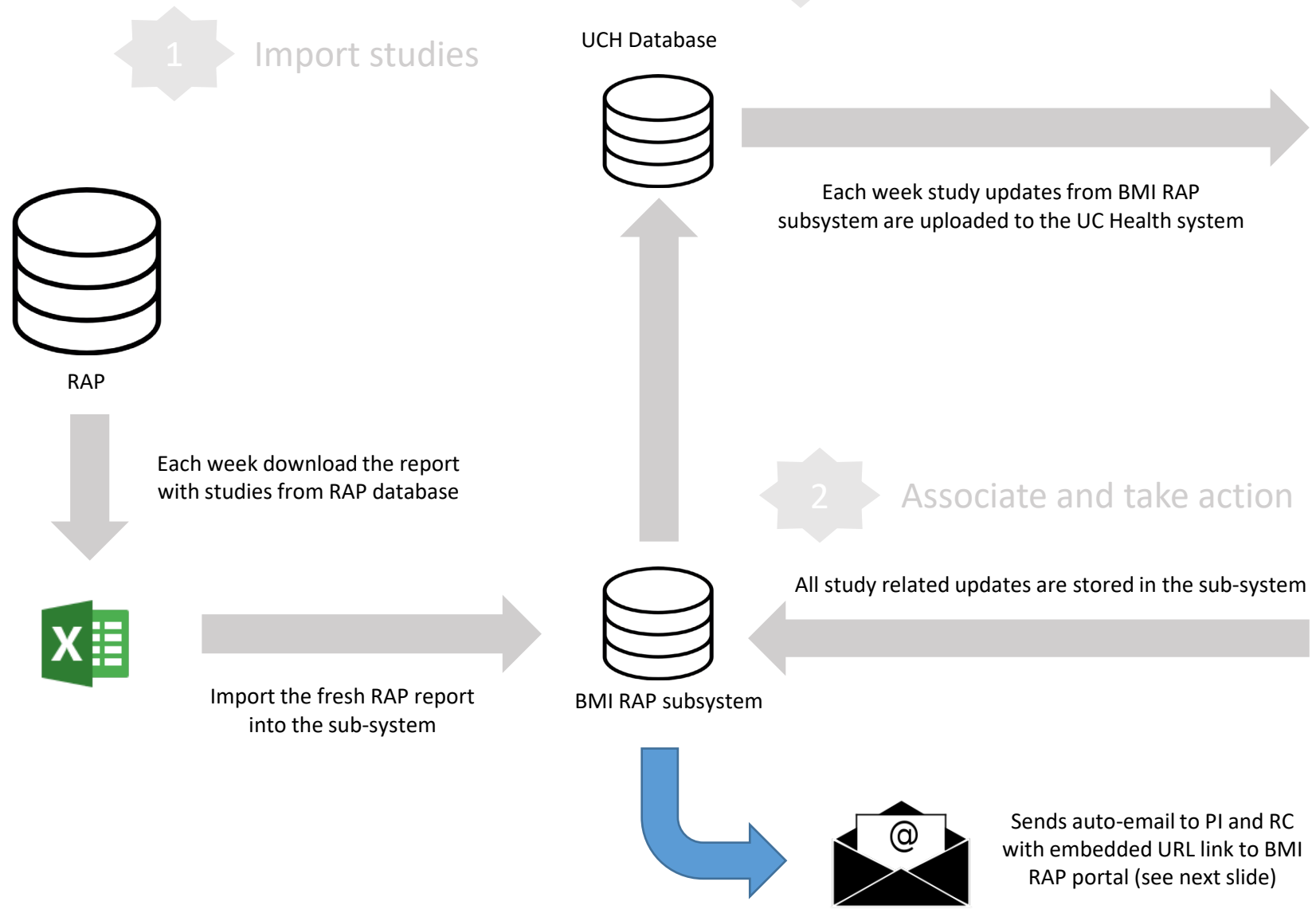


Design Solution

- Create a user-friendly intermediate system that would allow study teams:
 - Access and manage their studies
 - Display and remove studies from the public website
 - Add a user-friendly title and additional necessary information such as (Study Abstract, Type, Age Range, Contact Information, Eligibility Criteria, Keywords, and Categories)
 - Login using UC central login
- Push [selected] data from RAP ~~and ePAS~~ to the subsystem.
- Add additional information to align with the website UI.
- Generate data from subsystem in a compatible format for the UCH Clinical Trials office to update the website.

2. PROCESS

PROCESS



Sends auto-email to PI and RC with embedded URL link to BMI RAP portal (see next slide)

Dear Brett Harnett,

You are receiving this email because you are associated with a study in the Research Administration Portal (RAP) that can be published.

Study ID: 2019-1238

Study Title: BMI Practicum

Your help is needed to publish this study to the UC Health Office of Clinical Research website. Please use the following link to review and publish your study from the BMI-RAP Subsystem:

<https://chi-tools.uc.edu/study/2019-1238/bEGbTqG2tqUvI1qrCvEKWL7cYV9y>

You can access this link and make edits directly. You may forward this link to someone (typically research director/manager/coordinator) who can edit the studies on your behalf. Anyone with access to this link will be able to edit the study information. Alternatively, you can follow the link and select "Assign Additional User".

In case someone/research coordinators would access the study using the above direct link then they need to make sure that they assign the study to self in the BMI-RAP Sub-system using the same "Assign Additional User" button. This would help include the study in their list.

Please feel free to email us if you have any questions or issues related to this system at combmichi@uc.edu

Thank you,
UC Dept of Biomedical Informatics (BMI)
BMI wants to help you reach your accrual goals

ADDITIONAL LINKS

To manage all your studies available in the sub-system please login using your UC Credentials. If you do not have UC credentials please follow the direction on the login screen to request for a CHI account:

<https://chi-tools.uc.edu/>

View the UC Health Office of Clinical Research website:

<https://uchealth.com/research/>

Be sure PI and/or point research coordinator have correct e-mail address for their account in the UC RAP sub-system. If they don't, when we transfer the study data from UC RAP, the study gets associated with a "dummy" user and the PI will never get the e-mail that their study is ready for reviewing/editing/publishing.

3. USER INTERFACE (UI)



RAP STUDY LIST / EDIT STUDY: 2019-0698

Publish Study to OCR Website

HCC Recurrence

Study ID	2019-0698
Study Status	Approved
Posting Status	★ New
Investigator	Jordan Kharofa
Department	COM Rad Onc Physicians
Date Approved	July 5, 2019
UC Affiliated Locations	Other UCHealth Affiliated Clinic
Associated Users	Jordan Kharofa Hannah Heilman Michelle Marcum + ASSIGN ADDITIONAL USER note: you can also assign yourself to make this study easier to find later.

Data for OCR Website *required field

Study title*

please use layman-friendly terms

Keyword1* Keyword2 Keyword3

one keyword is required (ex. "breast cancer")

Study abstract*

Study eligibility criteria (sentence format)

Study contact name* Study contact email* Study contact phone number

Study sponsor* Study type*

study easier to find later.

Studies are published on the Office of Clinical Research website.

[UC Health Office of Clinical Research Website](#)

Categories on OCR website

- Select -

- Select -

View All Studies
View All Studies

Keywords
 Adolescent Psychiatry/Psychology (3)
 AIDS-HIV (2)
 Bipolar Disorder (2)
 Breast Cancer (11)
 Cancer (70)
 Cardiology (1)
 Cardiovascular Disease (3)
 Colorectal Cancer (2)
 Depression (4)
 Diabetes (1)
 Emergency Medicine (2)
 Endocrinology (1)
 Environmental Health (1)
 Epilepsy (2)
 Esophageal Diseases (1)
 Gastroenterology (2)
 Gynecologic Oncology (3)

Study age range*

Study type*

Observational/Survey

Categories*

- ADD/ADHD
- Anal Cancer
- Brain Tumor Center
- Cardiology
- Colorectal Cancer
- Emergency Medicine
- Epilepsy
- Gastroenterology
- Gynecology
- Hematology/Oncology
- Liver Cancer
- Lymphoma
- Mental Disorders
- Multiple Sclerosis
- Neurology
- Neurosurgery
- Orthopedics
- Pain Medicine
- Parkinson's Disease
- Psychiatry/Psychology
- Rectal Cancer
- Sickle Cell Disease
- Stroke
- Thyroid Cancer
- Uterine Cancer
- Adolescent Psychiatry/Psychology
- Bipolar Disorder
- Breast Cancer
- Cardiovascular Disease
- Depression
- Endocrinology
- Esophageal Diseases
- Gastrointestinal Cancer
- Head and Neck Cancer
- Kidney Disease
- Liver Disease
- Melanoma Cancer
- Movement Disorders
- Nephrology
- Neuromuscular Disorders
- Oncology
- Otolaryngology
- Pancreatic Cancer
- Phase I Cancer
- Pulmonary Diseases
- Renal Cell Carcinoma/Kidney Cancer
- Skin Cancer
- Surgical Oncology
- Transplant Nephrology
- Vascular
- AIDS-HIV
- Brain Tumor
- Cancer
- Cervical Cancer
- Diabetes
- Environmental Health
- Fibromyalgia
- Gynecologic Oncology
- Heart Disease
- Leukemia
- Lung Cancer
- Memory Disorders
- Multiple Myeloma
- Neuroendocrine
- Neuroradiology
- Ophthalmology
- Ovarian Cancer
- Pancreatic Disease
- Prostate Cancer
- Radiation Oncology
- Rheumatology
- Speech Pathology
- Thoracic Surgery
- University of Cincinnati Cancer Institute

✓ SAVE AND PUBLISH TO OCR WEBSITE

✗ CANCEL AND DON'T PUBLISH TO OCR WEBSITE

Use the red button on the study edit screen of a published (sent to website) study to remove (unpublished) it from the website.

RAP STUDY LIST / EDIT STUDY: 2019-0601

Publish Study to OCR Website

Site for Arnold AxSome MDD study AXS-05-MDD-301

Study ID	2019-0601
Study Status	Active
Posting Status	✔ Published ✘ UNPUBLISH
Investigator	Lesley Arnold
Department	COM Psychiatry Providers C
Date Approved	May 31, 2019
UC Affiliated Locations	Other UC Health Affiliated Clinic
Associated Users	Lesley Arnold + ASSIGN ADDITIONAL USER note: you can also assign yourself to make this study easier to find later.

Data for OCR Website *required field

Study title*

The purpose of this study is to evaluate the safety and efficacy of a study medication in adults with depression.

please use layman-friendly terms

Keyword1*

depression

Keyword2

Keyword3

one keyword is required (ex. "breast cancer")

Study abstract*

The purpose of this study is to evaluate the safety and efficacy of a study medication in adults with depression.

Study eligibility criteria (sentence format)

Adults 18-65 who have depression

Study contact name*

Kerri Earles

Study contact email*

kerri.earles@uc.edu

Study contact phone number

513-558-7104



Link to detailed user guide

RAP STUDY LIST / EDIT STUDY: 2019-0698

Publish Study to OCR Website

Or, if not selected to publish:

Your study has been marked as unpublished from the OCR website. It may take several days for the changes to take effect.

Studies published on OCR website facilitate Participant Recruitment and are for Informational Purpose. Posting of studies on website is optional.



UCHealth / Office of Clinical Research / Researchers

Researchers



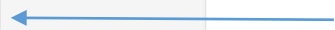
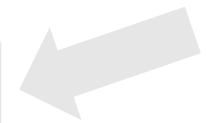
- UCLogin
- Research Areas
- Research Services
- Education & Training
- Resources

Search Clinical Studies

Search by Keyword

Search by Category
 - Select -

Search



Studies published on OCR website facilitate Participant Recruitment and are for Informational Purpose. Posting of studies on website is optional.

UC Health / Office of Clinical Research / Search Clinical Trials

Search Clinical Trials

Search results for All Clinical Studies.

Found 225 clinical studies.

Prevention Of Hemolytic Anemia Of The Fetus Using A Novel Intravenous Infusion

Investigator: Kara Markham
Posted Date: Jul 5, 2019
Type of Study: Drug

Prevalence Of Psychiatric Illnesses In Patients Undergoing Oral And Maxillofacial Surgery Procedures In An Outpatient Setting.

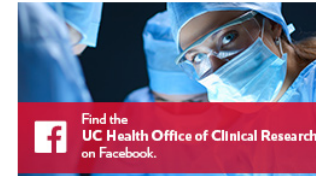
Investigator: Payal Verma
Posted Date: Jul 2, 2019
Type of Study: Observational/Survey

3000-01-004

Search Clinical Studies

Search by Keyword

Search by Category



Quick Links

Studies published on OCR website facilitate Participant Recruitment and are for Informational Purpose. Posting of studies on website is optional.

UCHealth / Office of Clinical Research / Clinical Study

Clinical Study

Prevalence Of Psychiatric Illnesses In Patients Undergoing Oral And Maxillofacial Surgery Procedures In An Outpatient Setting.

Posted Date: Jul 2, 2019

Investigator: Payal Verma

Specialties: Depression, Psychiatry/Psychology

Type of Study: Observational/Survey

Mental illness is highly prevalent among adults in the United States, with almost 1 in 5 adults living with some degree of mental illness [1]. It has been reported that as high as 18-26% of the US population has a mental disorder at any point during a 12-mo period [2,3]. Psychiatric diseases can place a significant burden on patient's diagnosis, treatment and prognosis when compared with patients without a psychiatric condition. Furthermore, pre-existing psychiatric comorbidities have been found to have deleterious effects on morbidity and mortality in post-surgical patients across multiple disciplines [4,5,6,7,8]. There has been no major investigations in the past looking at demographics and presence of preexisting psychiatric disorders in patient cohort with oro-facial injuries or pathologies except 2 that came across during our literature review [9,10]. In addition, no one has ever studied oral and maxillofacial surgical patient population in an outpatient setting. Given most of OMS procedures are anxiety generating for patients, we sought to determine the burden of psychiatric illness in this outpatient population at University of Cincinnati. We hypothesized psychiatric diagnoses would be common in this population. This data can further be used in the future to study how these illnesses impact treatment and prognosis of such patients and can help in better clinical management.

Criteria:

1) Any Patient Age >=15 Of Any Gender Or Race And Ethnicity That Underwent An Outpatient Oms Procedure At The Two Oms Clinic Locations (Hh And Mab) Of Uc.

Keywords:

Psychiatric Illnesses, Oral And Maxillofacial Surgery

For More Information:

Payal Verma
3154805295
payal.verma@me.com

Search Clinical Studies

Search by Keyword

 Search by Category
 - Select -

Help find and index studies in search results.

- Select -
 - Select -
View All Studies
 View All Studies
Keywords
 Adolescent Psychiatry/Psychology (3)
 AIDS-HIV (2)
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 Emergency Medicine (2)
 Endocrinology (1)
 Environmental Health (1)
 Epilepsy (2)
 Esophageal Diseases (1)
 Gastroenterology (2)
 Gynecologic Oncology (3)



Quick Links

- [Participate in a Study](#)
- [Research Areas](#)
- [Education & Training](#)
- [Staff Directory](#)
- [Contact Us](#)