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Harnessing Electronic Data Capture (EDC) Systems for Secure and Efficient Human Subjects Data Collection

Date: March 3rd, 2025

Time: 12:00-1:00 PM

Presenter: Dr. Shih-Fan Lin, DrPH

SDSU HealthLINK Center for Transdisciplinary Health Disparities Research
Funder: National Institute on Minority Health and Health Disparities (U54MD012397 & S21MD010690); MPIs: Guadalupe X. Ayala, PhD, MPH, MA and Kristen J. Wells, PhD, MPH

SDSU HealthLINK Center: Research Capacity Core Methods Groups

- Bio-Behavioral and Human Performance Methods Group (BBHP)
- Biomedical Methods Group (BMG)
- Health Data Analytic Methods Group (HDAG)
- Health Sensor Methods Group (HSMG)
- Information Technology Methods Group (IT)
- Intervention Methods Group (IMG)
- Measurement Methods Group (MMG)

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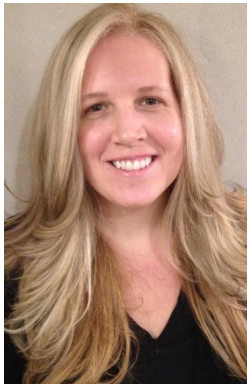
Research Capacity Core: Measurement Methods Group (MMG)

Shih-Fan Lin, DrPH

Co-Leader
Public Health



Kristen Wells, PhD, MPH

Co-Leader
Psychology

Yaritza Benitez, BA

MMG
Coordinator

Karl Williams, MPH

MMG
Research
Assistant

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Measurement Methods Group Services

- Support for survey measurements
  - Selecting scale(s)
  - Adapting scale(s)
  - Scale(s) panel translation (Spanish only)
- Support for conducting focus groups
- Support for conducting cognitive interviews
- Support for **Electronic Data Capture System**

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What is an Electronic Data Capture (EDC) System?

- A system that is used to collect and store data in an electronic form as opposed to paper form

- Typically used in Human Subjects Research, including clinical trials
  - Track recruitment
  - Calendar/Scheduling
  - Screen participants
  - Track enrollment and assessments
  - Collect participant consent
  - Collect data using a survey
  - Randomize participants
  - Concealment of treatment allocation (i.e., blinding)
  - Data import/export
  - Generate custom reports

Why Use an Electronic Data Capture System?

- Secure and compliant data collection (HIPAA, 21 CFR Part 11, GDPR)
- Increased data accuracy and efficiency
- Real-time monitoring and remote access
- Supports various research methodologies (surveys, Ecological Momentary Assessment [EMA], physiological monitoring)

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Electronic Data Systems Available at SDSU HealthLINK Center

qualtrics XM

REDCap
Research Electronic Data Capture

REDCAP CLOUD

REALTIME
CLINICAL TRIAL MANAGEMENT SYSTEMS

ilumivu

Labfront

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Qualtrics & Its Key Features

- What is Qualtrics?
  - A cloud-based survey and data collection platform used for distributing surveys, collecting responses, and analyzing data
- Features
  - Advanced survey design
  - Customizable workflows
  - Multi-channel distribution

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HealthLINK Cost Recovery Services Provided for Researchers Using Qualtrics

- Survey design and setup
- Multi-Language support
- Technical assistance
  - Guidance on survey setup, workflow, and best practices

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Academic REDCap & Its Key Features

- What is Academic REDCap (also known as REDCap)?
  - Secure web application for building and managing online surveys/forms and databases, widely used for research data collection and clinical studies.

- Features
  - Built for regulatory environments
  - Customizable forms and surveys with real-time data validation
  - Supports longitudinal studies and complex branching logic
  - Built-in audit trails for compliance
  - Secure user access controls and data encryption
  - Automated data export for statistical analysis (SPSS, R, SAS, etc.)
  - Run reports
  - Scalable for various research needs

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HealthLINK Cost Recovery Services Provided for Researchers Using Academic REDCap

- Set up the entire project in Academic REDcap
  - Fully configurated Academic REDCap project
- A-la-carte services
  - Recruitment tracking
  - Custom survey/interview forms (including calculated/piped fields and branching logics)
  - Blinding & randomization
  - Electronic consent (E-Consent)
  - Multi-language setup
  - Custom reports
  - Technical assistance (non-IT related)
    - Guidance on project setup, workflow, and best practice

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REDCap Cloud and Its Key Features

- What is REDCap Cloud?
  - Cloud-based version of Academic REDCap
  - Interface between REDCap and REDCap Cloud look very different
  - All data are hosted in the cloud vs. local server (Academic REDCap)
  - Ideal for institutions that lack sufficient server infrastructure or labor resources to host REDCap on local servers
  - License fee required
- Key features
  - Same as REDCap
  - Better for clinical trial reporting compared to Academic REDCap
- Some disadvantages compared to REDCap
  - Not able to track participants prior to screening
  - Can only export data in CSV format
  - Limited survey/form design functions (e.g., piping, default values…etc.)

HealthLINK Cost Recovery Services Provided for Researchers Using REDCap Cloud

- Set up the entire project in REDcap Cloud
  - Fully configured REDCap Cloud project
- A-la-carte services
  - Custom survey/interview forms (including calculated/piped fields and branching logics)
  - Blinding & randomization
  - Electronic consent (E-Consent)
  - Multi-language setup
  - Technical assistance (non-IT related)
    - Guidance on project setup, workflow, and best practices

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RealTime CTMS and Its Key Features

REALTIME
CLINICAL TRIAL MANAGEMENT SYSTEMS

- What is RealTime Clinical Trial Management (CTMS)?
  - Cloud-based platform designed to streamline and optimize the management of clinical trials.
  - All data are hosted in the secure cloud and compliance assured (Part-11 and HIPAA)
  - License fee required
  - Auditor access ready
- Key features
  - Calendar: on-site participant visit scheduling and tracking
  - Financial tracking: provider payments and participant stipend
  - Store eRegulatory documents and eConsent
  - Access recruitment/enrollment/visit reports
  - Integration with MailChimp, Facebook, and recruitment landing pages
  - Mobile Communication
- Some disadvantages
  - Cannot store large files (e.g. MRI scans)
  - Limited survey/form functions

HealthLINK Cost Recovery Services Provided for Researchers Using RealTime CTMS

- Set up the entire project in RealTime CTMS
  - Fully configured RealTime CTMS project
- A-la-carte services
  - Custom survey/interview forms
  - Participant visit/lab reports (eDocument)
  - Electronic consent (eConsent)
  - Mobile communication via text/email
  - Technical assistance (non-IT related)
    - Guidance on project setup, workflow, and best practices

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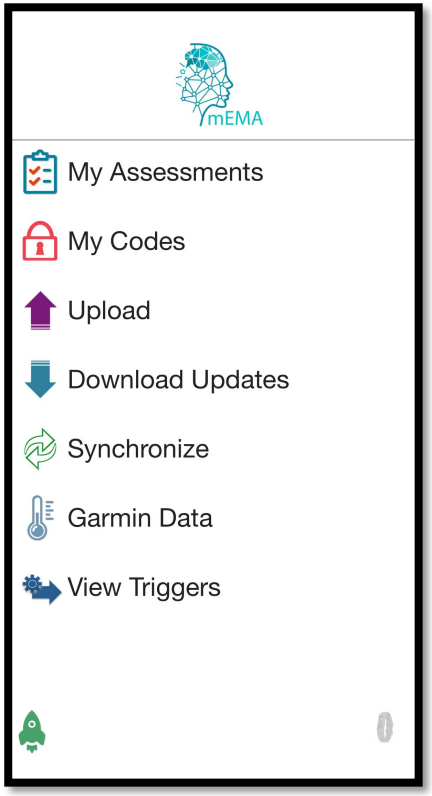
Ecological Momentary Assessment (EMA)

- A data collection method that captures real-time behaviors, experiences, and environmental factors in participants' natural settings
  - Repeated assessment over time to reduce recall bias
  - Mobile-based survey and notifications delivered at random or scheduled (e.g., 9am)
  - interval
  - Integration with physiological and sensor data (e.g., GPS, accelerometer)
  - Provides insights into how factors in the environment influence behavior, emotions, and health outcomes
- Example applications in research
  - Used to assess mood fluctuations, stress responses, health behaviors that are difficult to measure in other ways, and other symptoms or side effects

ilumivu mEMA and Its Key Features



- What is ilumivu mEMA?
  - mEMA web platform (survey & schedule setup) and mEMA mobile app (participants use to provide responses) to collect real time data
- Key features
  - Real-time survey notifications
  - Advanced survey configuration
  - Flexible scheduling (on demand, one-time scheduled, repeating, momentary)
  - Integration with sensor data (e.g., GPS, accelerometer, Garmin watch.)
  - Mobile app is compatible with iOS and Android devices

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HealthLINK Cost Recovery Services Provided for Researchers Using ilumivu mEMA

- Set up fully configured project in mEMA web platform including survey and schedule
- Training
  - Set up survey and schedule in mEMA web platform
  - Set up participants' mobile device to receive surveys
- Technical assistant (non-IT related)
  - Guidance on survey/schedule setup, workflow, and best practices

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Labfront and Its Key Features

Labfront

- What is Labfront?
  - Web-based platform designed to gather, manage, and analyze physiological and behavioral data from wearable devices
  - Labfront app can sync and upload data from wearable device to Labfront platform
- Key features
  - Compatible with Garmin, Movesense, Dexcom devices
  - Labfront app can collect high resolution data such as heart rate variability (HRV) and sleep actigraphy
  - EMA survey available with limited functionalities
  - Adherence dashboard for task completion and device wear time
  - Visualization tools

HealthLINK Cost Recovery Services Provided for Researchers Using Labfront (Not yet available)

- Set up survey, schedule, and tasks in Labfront
  - Fully configurated project in Labfront web platform
- Training
  - Set up sensor data collection in Labfront web platform
  - Set up participants' mobile device to receive sensor data
- Technical assistant (non-IT related)
  - Guidance on sensor data collection setup, workflow, and best practices

Pricing Structure for SDSU HealthLINK Center's Cost-Recovery Services

- A Scope of Work (SOW) will be drafted after the initial intake meeting with our recharge client
  - Include tasks requested with number of hours estimated to complete the task
- EDC services will be charged by hours
  - Staff level vs. PhD level
- Additional costs applied for using the ilumivu mEMA/Labfront system to recover licensing fees

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We look forward to serving your research needs!

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https://healthlink.sdsu.edu/resources-and-services/

Submit inquiry to HealthLINK.services@sdsu.edu

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