# **Study Coordinator Services**

Study Coordinator services are a resource that is available for members of the Center for Children's Healthy Lifestyles & Nutrition. Our study coordinators provide a variety of services ranging from eIRB submissions, participant recruitment, study management, training of study staff, and other services.

# **Benefits**

Our coordinators are available to provide support for long-term projects or for short term needs. In most cases, coordinators can be available immediately. Our experienced coordinators are well-trained and have a background in a variety of disciplines. Visit our coordinator's bio page to learn more.

# Services

Study Coordinators can provide services in the following areas and can be requested here: <a href="https://cmhredcap.cmh.edu/surveys/?s=4TF4CKK8ND">https://cmhredcap.cmh.edu/surveys/?s=4TF4CKK8ND</a>.

## IRB & Regulatory

- eIRB submissions, response to IRB concerns
- Writing of protocol, consent forms, and recruitment materials, and study documents
- Generate recruitment materials
- Assemble regulatory documents and help maintain Regulatory Binder
- Add students and staff to study protocols

#### Study Coordination

- · Subject recruitment and prescreening
- Obtain informed consent
- Data collection
- Manage study payments

## Technology Support

- Build REDCap project for e-consent and online participant surveys
- Create study websites (See example: iKanEat Study)

#### Data Processing and Analysis

- Database management and data analytics
  - Statistical software SPSS, SAS, and R
  - Actigraph accelerometer data processing
  - Data visualization software Tableau
  - ArcGIS mapping software

### Training with Study Teams

- Consent and e-consent training
- Mentoring, supervising, and training students on study procedures

# **Funding**

#### **No-Cost Services**

Some study coordinator services are offered at no cost to Center members, as coordinator time allows. These services may include:

- IRB submissions and regulatory management (including regulatory binder guidance) for studies funded by federal grants (NIH and CDC).
- All other services should be requested at no-cost via the redcap form (above). These requests
  are reviewed and approved by the Center Director on a monthly basis. Approval for no-cost
  services will depend on study coordinator uncommitted availability and priority, which is as
  follows:
  - 1. Research supported by extramural funding which have full indirect cost recovery
  - 2. Research supported by extramural funding from Federal or State sources or from foundations which have partial indirect cost recovery
  - 3. Research supported completely by intramural funds available from affiliated institutions
  - 4. Research supported by extramural funding from for-profit entities (e.g., pharmaceutical or nutritional companies)
  - 5. Investigator-initiated studies with no form of intramural or external support
  - 6. Clinics

#### **At-Cost Services**

Ensuring protected study coordinator time for your study is offered at-cost. There are 2 options for funding study coordinator support:

- Including paid FTE for coordinators in funded grant budgets is the most frequently used model.
  For any investigators who include paid FTE for a study coordinator in their funded grant budget,
  they will receive a multiplier of coordinator time of 1.5. For example, an investigator who
  includes 20% FTE in their paid grant budget (or any source of paid funding), will receive 30%
  (20% x 1.5 = 30%).
- Hourly: This is the less frequently used option. The hourly rate option is primarily for very shortterm needs (e.g. covering for Study Coordinators out on leave). Investigators will only pay for the hours worked at \$60 per hour.

--- separate page containing study coordinator's bios --

#### Our Team

#### Kelsey Dean

Clinical Trials Coordinator II

Kelsey is a registered dietitian and a clinical trials coordinator with over 10 years of experience. Kelsey has coordinated multiple research studies with various investigators that range from clinical drug trials to local nutrition and exercise interventions. Kelsey is currently working as the lead study coordinator for a nationwide multi-site drug trial and has experience with onboarding new research sites and training study teams. She has a joint appointment at Children's Mercy and The University of Kansas Medical Center and works with study teams and the IRB's at both locations. Kelsey has extensive experience in working with accelerometers, building projects in REDCap, creating study websites, and running analysis in SPSS software. Kelsey's skills include writing of protocols and consent forms, study start-up procedures, training of study staff, overseeing daily aspects of research studies, database management, and analysis and dissemination of study results. As a dietitian, Kelsey has experience in outpatient nutrition counseling for weight management, enteral nutrition, and gastrointestinal disorders, as well as delivering group-based behavioral curriculum and one-on-one health coaching as part of several research interventions.

Unique skills, at a glance:
Registered dietitian
SMART IRB navigation
Multi-site project management
Statistical Software SPSS
Accelerometer data processing
Website design

# Amy Papa Clinical Trials Coordinator II

Amy has over 7 years of professional clinical trials coordination experience. Her higher education background is in mathematics, psychology, and art. She holds a master's degree in Counseling Psychology (Qualification Level B for most standardized tests, and Qualification Level C with extra certification). Before her time at CMH, she worked as a blinded Independent Evaluator and Neuropsychological Rater for clinical studies examining depression and schizophrenia at the Department of Veterans Affairs Hospital. In her current position, Amy is an expert in many aspects of starting, running, and completing a study from pre-award to study closure. Her skills include drafting scientific protocols from grant applications, writing permission/assent/consent forms, creating novel surveys and recruitment materials, training study staff, and gathering the necessary paperwork to complete IRB and

OPS applications. She is also at home in the lab running specimen samples or completing testing procedures with participants. Amy has helped mentor, supervise, and train many students at the Center on topics such as permission/assent/consent, data entry, and compliance. Amy excels at database management and data analytics. She works with the statistical softwares SPSS and SAS regularly, and has experience with R. She championed the use of the data visualization software Tableau at the Center. She is also the only coordinator trained in the use of ArcGIS mapping software. In her free time, she enjoys creating Raspberry Pi projects, which involve light Python coding in a Linux OS environment (typically Raspbian, a Debian distro), woodworking, tinkering with ham radios, Retro Gaming, and playing with her cats.

Unique skills, at a glance:

Background in Counseling Psychology, Qualification Level B for most standardized tests Laboratory trained and certified Statistical software SPSS, SAS, and R Data visualization software Tableau ArcGIS mapping software