Introduction to the Clinical Research Centers and Clinical Research Unit
Agenda

- Overview
- Administrative Issues
- Role of the Research Subject Advocate
- Nursing
- Policies and Procedures
- Bionutrition
- Specimen Processing
- Gateway Services
  - Statistics, Information Technologies
- Question & Answer
The Aims of the Clinical Translational Science Award (CTSA)

To ensure new discoveries lead to improved public health by:

- Rapidly testing and implementing biomedical discoveries.
- Developing, testing and implementing new prevention strategies.
- Catalyzing change by lowering barriers between disciplines.
- Encouraging creative and innovative approaches.
Interaction Among Organizational Structures

Clinical Research Ethics

Biomedical Informatics

Clinical Resources

Biostatistics

Regulatory Support

Advanced Degree-Granting Programs

Participant & Community Involvement

Trial Design

CTSA HOME

NIH & other government agencies

Industry

Healthcare organizations
Institutes for Translational Sciences

<table>
<thead>
<tr>
<th>Institutional Title</th>
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</thead>
<tbody>
<tr>
<td>Center for Biomedical Informatics (CBI)</td>
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<tr>
<td>Centers for Community &amp; Academic Research Partnerships (CCARP)</td>
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<tr>
<td>Center for Clinical &amp; Translational Research (CCTR) - Clinical Research Centers (CRC)</td>
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<td>Office of Clinical Research (OCR)</td>
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<td>Disease Prevention &amp; Public Health Institute (DPPHI)</td>
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<td>Institute for Personalized Medicine (IPM)</td>
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<td>Experimental Therapeutics Institute (ETI)</td>
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<td>Pilot &amp; Collaborative Translational &amp; Clinical Studies (PCTCS)</td>
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<tr>
<td>Shared Research Facilities (SRF)</td>
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<tr>
<td>Translational &amp; Molecular Imaging Institute (TMII)</td>
</tr>
<tr>
<td>Center for Patient Oriented Research, Training, Education &amp; Development (CePORTED)</td>
</tr>
</tbody>
</table>

**Clinical Research Centers**
- Clinical Research Unit (CRU)
- Research assistance “without borders”

**Personnel and space for undertaking clinical research**
- CRU application undergoes scientific and resource review

http://www.mssm.edu/research/resources/general-clinical-research-center
Clinical Research Unit Overview

Services
- nursing, dietary, specimen processing

Ancillary
- Applications for pilot studies may include requests for limited funds for participants and ancillary tests (awarded case-by-case)

Hours
- 7 AM- 7 PM weekdays
- Additional hours with outside funding by arrangement
Annual Renewal

- Updated IRB approved consent forms and IRB approval letter
- Application for Human Research (HRP-211)
- Continuing Review Progress Report (HRP-212)
- Modification of Approved Human Research (HRP-213)

Once the IRB approval on file at the CRU has expired, subjects cannot be scheduled until updated paperwork is submitted and reviewed.
Updating CRU Paperwork

- Revised paperwork must be submitted whenever a change is made to the protocol that necessitates full IRB board review.
- CRC-Scientific Advisory Committee re-review may be required for changes to the budget/resources request, updated information regarding risk and safety monitoring, or changes to the scientific rationale of the study.
- Any changes to patient care, even in one-time situations, must be approved prior to being carried out on the CRU.
Financial Compliance

Pharmaceutical supported studies are responsible for all charges incurred as a result of carrying out the study.

Studies with funding for patient care costs must pay for services at the CRU.

Studies are typically billed twice a year.

Investigators are expected to pay in a timely manner, whether or not they have already received payment from the sponsor.
Research Subject Advocacy: Development of the RSA Role

- In response to several unfortunate events....
- NIH mandated a role for a Research Subject Advocate (RSA)
- Enhanced safety and oversight of studies conducted on the CRC
RSA Responsibilities

- Patient advocacy
- Informed consent
- Protocol compliance
- Data and safety monitoring
- Education of study personnel
Informed Consent

The RSA is available to be an impartial observer of the consent process.

Advise study participants who may have questions about their rights as research subjects.

Assist investigators/coordinators in consent presentation
Protocol Compliance

Protocol approval process: RSA ensures research protocol and consent documents are congruent.

Protocol compliance in practice: RSA ensures research practice is congruent with protocol & consent and resolves any discrepancies.
Keep RSAs in The Loop

The RSA should receive copies of all correspondence to and from the IRB, FDA, and the sponsor related to conduct, safety, clinical holds, removal of holds, changes and other relevant information concerning protocols on the CRU.
Frequently Encountered Problems

- Attempted add-on procedures
- Delayed compensation
- Incomplete/poor quality copies of consent
- Consent form and medical record subject name discordance
- Children undergoing procedures requiring aggressive support
Reconsenting annually is NOT necessary

Reconsenting should be performed if there is:

- new risk information
- a change in procedures
- any new information that may affect subject decision to participate
Nursing Services Available

- Inpatient and outpatient nursing care
- H&P for outpatient protocols
- Administration of Infusions
- Telemetry monitoring
- Phlebotomy
Role of the In-service

- Mandatory, after final Scientific Advisory Committee review

- Carried out before any admission but after the orders have been reviewed

- Provides the opportunity to explain the rationale and scientific background of the study to the research nurses

- Describes the study procedures and reviews the nursing needs of the study

- Identifies potential logistical problems
Who to contact & when?

Blanca Campos, BA
Monday – Friday
7am – 3:30pm
Email: schedule-crc@mountsinai.org
Phone: ext. 241-6041
Scheduling Continued: Example of Request for Admission email

Please schedule the following participant:

- Name: John Doe
- Date of Birth
- Type of visit: outpatient
- PI: George Washington
- GCO#: 00-2010
- Date and time of appointment: 10/10/10 @ 10am
- Services required: medical clearance
- Name and contact information of study coordinator: Mary Coordinator, RN, x46010

48 hour minimum, advance notice must be received. All appointments will be confirmed via email.
Study: Continuation IV Ketamine in Major Depressive Disorder

GCO #: 06-1225

PI: Dennis S. Charney, M.D. (office) 212-241-5674
Co-PI: Sanjay J. Mathew, M.D. (office) 212-241-4480 (cell) 917-287-2646

Screening/Medical Clearance

- Verify signed consent and HIPAA
- Confirm fast (nothing PO except water 8 hours before blood draw). If PO, do not take blood and notify Co-PI.
- Vital signs-supine and standing, height (cm), weight (kg)
- H & P (use CRU form)
- Send to MSH lab:
  - **Hematology**: (4ml LTT) 203: CBC w/ diff & plt
  - **Chemistry**: (5ml gold TT) 1085: Comprehensive Metabolic Panel 076: Bilirubin (Direct)
  - **Endocrinology**: (3.5ml STT) 749: TSH
  - **Virology**: (8.5ml STT) 4271: Hep B Surface Ag 4277: Hep C Anti HCV antibody
  - **Urine Collection**: 5589: Drug Abuse Screen, Urine 221: Urinalysis 729: Pregnancy
- EKG

D/C by study team – pager 917-666-4064. Pt must be escorted back to clinic.
Example of Inpatient Orders

**Order Sheet**

**Study:** Continuation IV Ketamine in Major Depressive Disorder

**GCO #:** 06-1225

**PI:** Dennis S. Charney, MD (office) 212-241-5674

**Co-PIs:**
- Sanjay J. Mathew, MD (office) x44480 (cell) 917-287-2646
- James Murrough, MD (office) x89118 (cell) 617-686-1484
- Marije aan het Rot, PhD (office) x47910 (cell) 646-464-4252

**Study Visit (circle one)**
- [ ] 2
- [ ] 3
- [ ] 4
- [ ] 5
- [ ] 6

**DAY 0: Night before Ketamine Infusion**

- Admit to CRU
- Verify signed consent and HIPAA forms
- Diagnosis: Major Depression
- Activity: Restrict to unit
- Keep NPO after midnight. Ice chips permitted.
- Allergies:
- Urine collection:
  - HCG Icon Urine pregnancy test. If test is positive, please notify PI to discharge patient. Study to be cancelled.
  - 5589 Urine toxicology (send to MSH lab)

**DAY 1: Day of Ketamine Infusion**

- Keep NPO until 4 hours post start infusion, then regular diet. Ice chips permitted.
- 7am: Insert 22G IV to saline lock for infusion (antebrachial vein preferred)
- 7am: Insert 20G IV to saline lock for blood draws (contralateral arm)
- Place on telemetry and obtain BP, HR, RR, & SpO2
- Sum (Time 0):
  - Nasal cannula O2 with side-stream capnometry monitoring (done by anesthesiologist)
  - Infusion of ketamine hydrochloride (up to 0.5mg/kg) [ ] mg IV over 40min (done by anesthesiologist - MD will remain on site until end of infusion). Ketamine is stored in Pyxis at CRU.

**INSTRUCTIONS:**
- Enter all orders for procedures and drugs for the patient.
- To call attention to the order, name and drugs must be written on "ORDER INDICATOR" sheet on front cover of order book.
- Urgent orders must be called to the attention of the nurse in charge.
- Doctor's signature must follow each set of orders.
- To discontinue an order, a complete new entry must be made. Medications not prescribed as to a specific duration will be stopped after four (4) days. Controlled drugs (e.g., narcotics, barbiturates, etc.) will be automatically stopped after three (3) days.

**ORDER SHEET**

<table>
<thead>
<tr>
<th>DATE</th>
<th>TIME</th>
<th>ORDER</th>
<th>SIGNATURE</th>
<th>TIME</th>
<th>DATE</th>
<th>DISC.</th>
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<tbody>
<tr>
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<td>Study: Continuation IV Ketamine in Major Depressive Disorder</td>
<td>GCO #: 06-1225</td>
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Special Provisions

- We do make special provisions for the parents/guardians of children staying at the CRU, and in some cases, the spouse/partner of dependent adult study participants.

- However, we cannot accommodate the relatives and friends of adult study participants.

- The needs of patients/subjects who smoke cigarettes should be addressed prior to their inpatient stay.
Inpatient Policies

- A physician with admitting privileges must be a listed investigator and is responsible for the patient during their stay.

- Orders must be signed and dated by a physician listed on the protocol as a PI or Co-Investigator. Fellows assuming this role must be listed as investigators and must have current IRB Human Subject and HIPAA Certificates.

- All Hospital and JCAHO regulations apply to CRU admissions:
  - Admission note on chart within 24 hours
  - Medication Reconciliation Form
  - JCAHO unapproved abbreviations
  - Patient identification and procedure verification before invasive procedure
Medication Reconciliation Form

The Mount Sinai Hospital
One Gustave L. Levy Place NY, NY 10029

Medication Reconciliation Form
This is a medication order form. All orders must be written in TDS

Source of Information (check all used):
- Previous discharge paperwork
- Primary care physician list
- Med. admin record from facility
- Other

Allergies (list reactions):

List below all of the patient’s medications PRIOR TO ADMISSION, including OVER-THE-COUNTER and HERBAL MEDICATIONS

<table>
<thead>
<tr>
<th>Medication name (Rx/OTC)</th>
<th>Date (fing. ink)</th>
<th>Route</th>
<th>Frequency</th>
<th>Last dose</th>
<th>Date/Time</th>
<th>Record of pre-admission</th>
<th>Record of admission</th>
<th>Recalled at discharge</th>
<th>Comments</th>
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</table>

Clinical Provider please date, initial, sign and PRINT full name and title (RN, MD, NP) LEGIBLY

Admission

Initials Signature/PRINT NAME/Date

Discharge

Initials Signature/PRINT NAME/Data

IMPORTANT:
- Complete form within 24 hours of arrival on unit and place the yellow copy in the medication room on your unit for pick-up by pharmacy
- Do NOT use unapproved abbreviations (see instructions on back of this form)
- This is not an Order for medication, please write your medication orders in TDS

MR 1326 (Apr. 4/06) Attach to the History and Physical White - Medical Record Yellow - Pharmacy
# List of Unapproved Abbreviations

<table>
<thead>
<tr>
<th>NEVER !!</th>
<th>ALWAYS !!</th>
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<tbody>
<tr>
<td>QD</td>
<td>Daily</td>
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<tr>
<td>OD</td>
<td>Daily</td>
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<tr>
<td>QOD</td>
<td>Every other day</td>
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<tr>
<td>U</td>
<td>Unit</td>
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<tr>
<td>IU</td>
<td>Int. Unit or International Unit</td>
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<tr>
<td>Trailing zeros (<em>i.e.</em> 1.0 mg)</td>
<td>1 mg</td>
</tr>
<tr>
<td>Naked decimals (<em>i.e.</em> .1 mg)</td>
<td>0.1 mg (Leading zero)</td>
</tr>
<tr>
<td>MS, MSO₄</td>
<td>Morphine or Morphine Sulfate</td>
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<tr>
<td>MgSO₄</td>
<td>Magnesium or Magnesium Sulfate</td>
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<tr>
<td>TIW</td>
<td>Three times a week</td>
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<td>BIW</td>
<td>Twice a week</td>
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<tr>
<td>cc</td>
<td>mL</td>
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<tr>
<td>OD, OS, OU</td>
<td>Right eye, Left eye, Both eyes</td>
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<tr>
<td>AD, AS, AU</td>
<td>Right ear, Left ear, Both ears</td>
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<tr>
<td>x 2/D</td>
<td>x 2 doses or x 2 days</td>
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<td>gr or grains</td>
<td>mg or G</td>
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<tr>
<td>(apothecary system)</td>
<td>(metric system)</td>
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</table>
### Section I - Pre-Procedure Verifications

Checklist completed in pre-procedure area by operating room (OR) nurse or a designated licensed member of the procedure team for non-OR procedures and signed below by involved practitioners. The surgery/interventionalist must review any discrepancies identified.

**Planned Procedure - Site/Size/Level/Structure:**

<table>
<thead>
<tr>
<th>For</th>
<th>A</th>
<th>X</th>
<th>Patient verbalized name &amp; Date-of-Birth (DOB) concurs with information on ID Band and Medical Record</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Surgical site and side marked with surgeon initials using a permanent marker</td>
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<td>Surgical purpose/notes/long name/scrub name/DATE/PROCEDURE and date of birth for patient is visible</td>
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<td></td>
<td>Procedure consent form concurs with patient verbalization of procedure and schedule</td>
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<td>Relevant documentation available and accurately matched to patient (e.g., lab results)</td>
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<td>Correct blood products available (if applicable)</td>
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<td>Correct implants, supplies, medications or special equipment available (if applicable)</td>
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<td>Correct diagnostic and radiology imaging results present, correctly labeled with patient name and</td>
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<td>DOB (if applicable). e.g., imaging reports are name- or patient-identifiable</td>
</tr>
</tbody>
</table>

**Practitioner Attestations**

<table>
<thead>
<tr>
<th>(Registered Nurse)</th>
<th>First Name</th>
<th>Signature</th>
<th>Date</th>
<th>Time</th>
<th>Did #</th>
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<tr>
<td>Surgeons/Proctor #1</td>
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<td>Surgeons/Proctor #2</td>
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<tr>
<td>Surgeons/Team Member</td>
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</table>

### Section II - Time-Out

An event will occur during the process. Agreement by interactive verbal communication must occur and be intended to follow the procedure leading to the event.

<table>
<thead>
<tr>
<th>A</th>
<th>X</th>
<th>Correct patient identity (Name and DOB) and intended to follow the procedure leading to the event.</th>
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<tbody>
<tr>
<td></td>
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<td>Accurate Procedure Consent form</td>
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<td></td>
<td></td>
<td>Agreement on procedure to be done</td>
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<td></td>
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<td>Correct patient position and correct side &amp; side marked and visible (e.g., position, side, area, and</td>
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<td></td>
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<td>Scrub nurse recorded outside</td>
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<td></td>
<td></td>
<td>Relevant imaging results, properly labeled with patient name &amp; DOB</td>
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<td>Pre-op antibiotic medication given and/or ingested fluid administered (e.g., surgical anesthesia)</td>
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<tr>
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<td>Pre-op anesthetic medication given and/or ingested fluid administered (e.g., surgical anesthesia)</td>
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<tr>
<td></td>
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<td>Safety precautions observed and/or ingested fluid administered (e.g., surgical anesthesia)</td>
</tr>
</tbody>
</table>

**Event/Time-Out Attentions:**

<table>
<thead>
<tr>
<th>(Practitioner)</th>
<th>First Name</th>
<th>Signature</th>
<th>Date</th>
<th>Time</th>
<th>Did #</th>
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<tbody>
<tr>
<td>Before registered nurse block</td>
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<td>Before start of procedure 1</td>
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<td>Before start of procedure 2</td>
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<td>Additional Time-Out 1</td>
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<td>Additional Time-Out 2</td>
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</table>

**Organ Transplantation (Blood type match & UNOS number verification prior to implantation):**

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>AB</th>
<th>O</th>
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<tbody>
<tr>
<td>Nurse Name</td>
<td>Signature</td>
<td>Date</td>
<td>Time</td>
</tr>
<tr>
<td>Surgeon Name</td>
<td>Signature</td>
<td>Date</td>
<td>Time</td>
</tr>
</tbody>
</table>
Subjects may go off premises if PI and patient have signed and dated the proper form (permission sheet #14 - Off Premises Activities)

Pediatric patients may use THE ZONE if the admitting physician has cleared them to do so
Medication Policy

- All investigational drugs administered at the CRU must be dispensed from the Mount Sinai Medical Center Research Pharmacy.

- Inpatients who are currently taking prescription meds. (except schedule II drugs) should be encouraged to bring their medications in original containers for pharmacy re-labeling and administration by our nursing staff.
Specimen Processing

- Samples may be stored temporarily
- Limited specimen processing
- Discuss specialized services
  – George Diaz, MD, PhD, 4-6947
The Bionutrition Unit

**Services:**

- Design and develop the nutrition component of research protocols
- Determine appropriate diet methodology
- Nutrition assessments
- Calorie counts & precise nutrient analysis
- Anthropometrics & body composition analysis
- Kitchen on site develop research diets
  - meal studies
- Others as needed per protocol
The Bionutrition Unit

**Facilities - Kitchen**

- Closed on weekends for specialty meals/snacks
- Provide meals & snacks to all patients per protocol (must be requested)
- Offer meals for one parent of children < 5 years of age
- Only dietary staff are allowed in the kitchen
  - patient safety
The Bionutrition Unit

Facilities - Pantry:

- Used for patient’s meals & snacks
- If you need anything for your patient during the day, please let the nurse on duty know and we will be notified
- Meals & snacks for evening will be in the refrigerator with patient’s name on it
The Bionutrition Unit

Team Work:

- Diet change reports
  - generated from schedule book (from orders)
  - menus need to be in by 8:30 am
- CRU Protocol Application
  - indicates if any meals, snacks, or special diets are needed
- Communication - Nursing, Investigator, Dietary
  - anticipated time of meal after procedure/test
Gateway Services

- Information Technology
- Statistical Services

The Mount Sinai Institutes of Clinical and Translational Sciences provide numerous additional related services
Informatics Services

- **Web-Based Applications:**
  - **Electronic Research Application Portal (eRAP)**
    - Secure Access to Web-Based Applications based on Username with Role-Based Security
      - Compliant with Mount Sinai HIPAA and IT Security policies
      - Capability for Multi-Center Trials
  - **Rapid Database Generator (RDG)**
    - Design customized databases to enter, store and present clinical data via user-defined web-based forms
    - Generate custom reports, export data to Excel / plain text file
    - Assist in data analysis, management, and reporting
    - Conversion of legacy databases to web accessible databases
    - Ensure compliance with security policies
    - Provide technical leadership, support, and advising
Informatics Services

- **Database / Program Life Cycle:**
  - Analyze Data / Forms of Research Project (1-2 meetings)
  - Design the Program / Database (3-4 meetings)
  - Develop / Code the Program / Database (from 1-3 wks)
  - Formalize, Test, and Debug (from 1-2 wks)
  - Finalize Program / Database (from 1-2 wks)
  - Monitor and Update as needed
Informatics Services

- **Initiatives and Support:**
  - **InfoEd Clinical Trials Module**
    - Protocol Design, Case Report Forms, Patient Enrollment, Scheduling, Billing Reconciliation, AE Reporting

- **Mass Storage Area Network**
  - Fully Redundant Large Scale Data Storage for Active Protocols
Informatics Services

- Freezerworks Sample Labels and Tracking:

  - Generation and creation of generic and customized samples’ labels
  - Creation of study-specific, automated labels’ templates to prepare data for uploading into Freezerworks
  - Ensure data integrity and increase efficiency
CONTACT INFORMATION

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Questions and Answers