Children's Nutrition Research Center-Metabolic Research Unit (CNRC-MRU) Protocol Application

INSTRUCTIONS: Complete the protocol application as follows:

1. The protocol must be IRB approved prior to submitting this protocol application.
2. Grant 'Read only' access to sarah.grant@bcm.edu for this protocol in BRAIN. The 'email box' must be checked for notification of protocol updates to be received by the unit.
3. Review process: CNRC-MRU staff will contact the designated point of contact person with further instructions, as needed.
4. A protocol meeting will be scheduled with PI, and/ or Co-PI, research coordinator and other core services prior to making a final decision on submitted protocol application.

INCLUDE: The following documents should all be submitted in PDF format.

1. IRB approval letter
2. IRB full protocol
3. IRB approved consent form
4. Schedule of events (protocol orders) - exception: ***submit in word format to allow for edits, if needed.***
5. Clinical trial agreement (CTA), if industry funded budgets from other grants or industry
6. Provide a list of pertinent protocol staff members including, but not limited to:
    1. PI, Co-PI, research coordinator and other pertinent staff members ***who will need access to CNRC-MRU and involved in direct volunteer study functions. If additional space needed for additional staff members, please make list on a separate page and attach to this application.***

Protocol staff member name	Phone #	E-mail	In need of CNRC access card?
			☐ Yes, see notes on 8 and 9
			☐ Yes, see notes on 8 and 9
			☐ Yes, see notes on 8 and 9
			☐ Yes, see notes on 8 and 9
			☐ Yes, see notes on 8 and 9
			☐ Yes, see notes on 8 and 9

7. Other: All documents listed below are required for all pertinent protocol staff members listed in this application.
    a. (CITI) Human Research Subject Training: complete and submit report for *Biomedical Research (HSR), Good Clinical Practice (GCP), Research Conflict of Interest (COI), Responsible Conduct of Research (RCR), and Health Information Privacy and Security (HIPS).*
        Go to https://www.citiprogram.org/, log-In, select '*Add a Course of Update Learner Groups.*'
    b. Current CPR training: must have automatic external defibrillator (AED) component.
    c. Blood Borne Pathogens online training: login to BCM success factors->learning->IATA biological shipping Training.
    d. High-Rise Fire Safety training: this is a CNRC administration requirement for any employee responsible or designated to escort volunteers/research subjects to the MRU (3rd and 4th floor).
    e. If a protocol staff member isn't a BCM employee, we may accept corresponding training modules from their employer.
8. If any of the protocol staff members are non-CNRC employees, they will need to file for a CNRC access card with CNRC security and administrator
    a. Additional documentation will be required for this process to be completed.
9. Once all documents listed on this application and CNRC access card application is complete, an authorization for MRU access will be sent to CNRC security to provide and activate access card.

SUBMIT: Send completed application and documents to DL-BCM-Pediatrics-CNRC-MRUProtocols@bcm.edu

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DESIGNATED POINT OF CONTACT PERSON FOR APPLICATION INQUIRIES (if other than PI)

Name			
Phone #		Email	

PROTOCOL INFORMATION

IRB #	H-	Application date		
Protocol Title				

	Include overall totals in this column	Pediatric (0-17 y/o)	Adult (18-64 y/o)	Geriatric (65+ y/o)
Estimated duration of study (include in years)				
Total # of subject for study				
Visits per subject				
Total subjects per year				
Hourly visits (Non-Resident/ Out-patient) per year	☐ None ☐ Yes, include total			
Overnight visits (Resident/ In-patient) per year	☐ None ☐ Yes, include total			

MRU CORE DEPARTMENTS

Select the CNRC-MRU resources required for this protocol:

Nursing Staff	Dietary/ Bio-nutrition	Energy Expenditure Core	Eating Observation Laboratory	Body Composition Laboratory	CNRC Parking & Transportation	CNRC Recruiting (available only for CNRC PI's)
☐	☐	☐	☐	☐	☐	☐

List all research services, procedures, tests, and supplies you are requesting the CNRC-MRU provide assistance with and/or perform.

Procedure/ Test/ Scan name/Sample processing	Indicate expected quantity per subject

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PROTOCOL FINANCIAL SUPPORT

Principal Investigator	
Granting Agency or Industry Sponsor	
Grant account #/ Cost Center # /WBS #	

IRB ROLE AND PRINCIPAL INVESTIGATOR RESPONSIBILITIES AGREEMENT

The Baylor IRB is responsible for the review and approval of research studies involving humans including but not limited to adjudication of the propriety of the science, human risk, the wording of the consent form(s), public advertising, compensation to the volunteers, power calculations, protocol design, measurements to be made together with annual review and audits of the protocol. All studies must have IRB approval and be currently active at the time of the subject study.

A SIGNATURE FROM THE PRINCIPAL INVESTIGATOR BELOW CONFIRMS HER/HIS AGREEMENT TO THE FOLLOWING ITEMS:

Develop the study scientifically and initiate protocol approval by the BCM IRB.

Communicate with appropriate staff on the MRU during the development, approval, study execution and renewal.

Grant 'Read only'' access in BRAIN to the MRU Nurse Manager. The 'email' box should be checked in BRAIN to be notified of changes in the protocol.

Provide appropriate study tools and submission of the required forms, e.g. scheduling, cancellations, MRU orders, the consent form, completion of study encounter forms, etc. per MRU Policies and Procedures and IRB guidelines.

Provide MRU with the signed, original consent form of each participant for scanning or a paper copy to file in subject chart.

Maintain study folder for each participant, and make it available to the Director of the MRU.

Initiate protocol per SOP for the MRU and review and comply with the MRU SOP.

Present to MRU staff and resource directors the nature and specifics of the protocol.

Perform the study execution, DSMB and data monitoring as required by the IRB and federal regulation.

Report adverse events to IRB, along with a copy to MRU staff in compliance with federal regulations and IRB policy.

Meet all institutional and federal requirements for reporting results (e.g., IRB, FDA, etc.) and fulfill all other regulatory reporting requirements.

Acknowledge the use of CNRC and MRU resources in IRB protocol and any publications of this protocol.

Confirm appropriate coverage for his/her responsibilities in the event of a planned or unplanned absence.

Monitor subject enrollment to ensure that the maximum number of participants enrolled is equal to or less than the number of participants listed in the IRB application, and that all participants meet inclusion criteria for the study.

Communicate in a timely manner with MRU and other study staff in regard to major changes in scheduling, or any changes that may alter the needs of the study visit.

Review MRU Policies and Procedures manual with pertinent protocol staff and agree to comply with policies and procedures.

SIGNATURE SECTION

Principal Investigator's Signature REQUIRED_____

- *If sent from PI's email account, that will serve as her/ his signature. If any other research personnel/ staff is completing this form, send with PI's signature.*