

**Standard Laboratory Procedure**

Children’s Clinical and Translational Discovery Core

Created on 21 JUN 2022



EMORY  
UNIVERSITY  
SCHOOL OF  
MEDICINE

Department of Pediatrics

**Emory University  
Department of Pediatrics  
Children’s Clinical and Translational Discovery Core**

**Study Start-up**

Name of Primary Investigator: \_\_\_\_\_

Project Title: \_\_\_\_\_

Estimated timeframe: \_\_\_\_\_

Samples to be Collected and Processed (specify tube collection type and volumes):

- Whole Blood \_\_\_\_\_
- Plasma \_\_\_\_\_
- Serum \_\_\_\_\_
- PBMC \_\_\_\_\_
- Urine \_\_\_\_\_
- Stool \_\_\_\_\_
- Saliva \_\_\_\_\_
- Biopsy \_\_\_\_\_
- Other \_\_\_\_\_

Notes:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_ I approve of the attached protocol and its use in processing the indicated sample types collected for this study.

\_\_\_\_\_ I do not approve of the currently used protocol and wish to use a different protocol for processing samples collected in this study. I have provided this protocol to the Children’s Clinical and Translational Discovery Core.

X \_\_\_\_\_  
Principal Investigator Name (PRINTED)

X \_\_\_\_\_  
Principal Investigator Signature & Date

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### Investigator Agreement

By signing the following document, you acknowledge understanding of the following:

I have read and understand the current rates for the processing, storage, and retrieval of biological samples from the Children's Clinical and Translational Discovery Core (CTDC).

I understand that I must provide the CTDC with at least one week to create a study budget, LIMS request, REDCap, standard operating protocol, and/or any relevant documentation.

I understand that all study budgets, requests and protocols require written approval within 48 hours. The CTDC will not receive or process samples without written approval or confirmation.

I understand that the published rates for processing, storage, and retrieval of biological samples may change at any time. For all changes, the CTDC will provide at least 30 days of notice prior to the effective date.

I understand that any policy is subject to change at any time. If any changes in policy take place, the CTDC will provide at least 30 days of notice prior to the implementation of these changes.

I agree to acknowledge the use of the CTDC in all publications. I will reference the "Children's Healthcare of Atlanta and Emory University's Children's Clinical and Translational Discovery Core" in the acknowledgements section of all publications that use samples stored by or obtained through the CCTR Biorepository.

I agree to provide the CTDC with an annual update on grant applications and publications that use samples stored by or obtained through the CTDC.

I agree to oversee my study staff's use of and interaction with the CTDC. My study staff will provide, when necessary, information on amendments to study protocol that could affect the use of and interaction with the CTDC. Additionally, my study staff will communicate things like dropping off samples, changes in the schedule, issues with protocol adherence, etc. in a timely manner.

I understand that any changes to services requested from the CTDC will require a change in budget and PI approval prior to implementation of those changes.

At this time, all questions related to the policies and procedures of the CTDC have been answered.

X \_\_\_\_\_

Principal Investigator Name (PRINTED)

X \_\_\_\_\_

Principal Investigator Signature & Date

X \_\_\_\_\_

CTDC Director Name (PRINTED)

X \_\_\_\_\_

CTDC Director Signature & Date

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**Study Start-Up Checklist**

- A member of the Children’s Clinical and Translational Discovery Core (CTDC) has met with the Primary Investigator (PI) and/or member of the PI’s study staff to review the study.
- The PI and/or a member of the PI’s study staff has provided an updated study protocol to the CTDC.
- A member of the CTDC has reviewed, with the PI and/or member of the PI’s study staff, Standard Operating Procedures (SOPs) for: sample collection scheduling, sample drop-off, and requesting study samples.
- The Study has been created in REDCap and/or LIMS and reviewed/approved by the PI and/or member of the PI’s study Staff and member of the CTDC.
- The Budget Form has been reviewed/approved by the PI or lead coordinator.
- A member of the CTDC has created a file for the study that includes both hard copies and electronic copies of all pertinent study information.

By signing below, you are indicating that all of the above points have been addressed and that the study is ready to begin using the Children’s Clinical and Translational Discovery Core.

X \_\_\_\_\_  
Principal Investigator Name (PRINTED)

X \_\_\_\_\_  
Principal Investigator Signature & Date

X \_\_\_\_\_  
CTDC Director Name (PRINTED)

X \_\_\_\_\_  
CTDC Director Signature & Date