Tripartite Request Assessment Committee (TRAC)

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What is TRAC?

- Tripartite Request Assessment Committee
- Established and shared by CUIMC, WCM, and NYP
- Provides governance and oversight for data sharing across institutions for research, clinical care, operations, and quality improvement
    - Reviews and approves (or seeks clarification and additional information about) data requests
- Overview of the TRAC Process for Research Data Requests

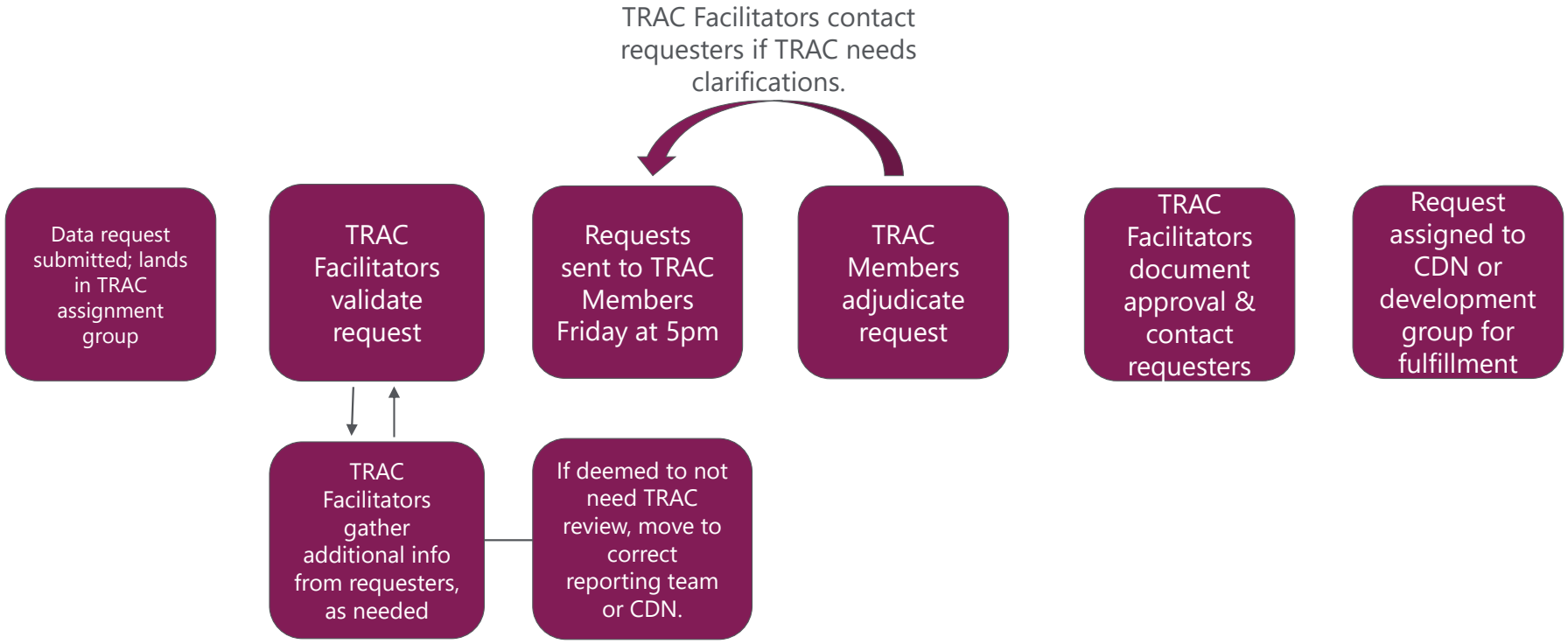
TRAC Roles - Members

- Members by Institution:
  - CUIMC:
    - Karen Pagliaro-Meyer – Chief Privacy Officer
    - Dr. Ian Kronish – Associate Professor of Medicine
    - Brenda Ruotolo – Associate Vice President for Human Research Protection, IRB
  - NYP:
    - Dr. Sarah Rossetti – Assistant Professor of Biomedical Informatics and Nursing
    - Greg Hruby – Program Director, Research Science
  - WCM:
    - Evan Sholle – Assistant Director, Research Informatics
    - Dr. J. Travis Gossey – Associate Chief Medical Information Officer, Asst. Professor in Population Health Science and Medicine

TRAC Roles - Facilitators

- TRAC Facilitators
  - Assess requests meeting TRAC review criteria for clarity and completeness prior to providing to the committee
  - Liaise with TRAC, requesters, and other applicable committees and leadership
  - Not members of TRAC and do not have authority to make adjudications on requests
- Facilitators by Institution:
  - CUIMC: Jori Grossman (jpg2157@cumc.columbia.edu)
  - NYP: Allison Clayton (alc9090@nyp.org)
  - WCM: Nivedita Chang (nik2004@med.cornell.edu)

TRAC Workflow



Submitting Data Requests

How can I submit a data request for research?

- CUIMC Report Request Form
  - Requests for New or Modifications to Reports, Dashboards, or Data

How do requests get routed to TRAC?

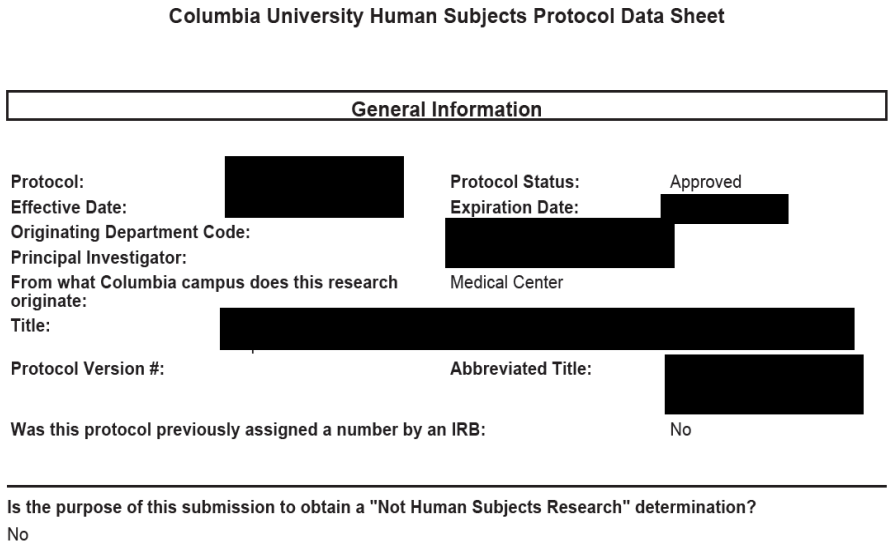
- A subset of requests submitted through the request form are routed to TRAC
- "Research" selected under "Report Type"
- More than one option selected under "Data from which institutions"
- "Institutional Affiliation" of requester is not same as the value in "Data from which institutions"

CUIMC-Only Research – Common Documentation Needs

- All requests for patient-level clinical data for research at CUIMC must have been approved by the CUIMC IRB prior to being submitted for review by TRAC
  - TRAC will not review or approve research requests for patient-level data lacking IRB approval
- Data Sheet
  - Contents of data request and data sheet should match
- HIPAA Form B - Application for a Waiver of Authorization
- HIPAA Form D - Investigator's Certification for Reviews Preparatory to Research

CUIMC-Only Research – Data Sheet

- Is the associated protocol's data sheet attached to the request?
- Does the study have IRB approval (Protocol Status of "Approved" on the data sheet)?
- Does the data requested match the data approved in the research protocol ("Research Aims & Abstracts")?
- Are the dates on the data request form consistent with the dates approved in the research protocol ("Analysis of Existing Data and/or Prospective Record Review")?
- Are the report recipients all listed on the research protocol ("Personnel")?



Columbia University Human Subjects Protocol Data Sheet

General Information

Protocol: [redacted]
Protocol Status: Approved
Effective Date:
Expiration Date: [redacted]
Originating Department Code:
Principal Investigator: [redacted]
From what Columbia campus does this research originate: Medical Center
Title: [redacted]
Protocol Version #:
Abbreviated Title: [redacted]
Was this protocol previously assigned a number by an IRB: No

Is the purpose of this submission to obtain a "Not Human Subjects Research" determination?
No

CUIMC-Only Research – Locations

- Facilities covered by the CUIMC IRB:
  - ColumbiaDoctors
  - NYP/AH
  - NYP/CU (including Milstein and MS CHONY)
  - NYP/HVH (only if HVH is explicitly listed in IRB protocol)
  - NYP/Westchester (formerly NYP/Lawrence)
- The CUIMC IRB cannot unilaterally permit access to Weill Cornell Medical Center, Brooklyn Methodist Hospital, and Queens Hospital patients

Preparatory to Research

- Counts of CUIMC patients meeting a list of criteria
    - Not patient-level data
- Submit through the CUIMC Report Request Form
- Do not need to go through TRAC approval process before being assigned
    - Clinical Data Navigator
    - SlicerDicer

Multi-Institutional Research – BMH, Queens, & WCM

- Requires all documentation for CUIMC-only research
- Additional Documentation:
  - Executed Data Use Agreement (DUA)
    - Request a DUA or MTA for Research Purposes
    - External disclosures of data should be noted in the IRB protocol
  - Principal Investigators from each participating institution
  - Approvals by the IRB offices at each participating institution
- Each institution's group needs to submit a separate report request for their institution's portion of the study data
  - These paired requests will be routed to TRAC and evaluated together

Multi-Institutional Research – Beyond the Tri-Institution

- Requires all documentation for CUIMC-only research
- Additional Documentation:
  - Executed Data Use Agreement (DUA)
    - Request a DUA or MTA for Research Purposes
    - External disclosures of data should be noted in the IRB protocol

TRAC Send Out & Adjudications

- Requests are sent via email by TRAC Facilitators to TRAC Members every Friday at 5pm
- TRAC Members are expected to adjudicate on requests assigned to them in 5-8 business days
- TRAC Facilitators notify requesters of approval once one TRAC Member from each of CUIMC, NYP, and WCM approve a given request

Committees Other Than TRAC

- ACORD (Alignment Committee on Oversight of Requests for Data)
  - TRAC members can advance requests to ACORD if additional guidance is needed
  - CUIMC ACORD Members:
    - Tim Crimmins, CMIO
    - Wil McCoy, CFO
    - Chad Neal, CIO
    - Helen Kim, Associate Vice President, Clinical Trials
    - Soumitra Sengupta, Associate Professor, DBMI
- NYP EDUS (External Data Use and Sharing)
- P-DiSCO (Pediatric – Digital Science and Outcomes)
  - Data Request Process for the Department of Pediatrics

Review

Complete the entire form

Data Request should match data sheet

- Sponsor should be Principal Investigator for Research and Department Administrator
- Confirm that the person requesting the data is listed on the protocol
- Dates, data type, prep to research, retrospective, etc.
- Ideally research protocol should indicate if you plan to query Epic to obtain information to identify or recruit research subjects or conduct retrospective research
- If research includes disclosure of research information outside the organization (e.g. Registry, Consortium, Collaborative Research), attach the Data Sharing Agreement or reference the agreement. Complete SPA submission form to facilitate execution of agreement.

Useful Links

- Overview of the TRAC Process for Research Data Requests
- CUIMC Report Request Form
- Requests for New or Modifications to Reports, Dashboards, or Data
- Data Request Process for the Department of Pediatrics
- Request a DUA or MTA for Research Purposes

Questions?