

# Specimen Acquisition, Processing, and Experimental Design

Credit: Lacy Simons

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Pathogen Genomics  
and Microbial Evolution

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Translational research is a ...

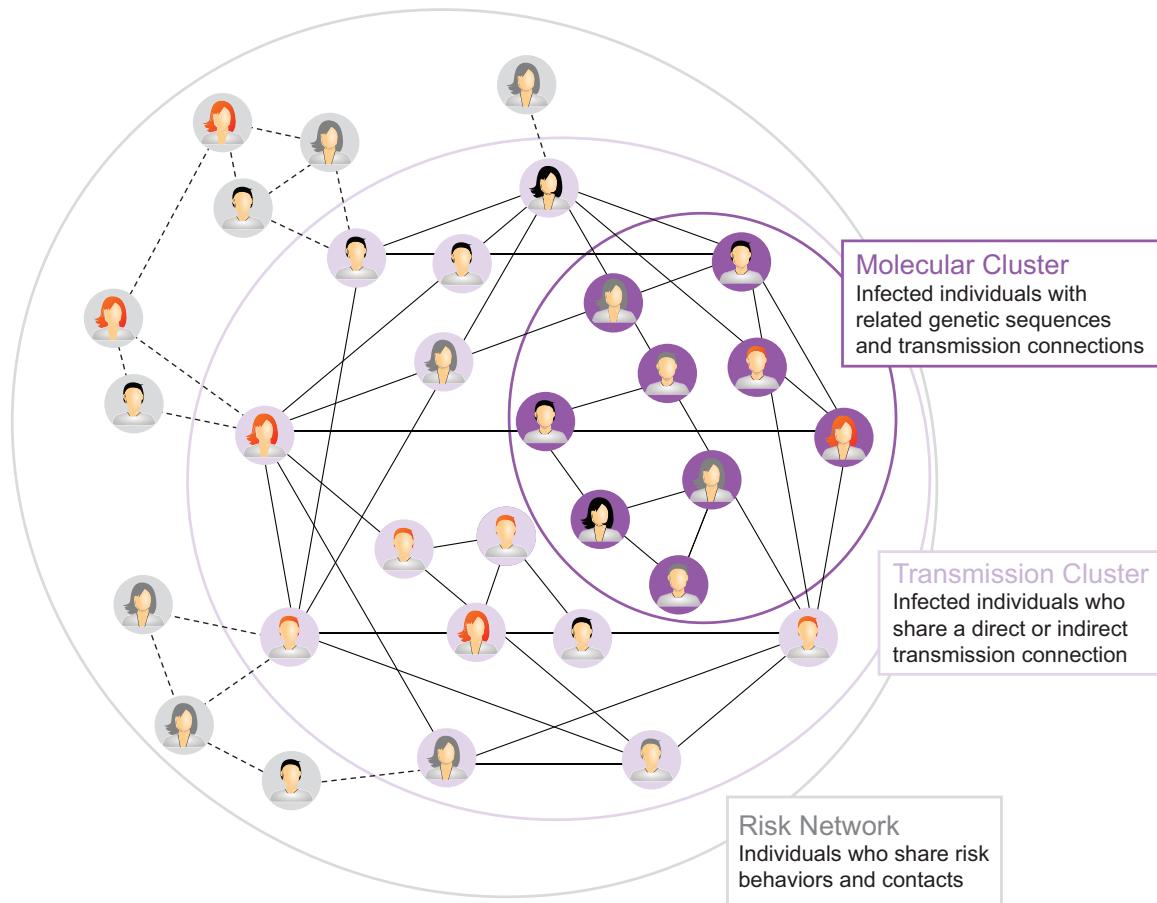


# Overview

1. Study Design
2. Study Implementation
3. Data Collection  
and Management



# Molecular Epidemiology



- Complement traditional epidemiological methods
- Molecular diagnostics (incl. serology and PCR) → robust tools to track disease spread
- Genome sequencing for phylogenetics and phylodynamics to track transmission
- Electronic medical record (EMR) can link patient demographic and clinical care data with molecular data

# Research Infrastructure and Biobanking



Diagnostic Molecular Biology Lab  
Clinical Microbiology Lab



Residual diagnostic samples  
-Pre-surgery  
-Drive-thru clinic  
-Health care workers  
-Outpatients  
-Inpatients



Repository  
(>30,000 positive samples)



QiaCube HT  
Viral RNA  
Extraction



Quantify viral load  
(CDC qPCR assay)



cDNA synthesis  
and Multiplex PCR  
(ARTIC protocol)



Whole Genome  
Sequencing on  
Illumina MiSeq



Sequence Reporting  
(>2500 genomes)

# Study Design

- Defining Study Scope
- Infrastructure Consideration
- IRB Submission and Approval
- MTA and DUA
- Development of Safety Protocols



# Defining Scope

- What is your question?
- What is the population that can best address that question?
- What is the sample size, biostats for significance?
- Control group?
- Sample Type
  - residual vs research acquired
- Clinical Data Type
  - Prospective
  - Retrospective
  - Deidentified or PHI



# Infrastructure Considerations



Specimen Volume & Storage

Specimen Transportation

Specimen Processing  
& SOP Development



# IRB Submission

- Title
  - Investigators
  - Introduction
  - Hypothesis
  - Objectives
- Selection of Participants
  - Type of Study
  - Date Range of Data
  - Study Methods
- Confidentiality of Data
  - Consent
  - Risks and Benefits
  - Statistical Consideration



# MTA, DUA, and Subcontracts

## Material Transfer Agreements

- Inbound or Outbound
- Material Type
- Shipment Conditions
- Domestic or International
  - Customs Forms
  - Shippers Declaration
  - CDC Permits
- Shipping Services



## Grant Subcontracts

## Data Use Agreements

- Use of Data
- Ownership and Data Rights
- PHI
- Data Storage

# Global Health: SARS-CoV-2 in Nigeria



Dr. Babafemi O. Taiwo  
Northwestern University



Dr. Olubusuyi Moses Adewumi  
University of Ibadan



Abuja  
1.2 million

Ibadan  
3.6 million

Lagos  
14.8 million



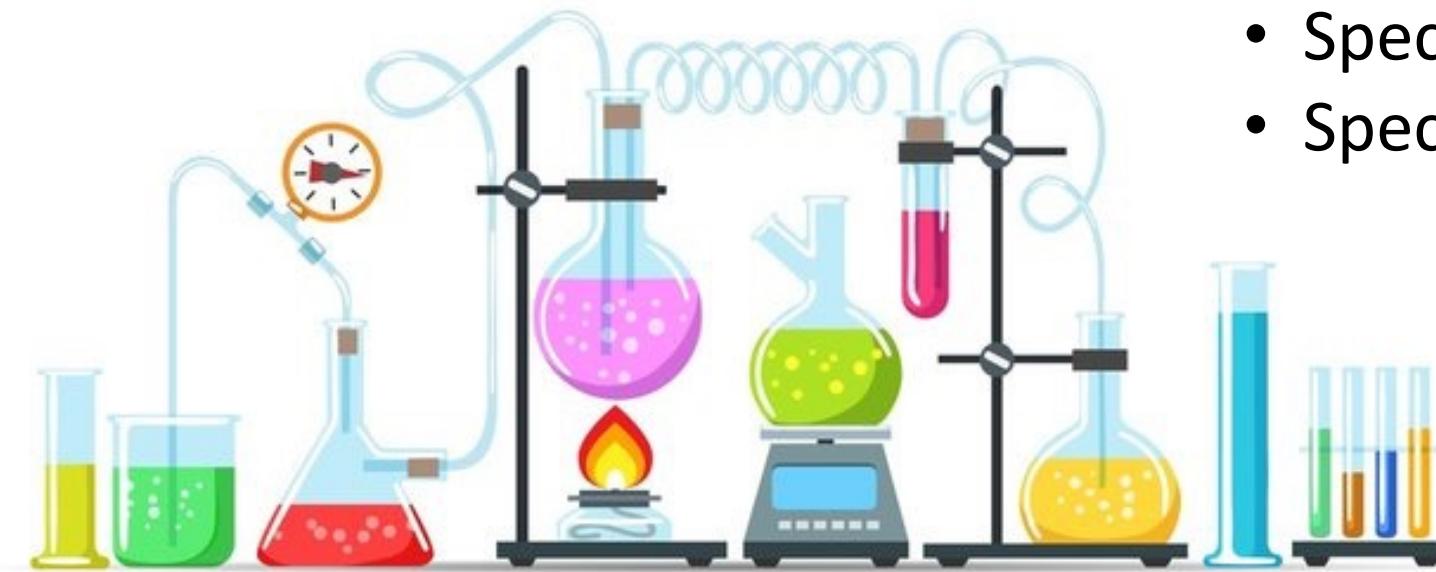
# Safety Protocols

- ❖ Biosafety Level
- ❖ Environmental Controls
- ❖ Staff Training
  - CITI Training for Human Subjects
  - Lumen/MyHR Lab specific Training
- ❖ Lab Safety Platforms
  - Lab Profile
  - Project
  - Identify Biological Materials
  - Authorizations and Permits
  - Rooms & Spaces
  - Transportation Protocols
  - Risk Assessment
  - Pathogen Forms



# Study Implementation

- Identifying and Training Key Personnel
- Specimen Acquisition and Storage
- Specimen Tracking



# Personnel

## Clinical

- MDs
- Medical Fellows
- Nurses
- Clinical Coordinator
- Medical Students

## Research

- PIs
- Lab Manager
- Study Coordinator
- Technicians
- Bioinformaticians
- Graduate Students
- Post-Docs



*\*New hire processing and on-boarding can take up to 6 months and funding must be in place prior to position posting.*

# Specimen Acquisition and Storage

- Specimen Origin
  - Site
  - Scheduling
  - Transportation
- De-identification & Study ID
- Labeling
- Specimen Storage
  - Proper vial/container
  - Temperature
- Accessibility



# Study Data Collection and Management

- Database Management
- Clinical Data Acquisition
- Data Validation
- Analysis



**REDCap**  
Research Electronic Data Capture

**EDW**

# Database Management

- Specimen logging
  - Paper vs Electronic records
- Specimen tracking
- Specimen Processing
- Data Dictionary
  - PHI variables
  - Non-PHI variables
- Repeat values



**REDCap**

Logged in as lms979 | Log out

My Projects  
REDCap Messenger

**Project Home and Design**

Project Home · Project Setup  
Designer · Dictionary · Codebook  
Project status: Production

**Data Collection**

Record Status Dashboard  
Add / Edit Records  
Show data collection instruments

**Applications**

Project Dashboards  
Alerts & Notifications  
Calendar  
Data Exports, Reports, and Stats  
Data Import Tool  
Data Comparison Tool  
Logging  
Field Comment Log  
File Repository  
User Rights and DAGs  
Data Quality  
REDCap Mobile App

**Reports**

Search Organize Edit

1) Biobank Samples Only for Clinical Data pull  
2) dates and CT values  
3) SCRIPT patients  
4) Sequencing Data  
5) Dates and Zips  
6) clinical data

**SARS-CoV-2 Biobank** PID 6933

**Record Status Dashboard (all records)**

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Dashboard displayed: Default dashboard ▾ Create custom dashboard

Displaying record Page 1 of 283: "1" through "100" of 28,292 records 100 records per page

+ Add new record

Displaying: Instrument status only | Lock status only | All status types

Record ID	Biobank Sample Log	Physician Requests	RNA Extraction	qPCR	cDNA synthesis	Multiplex PCR	Whole Genome Sequencing	Sequencing Results	Link to other studies	Clinical Overall	Vaccine Administration	Clinical Lab Data	Severity Scores
1	Green	Grey	Grey	Yellow	Grey	Grey	Grey	Green	Grey	Green	Green	Green	Grey
2	Red	Grey	Grey	Grey	Grey	Grey	Grey	Red	Grey	Grey	Green	Green	Grey
3	Green	Red	Red	+	Red	+	Red	+	Red	Red	Green	Red	Green
4	Green	Grey	Grey	Yellow	Grey	Grey	Grey	Green	Green	Green	Green	Green	Grey
5	Red	Grey	Grey	Grey	Grey	Grey	Grey	Red	Grey	Green	Green	Green	Grey
6	Red	Grey	Grey	Yellow	Grey	Grey	Grey	Green	Green	Green	Green	Green	Grey
7	Red	Grey	Grey	Yellow	Grey	Grey	Grey	Green	Green	Green	Green	Green	Grey
8	Red	Grey	Grey	Yellow	Grey	Grey	Grey	Green	Green	Green	Red	Green	Grey
9	Red	Grey	Grey	Yellow	Grey	Grey	Grey	Green	Green	Green	Green	Green	Grey
10	Red	Grey	Grey	Yellow	Grey	Grey	Grey	Green	Green	Green	Green	Green	Grey

**Legend for status icons:**

- Incomplete (Red)
- Incomplete (no data saved) (Grey)
- Unverified (Yellow)
- Many statuses (all same) (Green)
- Complete (Green)
- Many statuses (mixed) (Yellow/Green)

# Clinical Data Acquisition

- Requires IRB Approval
- Consultation with EDW Analyst
- Provide as many specifics as possible



The screenshot shows the EDW portal's user interface. At the top, there is a dark purple header bar with the EDW logo on the left and a "Welcome, Lacy Simons" message on the right, along with icons for notifications, settings, and help.

The main content area has a light gray background. On the left, there is a sidebar with two sections: "RESOURCES" and "REQUEST ACCESS". Under "RESOURCES", there are links for "All Resources", "Favorites", "Research Requests", and "Product Pages". Under "REQUEST ACCESS", there is a large, semi-transparent purple rectangular area.

The main content area is titled "All Resources" and includes a "Filter By Resource Group" section with a dropdown set to "All Individual Resources". Below this is a "Reports" section with a table:

	REPORT NAME	MODIFIED	DESCRIPTION	RATING
	<a href="#">COVID19 Infections from Central Region</a>	10/13/2021	Positive COVID-19 patients from Central region	
	<a href="#">Influenza A and B positive main report</a>	10/27/2021	report	
	<a href="#">Influenza A and B positive main report Notes</a>	07/17/2018		
	<a href="#">Influenza Infections from Central Region</a>	09/15/2021	Positive Influenza patients (from both inpatient and outpatient) from Central region between 01/01/2018 and now	
	<a href="#">Patients with Positive RSV result</a>	10/27/2021	report	
	<a href="#">Patients with Positive RSV result Notes</a>	07/17/2018		
	<a href="#">RSV Infections from Central Region</a>	09/15/2021	Positive RSV patients (from both inpatient and outpatient) from Central region between 01/01/2018 and now	

<https://edw.nm.org/portal/#/login>

# Data Validation

No System is Perfect!

- Data Entry Errors
- Incomplete Data
- Unavailable Data
- Variable Switching
- Increasing Variables

