



MATRIX Laboratory Policy

OVERVIEW

All MATRIX Clinical Research Sites (CRS) and affiliated laboratories (Local Labs) are required to adhere to the guidelines, procedures and practices outlined in this document when performing any laboratory related activity for MATRIX, including specimen management, testing, and reporting.

All CRS and Local Labs must comply with all national regulations and institutional policies for specimen management, reporting of patient results and safety procedures including waste disposal.

CRS in the United States are required to file documentation of CLIA (Clinical Laboratories Improvement Act) certification from laboratories that provide results for participant diagnosis or care.

APPLICABLE REGULATIONS AND GUIDELINES

Because the MATRIX project is funded by the U.S. Agency for International Development (USAID), all project activities must be conducted in accordance with applicable sections of the U.S. Code of Federal Regulations (CFR) (<http://www.ecfr.gov>):

- 2 CFR 200: Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards
- 2 CFR 225: Human Subjects Protection
- 2 CFR 700: Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards

Furthermore, US 42 CFR 493: Laboratory Requirements sets forth the conditions that all laboratories in the US must meet to be certified to perform testing on human specimens under CLIA.

Good Clinical Practice Guidelines (ICH E6 GCP)

In addition to the above U.S. federal regulations, MATRIX specifically requires that all its clinical studies be conducted in accordance with the International Council for Harmonisation (ICH) E6 (R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) (or ICH E6 GCP for short):

<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219488.htm>. Additional guidance can be found at:

https://www.who.int/medicines/areas/quality_safety/safety_efficacy/gcp1.pdf, and

https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-6-r2-guideline-good-clinical-practice-step-5_en.pdf.

Furthermore, the World Health Organization recommends that any organization that analyses samples generated by a clinical trial should follow Good Clinical Laboratory Practice Guidelines to assure the reliability, quality and integrity of the results generated. The GCLP Guidelines can be found at: <https://fctc.who.int/publications/i/item/good-clinical-laboratory-practice-%28-gclp%29>. CRS and Local Labs needing additional guidance on GCLP may contact the Clinical Trials Hub Laboratory Center (CTH-LC).

Investigational New Drug (IND) and Investigational Device Exemption (IDE) Studies

All MATRIX clinical studies conducted under an Investigational New Drug (IND) application will be subject to additional regulation by the U.S. Food and Drug Administration (FDA) and must be conducted in accordance with the following (<http://www.ecfr.gov>):

- 21 CFR 11: Electronic Records, Electronic Signatures
- 21 CFR 50: Protection of Human Subjects
- 21 CFR 54: Financial Disclosure by Clinical Investigators
- 21 CFR 56: Institutional Review Boards
- 21 CFR 312: Investigational New Drug Application
- 21 CFR 314: Applications for FDA Approval to Market a New Drug

Studies conducted under an Investigational Device Exemption (IDE) application will also be subject to regulation by the FDA and must be conducted in accordance with 21 CFR 812, Investigational Device Exemptions and 21 CFR 814, Premarket Approval of Medical Devices, rather than 21 CFR 312 and 21 CFR 314.

Health Insurance Portability and Accountability Act (HIPAA)

The HIPAA Privacy Rule establishes U.S. standards to protect individuals' medical records and other personal health information. The rule applies to health plans, health care clearinghouses and those health care providers that conduct certain health care transactions electronically. The rule requires appropriate safeguards to protect the privacy of personal health information and sets limits and conditions on the uses and disclosures that may be made of such information without the patient's authorization. HIPAA also gives patients' rights over their health information, including the rights to examine, obtain a copy of, and request corrections to their health records.

The HIPAA Privacy Rule is located at 45 CFR Part 160 and Subparts A and E of Part 164 (<https://www.ecfr.gov>). All applicable U.S.-based organizations participating in MATRIX studies must comply with CFR Title 45, Parts 160 and 164, Standards for Privacy of Individually Identifiable Health Information, which include subparts related to the following:

- Standards for use and disclosure of protected health information (PHI)
- Authorizations to use and disclose PHI or waivers of authorization
- Tracking of PHI uses and disclosures

LABORATORY CENTER OVERSIGHT

The CTH-LC staff may conduct periodic site visits and/or "for cause" site visits to assess the implementation of laboratory quality control (QC) and quality assurance (QA) procedures, including the

proper maintenance of laboratory testing equipment and appropriate use of reagents. The purpose and scope of the visit are discussed with site personnel prior to the visit. The CTH-LC staff work directly with the MATRIX CRS and Local Lab staff to address and resolve any QC or QA problems that are identified by the site through proficiency testing, site visits or by the site during study preparation or implementation.

QUALITY ASSURANCE

Each Local Lab involved in MATRIX research is expected to have a laboratory QA plan available for review on request. The site-specific QA plan is designed to ensure accurate, timely and reliable test results by providing routine monitoring of the overall laboratory operation. Some specific considerations for MATRIX are described below.

External Quality Assurance

Testing done under CLIA certification is exempt from these EQA requirements.

External Quality Assurance (EQA) is required for all tests which are used for participant diagnosis and treatment. CRS and Local Labs are to contact the CTH-LC for guidance on any EQA gaps. It may be required for select research only assays. EQA must be obtained from an external provider; this may be a commercial EQA provider, such as College of American Pathologists (CAP) or another laboratory. EQA samples should be received blinded and graded by the EQA provider. CRS or Local Labs performing EQA will maintain an SOP describing the schedule of evaluations/panels and corrective action for sub optimal results. CRS and/or Local Labs will submit EQA results to the CTH-LC when requested prior to study activation and during study implementation.

In any situation where at least 2 of the 3 most EQA recent panels have a grade of less than 100% the CTH-LC may require an investigation; testing can be halted or sent to a backup laboratory at the discretion of the CTH-LC.

Quality Control

Testing done under CLIA certification is exempt from these QC requirements.

Laboratory QC activities are an integral part of the laboratory QA program. QC must be performed to meet all manufacturer's guidance, institutional and local regulations.

SPECIMEN MANAGEMENT

Specimen Handling and Processing

Only properly trained personnel may perform specimen collection. It is essential that staff is aware of proper collection techniques, container types, special requirements and proper care for research participants. Specimens must be transported to the laboratory under proper conditions and within predefined time limits.

Laboratory Data Management System (LDMS)

LDMS use by Local Labs is used to log and track select samples for storage and shipment. The Frontier Science and Technology Research Foundation (FSTRF) and the CTH-LC are responsible for providing training and support to local laboratory staff on the use of the LDMS; however, each Local Lab is responsible for ensuring its staff members are trained and competent. The Local Lab is responsible for maintaining its general LDMS program, including local validations of the program. Study Specific details such as specimen codes are included in the Study-Specific Procedures (SSP) Manual for each study.

Specimen Shipment

Specimens will be packaged and transported in accordance with International Air Transport Association (IATA) regulations and all laws and regulations that govern specimen transport to and from each country. This applies to transporting specimens, test supplies and reagents on site; to and from the clinic and the laboratory; and from the site to the CTH-LC. Study and laboratory personnel who are involved with packaging and transporting specimens must receive adequate and appropriate training to ensure compliance with all applicable guidelines and regulations. Documentation of training must be filed on site and a copy sent to the CTH-LC upon request.

The IATA regulates the safe air transportation of dangerous goods in accordance with its legal requirements. The IATA requires training and certification for individuals who are involved with shipping Class 6.2 infectious substances and diagnostic specimens. The IATA regulations define infectious substances, cultures and stocks, biologic products and diagnostic specimens. The regulations also specify the requirements for handling and shipping each of these substances. Diagnostic specimens and infectious substances are further separated into risk groups based on the sample having known or suspected organism. Most samples will be handled as diagnostic specimens and labeled as UN3373 Biological Substances, Category B.

Renewal of IATA shipping certification is required every two years with an annual review of the IATA Dangerous Goods Regulations to check for any new or changed requirements. The CRS and laboratory personnel are responsible for obtaining the appropriate training and annual IATA Dangerous Goods Guidelines. Each staff member who handles shipments must be trained (internally or externally) and certified. New staff must be trained within 90 days of their start date. Site personnel should review IATA regulations, which are updated annually. All training should be documented and kept on permanent file.

The CTH-LC will maintain a CDC Infectious Diseases Import Permit to allow for importation of biological samples into the USA.

Specimen shipping from Local Labs to the USA based MATRIX laboratories may require Specimen or Material Transfer Agreements (MTA). Sites need to notify the CTH-LC during study activation of these requirements, so they can be completed before specimen shipping is required.

An MTA or similar agreement is required to ship samples to any non-MATRIX affiliated USA laboratory.

Policy for Testing of Stored Specimens

Some specimens that are collected as part of MATRIX studies may be stored for future use and testing, including as part of an ancillary study.

MATRIX Leadership and Study Leadership will determine if samples may be used for ancillary studies. The following will be evaluated before any non-protocol testing can be performed:

- All primary study endpoints should be ascertained prior to any testing of stored specimens. In addition to ascertaining primary endpoints, all protocol-specified laboratory testing that involves the stored specimens at issue (including QA/QC testing to be performed by the CTH-LC) should be completed prior to any other testing of the specimens.
- All protocol-specified data analyses should be completed and considered final by the protocol team prior to any testing of stored specimens. Retesting of samples for participant safety and clinical management, QA purposes or ambiguous results may be done at the discretion of the CTH-LC or site.

Any residual specimens remaining in storage from participants who did not consent to long-term storage and/or possible future research testing of their specimens **must** be destroyed after all primary endpoints have been ascertained, all protocol-specified laboratory testing involving the stored specimens at issue has been completed and protocol-specified data analyses have been completed and determined to be final by the study leadership.

Destruction of Samples

The CRS and Local Lab are responsible for storing samples collected in any MATRIX study taking place at the site, although some of these samples may be sent out to other laboratories for other required testing as mandated by the specific protocol. If a site is storing specimens after the completion of a study, a determination is made whether to destroy the specimens in question or continue to store them. In certain situations, specimens must be destroyed (for example, specimens from improperly enrolled participants who have been removed from a study, or specimens that per the protocol should not have been stored).. When potential specimen related deviations are noted by any party (Local Lab, data team, etc.), these will be discussed in real time to determine if a deviation occurred and related specimen management. As needed, the CTH-LC will then notify the CRS and/or Local Lab if specimens need to be destroyed, and which samples are to be destroyed.

Each site will have an SOP on sample destruction, which should include a form to use to maintain the chain of custody of the samples throughout the destruction process. Laboratory staff should complete the form with the information such as: date and time of destruction, protocol number, notifying authority, the nature of the samples, the laboratory staff member's signature and date, and the Laboratory Director or designee's signature and date. Final sign-off is required from the CRS leader or designee. These records should be kept in the appropriate folder. Specimen inventories should be checked prior to destruction. Any discrepancies should be noted and documented on the form. The CTH-LC will provide the laboratory with a date by which the specimens must be destroyed. This notification also may include any special requirements for destruction or documentation. Confirmation of destruction

will be sent out as requested by the CTH-LC. Specimens will be removed from the specimen storage section of the LDMS.

NOTE: In some cases, it may be necessary to store specimens from participants during the screening process before they enroll in a study. If the participant is deferred from the study during a failed screening attempt, the specimens may be destroyed without MATRIX's authorization. These specimens may be destroyed in real time or batched at the end of the study. Site laboratories are encouraged to verify deferral against their site's screening and enrollment logs to avoid destroying specimens from enrolled participants in error. Specimens from failed screening attempts cannot be shipped away from the site without written approval from the CTH-LC or the protocol team.

Destruction of Samples Not Consented for Long-Term Storage

Study participants who decline long-term storage will be referred to as non-consenters. Samples from non-consenters are destroyed once all protocol-defined testing is complete. *NOTE: Protocol-defined testing may take several years.* Once protocol-defined testing is complete, the CTH-LC will contact the MATRIX Data Center to request site-specific specimen lists for non-consenters. The lists will generally contain PTIDs and location of samples identified by the LDMS laboratory ID or that they were shipped to a non-LDMS laboratory.

On a study-by-study basis, the CTH-LC may request LDMS global specimen IDs or other information to expedite the destruction process. Any other study-specific requirements will be relayed at this point. The MATRIX Data Center will then generate the lists and send to the CTH-LC.

Large Scale Post Study Closure Specimen Destruction/Release

Once studies have been completed, it may be determined that protocol-defined testing is complete and that any remaining samples may no longer be of scientific interest. In these cases, destruction or release of all pending samples may be indicated.

The CTH-LC point of contact (POC) or designee will ensure that the following groups/people have given authorization for sample destruction/release:

- Protocol Chair(s)
- IND holder
- Product developer (if different from IND holder)
- CTH co-lead PIs
- Each CRS IOR

Other parties may be contacted for approval as warranted. If any specific people are no longer available, the decision will be made on consensus of the other people/groups. Once all approvals are obtained, the CTH-LC POC or designee will move towards destruction/release of samples.

TESTING AND WORKFLOW CONSIDERATIONS

Method Validation

All methods, instruments or test kits must be validated. Changes to existing tests and methods require validation. The CTH-LC may request validation documentation for review.

Laboratory Safety

The transmission of HIV and other blood-borne pathogens can occur through contact with contaminated needles, blood and blood products, and bodily fluids. All study personnel must take appropriate blood and secretion precautions when drawing blood and shipping and handling specimens for all MATRIX studies. All CRS and Local Labs will have procedures in place to dispose of all laboratory related waste in compliance with local regulations and to mitigate any environmental hazards.

Document Standards

All laboratory results must be traceable to a defined source document that is the first place a result was recorded, traceable to the date performed and person performing the testing. These must be archived based on the retention policy relevant to each study. Error correction must be performed per MATRIX's Good Documentation Practices (GDP) Policy, which can be found at <https://www.matrix4prevention.org/resources>. Major events in the laboratory need to be documented appropriately (e.g., Note to File, Corrective Action/Preventative Action, etc.) and communicated immediately to the CTH-LC representative.

Training and Competency

All staff records must show education records and work experience appropriate to their job description. All employees, as well as their supervisors, must sign, initial and date their own job description to acknowledge understanding of their responsibilities. All clinical laboratory staff must have documented training and established competency before they are allowed to report test results back to care providers or study clinics or perform certain other laboratory activities (such as phlebotomy). Competency must be re-assessed after the first six months of completion of training, 12 months and annually thereafter. All staff must be listed on a signature log that includes their signature and initials for reference. Key laboratory staff members may be required to sign a Delegation of Duties Log (or equivalent) maintained by CRS research staff.

FACILITY AND MAINTENANCE

Maintenance

CRS and Local Labs have a program of scheduled preventative maintenance for all relevant pieces of equipment. This program must meet manufacturer's specifications and institutional guidelines. This maintenance must be documented and available for review as requested.

Temperature Monitoring

All temperature-sensitive equipment, such as freezers, refrigerators, water baths and incubators, must be monitored on a regular basis. Additionally, all test work areas and reagent storage areas must be monitored on a regular basis. This includes room temperature monitoring where equipment and testing is done as well as where room temperature reagents are stored.

The monitoring program must document temperatures taken, any temperature excursions and corrective action.

All CRS and Local Labs will maintain SOP(s) that describes the frequency of temperature monitoring and related procedures such as certification of thermometers and corrective action. The SOP will be available to the CTH-LC for review on request.

DOCUMENT HISTORY

Version / Date Effective	Summary of Changes	Revised by / Approved by
1 / Nov 2 2023	Original Release	E. Livant / N. Mgodì / S. Hillier / T. Palanee-Phillips

APPROVALS

DocuSigned by:
Ted Livant 11/2/2023

Author's Signature Date (month/day/year)

Signer Name: Ted Livant
 Signing Reason: I am the author of this document
 Signing Time: 11/2/2023 | 2:31:44 PM EDT
 DocuSigned ID: 9E61306A1141D3A698FBE00AECF2FC

Nyaradzo Mgodì 11/2/2023

Clinical Trials Hub Co-lead PT Signature Date (month/day/year)

Signer Name: Nyaradzo Mgodì
 Signing Reason: I approve this document
 Signing Time: 11/2/2023 | 9:33:43 AM PDT
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Sharon Hillier 11/2/2023

Clinical Trials Hub Co-lead PT / Executive Director's Signature Date (month/day/year)

Signer Name: Sharon Hillier
 Signing Reason: I approve this document
 Signing Time: 11/2/2023 | 9:01:35 AM PDT
 DocuSigned ID: 4D66F80A2B1541729992EA42A322B571

Thesla Palanee-Phillips 11/3/2023

Deputy Director's Signature Date (month/day/year)

Signer Name: Thesla Palanee-Phillips
 Signing Reason: I approve this document
 Signing Time: 11/3/2023 | 7:32:24 AM PDT
 DocuSigned ID: 181C61EA1C864278A18EEC3B415A76E3

Certificate Of Completion

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Nyaradzo Mgodl

Timestamp

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
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 elivant@mwri.magee.edu
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 Signing Reason: I am the author of this document
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Thesla Palanee-Phillips
 tpalanee@wrhi.ac.za
 Security Level: Email, Account Authentication (Required)

Thesla Palanee-Phillips

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Intermediary Delivery Events	Status	Timestamp
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Envelope Summary Events	Status	Timestamps
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Completed	Security Checked	11/3/2023 7:32:31 AM

Payment Events	Status	Timestamps
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If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

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If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. Further, you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

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