RUTGERS
Global Tuberculosis Institute
NEW JERSEY MEDICAL SCHOOL

CLOFAZIMINE PROCUREMENT PROTOCOL

1. Treating physician (TP)/consultant in the Northeastern region reaches out to GTBI. If clofazimine is determined to be necessary, GTBI will assist and facilitate FDA process and IRB approval through the Parent project for clofazimine use in drug-resistant TB.

2. TP/consultant will need to provide the following documents or completed forms to GTBI:

Forms					
FDA		Novartis		IRB	
☐	SPIND Form	☐	MAP Shipment Form	☐	FWA Number
☐	FDA FORM 3926	☐	TP Attestation Form	☐	Single Study Authorization Agreement
☐	Patient Sensitivities	☐	LoA	☐	Drug Storage, Handling and Dispensing Agreement
☐	TP CV	☐	Site Contact Form	☐	TP CV
		☐	TP Medical License	☐	Consent Form

3. SPIND, FDA 3926 and patient sensitivities are emailed to Alison Rodgers at the FDA by GBTI.

4. Once IND approval has been received, IND letter, site contact form, and treating physicians medical license are emailed to Novartis.

5. Novartis will email the following documents: Investigator's Brochure, Physician Safety Reporting Training, MAP Shipment Form, MAP Patient Re-Supply Follow up Form, Treating Physician Attestation Form and LoA (required only once for each treating physician).

6. LoA and attestation form are signed by the treating physician and returned to Novartis for drug order to be placed.

7. IRB modification under the Parent Project will be submitted. Once approved/stamped Informed Consent form will be emailed to the treating physician/consultant.

8. Treating physician will have the patient read and sign the informed consent prior to administering clofazimine, report any adverse events, and update on patient's ongoing treatment regularly.

For any questions, please feel free to reach out to Deborah Handler at dh661@njms.rutgers.edu or at 973-972-9100. Thank you.