

M O U
between

**National AIDS Control Organisation,
Ministry of Health and Family Welfare,
Government of India**

&

**Mahatma Gandhi Mission's
Medical College & Hospital, Kamothe,
Navi Mumbai -410 209**

This Agreement is made on 1 day of December 2018 by and between Competent Authority, National AIDS Control Organisation, Ministry of Health and Family Welfare, Government of India, 9th Floor, Chandralok Building, 36, Janpath, New Delhi 110 001 (hereinafter referred to as "NACO (First Party) ")

AND

Mahatma Gandhi Mission's, Medical College, Navi Mumbai (hereinafter referred to as ("Second Party")), run by Mahatma Gandhi Mission, a Public charitable Trust bearing registration number - F- 674(Nanded) having its registered office at - Nanded acting through Dean, MGM Medical College, Kamothe, Navi Mumbai - 410 209, the authorised signatory, hereinafter referred to as "Second Party", which expression shall, unless repugnant to the context, include its successor in business, administrators, liquidators and assigns or legal representatives.

WHEREAS NACO (first Party) is providing first line antiretroviral treatment (hereinafter referred to as ART) to persons living With HIV/AIDS (hereinafter referred to as PLHAs) in India through designated public hospitals as per the guidelines issued by the NACO (first Party) from time to time;

AND WHEREAS NACO (first Party) coordinates the aforementioned provision of ART at designated public hospitals by limiting the selection, procurement, distribution and rational use of drugs, including antiretroviral drugs, and prescribing guidelines for treatment of opportunistic infections and provision of ART;

AND WHEREAS NACO (first Party) is desirous of extending the provision of ART to more PLHAs in collaboration with not-for-profit non-governmental organisations;

Draft Approval

- ① Nabel M. *Nabel* 24/12/18
- ② MS.
- ③ Dean.

AND WHEREAS Mahatma Gandhi Mission's, Medical College, Navi Mumbai (hereinafter referred to as ("Second Party")) an Organization registered under the MGM Trust Registration. It has established a centre to extend AIDS related treatment, care and other services to its employees and their families living with HIV/AIDS and to extend these services to PLHA's in the nearby areas as a part of their corporate social responsibility;

AND WHEREAS the parties hereto had set up a collaborative ART project since 01/12/2018 (month & year) and hereby reduce the terms of the agreement to writing;

NOW THEREFORE THIS AGREEMENT WITNESSES AS FOLLOWS:

I. PURPOSE OF COLLABORATIVE ART PROJECT

The purpose of the present Agreement is to continue the collaborative ART project between NACO (first Party) and second Party that had been a model for high quality provision of ART and associated healthcare and medical management of PLHAs in Maharashtra, India.

II. RESPONSIBILITIES OF NACO

- 1) NACO (first Party) shall continue to organize refresher training or provide support for training of personnel of second Party involved in the collaborative ART project.
- 2) NACO (first Party) shall provide to second Party regular updates on National ART guidelines from time to time as earlier.
- 3) NACO (first Party) and second party shall form a committee comprising of representative from NACO (first Party), Nodal Officer / Director of second Party, which shall supervise and monitor the collaborative ART project to ensure provision of quality services.
- 4) NACO/SACS will continue to provide drugs on a [three] monthly basis on receipt of a requisition/s from second party and certificate of utilization of drugs in a prescribed format supplied earlier.

III. RESPONSIBILITIES of second party

Second party had set up a centre at MGM Medical College & Hospital, Kamothe Navi Mumbai, Maharashtra State and has appointed Dr. Umakant Deshpande, as Nodal Officer for the official contact for the collaborative ART Project.

- 1) Second party represents that it provides various health services to PLHAs, a description of which is set out at Schedule III to the present Agreement.
- 2) Second Party undertakes that it will comply with all the laws for the time being in force in India in the running of the ART centre as done earlier. Second Party has obtained all necessary government approvals and have appointed the necessary staff with the requisite technical qualifications.
- 3) Second Party strictly follows the National ART guidelines (drug regimen as well as physical standards) issued by NACO (first party) from time to time, follow the terms of reference for staff including qualifications as specified by NACO (first Party) and has ensured that mechanisms needed for good treatment adherence are in place.
- 4) Second party shall respect the autonomy and privacy of the patients, and to this end provides pre- and post-test counseling, obtains written informed consent from the patient prior to a test or treatment, and maintains confidentiality of the patients on the principle of shared confidentiality.
- 5) Second Party shall provide for data protection systems to ensure that the confidential records of the patients are computerized and are protected so that they are not accessible to any unauthorized person.
- 6) Second Party shall provide a copy of all medical records to the patients on their request.
- 7) Second Party shall provide all health services related to provision of ART and treatment of opportunistic infections, including those listed in Schedule III, free of cost to patients who require treatment. Second Party shall not deny services to any person living with HIV on any ground. The ARV drugs used for community will be supplied by NACO/SACS.
- 8) Second Party shall maintain all the registers and reporting formats as per NACO (first party) ART guidelines. They will send report of all adverse drug reactions to NACO (first party).
- 9) Second Party shall use standard NACO (first Party) Monitoring and Evaluation tools.

- 10) Second party shall provide standard, regular monthly reports of patient numbers and relevant details for the previous month to NACO (first party) by the 4th of each month in prescribed formats in accordance with the guidelines laid down by NACO (first Party) from time to time. NACO (first Party) will be free to use the data so sent to them in an anonymous manner.
- 11) Second party shall provide details of the ART team at their centre along with the names and technical qualifications of the staff in case of any change to NACO (first party) from time to time.
- 12) Second party shall entirely bear the costs related to the staff's salary (doctors, counselors, pharmacist, nurses, medical records officer and administrative staff) and the cost related to the infrastructure. Second party represents that it has enough funds to run the programme for the next three / five years. Second party will permit NACO (first party) to inspect its documents relating to the balance sheets, profit and loss accounts, grants and donors, financial and other documents so that NACO (first party) can verify the representation of sustainability of the collaborative ART project.
- 13) NACO/SACS will provide drugs for ART on receipt of a requisition/s from second party and certificate of utilization of drugs in a prescribed format supplied earlier.
- 14) Second party has already established a network with NGOs involved in HIV care and support as well as with the Indian Network for People Living With HIV/AIDS or PIHA groups in the area for increasing access to treatment and for follow-up support.
- 15) The designated representatives of second party shall continue to attend the coordination meeting with NACO (first party) at their own costs.
- 16) Second party shall not permit research or clinical trial, whether relating to the allopathic system of medicine or any alternate system of medicine or any combination thereof, at the designated ART centre, except with the approval of the Drugs Controller General of India for the conduct of such clinical trial. Further, in the event of an approved clinical trial, the Party of the Second Part will ensure that ethical protocols are complied with.
- 17) Use of any data obtained by second party during the course of its collaborative ART project shall be done in an anonymised manner such that the identity of the patients enrolled at the collaborative ART project is not revealed in any manner.
- 18) Second party shall maintain the records for a period of five years from the time that this Agreement is terminated or lapses by efflux of time.

- 19) Second party shall constitute a grievance redressal mechanism. [A model grievance redressed mechanism is annexed hereto.] Further, second party shall forward to NACO (first party) in an anonymised manner the nature of complaints received and action taken thereon on a monthly basis.
- 20) Second party shall continue to provide space, CD 4 machine and staff for the ART center.

IV. COMMENCEMENT

- 1) This Agreement shall become effective upon signature by both the Parties and It shall remain in full force from the last date of renewal till completing of 3 yrs of agreement.

V. RENEWAL OF AGREEMENT

- 1) This Agreement is renewable at the option of NACO (first party) and second party.
- 2) Six months prior to the expiry of the Agreement due to efflux of time NACO (first party) shall intimate second party if it intends to renew or not to renew the Agreement.
- 3) In the event that second party decides not to renew the Agreement, second party shall intimate three month in advance to NACO (first party) about its inability to continue to provide treatment free of charge to the patients enrolled. If second party fails to continue to provide treatment free of charge or expresses its inability to do so, they shall give notice to the patients and NACO (first party) about this and refer the patients to the nearest government hospital providing treatment for opportunistic infections and ART, as directed by NACO (first party). Further, upon such referral, second party shall forthwith forward a copy of all medical records of the patients to such hospital and to NACO (first party) or a person designated by NACO (first party) to receive such medical records. Thereupon, NACO (first party) will be responsible for ensuring that the patients continue to receive the drugs.
- 4) In the event that NACO (first Party) desires to renew the Agreement, the terms and conditions of this Agreement, as may be amended, will apply *de novo*. It is made expressly clear that in that event, second party will have to re-apply for and re-obtain certification.
- 5) Both parties shall ensure that there is no treatment interruption of the patients.

VI. TERMINATION OF AGREEMENT

- 1) The second party shall ensure that the infrastructure and manpower at centre is provided as per operational guidelines and in event of any deficiencies / reduction/withdrawal of space or staff, NACO (first party) (GOI) will exercise its option to terminate the agreement unilaterally
- 2) Any party may terminate this Agreement without giving any reasons after giving three months notice to the other party at the address provided in this Agreement for correspondence or the address last communicated for the purpose and acknowledged in writing by the other party.
- 3) On such notice of termination being received by any party, second party shall intimate NACO (first party) about its inability to continue to provide treatment free of charge to the patients enrolled. If second party cannot continue to provide treatment free of charge, they shall give notice to the patients and NACO (first party) about this and refer the patients to the nearest government hospital providing treatment for opportunistic infections and ART, as directed by NACO (first party). Further, upon such referral, second party shall forthwith forward a copy of all medical records of the patients to such hospital and to NACO (first party) or a person designated by NACO (first party) to receive such medical records. Thereupon, NACO (first party) will be responsible for ensuring that the patients continue to receive the drugs.

VII. BREACH BY second party

- 1) In case second party is not able to provide services as per agreement or defaults on the provision of this Agreement or declines the patients to provide medication or directly or indirectly makes any charges for the treatment of opportunistic infections or ART or otherwise enters into any malpractices, it shall be liable for breach of agreement and breach of trust and other consequences which may include black listing with NACO (first party), MOHFW, Ministry of Home affairs and External Affairs. This action shall also be intimated to their parent/ International NGO also for necessary action by them.
- 2) If second party is found to have made any charges for the treatment which was to be given free of charge under this Agreement or to have not provided the medicines to the named patients or to have otherwise misappropriated the funds or goods released by NACO (first party) to second party, then without prejudice to any other right or consequence or mode of recovery, NACO (first party) may recover the amount thereof from second party and/or its office bearers as arrears of land revenue.

VIII. SETTLEMENT OF DISPUTES

1. Any dispute or difference or question arising at any time between the parties hereto arising out of or in connection with or in relation to this Agreement shall be referred to and settled by arbitration under the provisions of the Arbitration and Conciliation Act, 1996 or any modification or replacement thereof as applicable for the time being in India.
2. The arbitration shall be referred to an arbitrator nominated by Secretary Department of Legal Affairs, Ministry of Law and Justice, Govt. of India Delhi. The Arbitrator may, if he so feels necessary, seek opinion of any health care personnel with experience of working in the field of HIV and care and treatment of PLHAs.
3. The place of arbitration shall be either New Delhi or the site of the collaborative ART project, which shall be decided by the arbitral tribunal bearing in mind the convenience of the parties.
4. The decision of the arbitrator shall be final and binding on both the parties.

LAW APPLICABLE.

This Agreement shall be construed and governed in accordance with the laws of India.

IX. ADDRESSES FOR CORRESPONDENCE

In witness thereof, the parties herein have appended their respective signatures the day and the year above stated.

<p>Signed For and on behalf of</p> <p>Mahatma Gandhi Mission's, Medical College, Navi Mumbai</p> <p>(Dr. Umakant Deshpande Nedal Office Dr. U. N. Deshpande Associate Professor Medicine Dept. MD Medicine MGM Medical College & Hospital Kamothe Reg. No. 32848</p> <p>Signature..... Date... 11/11/09...</p> <p>In the presence of Name and Signature (Mrs. Harapriya Kar)</p> <p>Date ... 11/11/09...</p>	<p>Signed For and on behalf of</p> <p>Competent authority NACO</p> <p>Signature</p> <p>Date.....</p> <p>In the presence of</p> <p>Name and Signature</p> <p>Date.....</p>
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[In case the contract is entered into by the President through the NACO, this needs to comply with the Rules of Business laid down in this behalf.] : Competent Authority , NACO

SCHEDULE I

MODEL LIST OF DRUGS TO BE PROVIDED BY NACO TO Second Party

S.no	LIST OF ARV DRUGS
	Adults
1.	Zidovudine 300mg + Lamivudine 150mg
2	Zidovudine 300 + Lamivudine 150 + Nevirapine 200
3	Tenofovir 300 mg + Lamivudine 300 mg + Efavirenz 600 mg
4	Tenofovir 300 mg + Lamivudine 300 mg
5	Nevirapine tablet/Suspension 200 mg/50 mg
6	Efavirenz 200 mg, 600 mg
7	Lopinavir 400 mg / ritonavir 100 mg
8	Atazanavir 300 mg / ritonavir 100mg
	Paediatric
9	Tablet. Zidovudine 60 + Stavudine 30
10	Tablet. Zidovudine 60 + Stavudine 30 + Nevirapine 50
11	Tablet. Abacavir 60 + Lamivudine 30
12	Tablet. Efavirenz 50 mg
13	Lopinavir / ritonavir 100/25 tablet
14	Lopinavir / ritonavir syrup

SCHEDULE II

MODEL FOR A ONE YEAR AGREEMENT

<u>Year</u>	<u>Centre</u>	<u>Number of PLHAs for whose treatment stock is to be provided</u>
2018-19		

SCHEDULE III

MODEL OF DESCRIPTION OF SERVICES PROVIDED / PROPOSED TO BE PROVIDED

Address of site	Mahatma Gandhi Mission's, Medical College, Kamothe, Navi Mumbai
Outpatient	As per Statistics attached
Days	Monday to Saturday
Timings	08.30 am to 03.30 pm(As per hospital timings)
Inpatient care	24 Hours
Number of patients registered	As per Statistics attached
Number of patients receiving ART	As per Statistics attached
Average number of patients attending OPD everyday	As per Statistics attached
Criteria followed in administering ARVs	As per NACO Guidelines
Treatment for OIs	As per NACO Guidelines
First line regimen	TLE/EFV
Description of follow-up of patients	As per NACO Guidelines
Facilities available	As per NACO Guidelines for ART Center
Personnel and their qualifications	As per NACO Guidelines for ART Center

ANNEXURE

MODEL GRIEVANCE REDRESSAL MECHANISM

[Note: This portion has been taken from the draft law on HIV/AIDS and it would be advisable for MGM Medical College & Hospital, Navi Mumbai to constitute a grievance redressal mechanism at the outset.]

- (a) Second party shall appoint a person of senior rank, working full time in the organisation, as the Complaints Officer, who shall, on a day-to-day basis, deal with complaints received from an aggrieved person or an authorised representative of such person.
- (b) Every aggrieved person or an authorised representative of such person, who has a grievance against the second party about the services provided or refused, has the right to approach the Complaints Officer to attend to such complaint and shall be informed of such rights by second party.
- (c) The Complaints Officer may inquire *suo motu*, and shall inquire, upon a complaint made by any aggrieved person or authorised representative of such person, into the complaint.
- (d) The Complaints Officer shall act in an objective and independent manner when inquiring into complaints made.
- (e) The Complaints Officer shall inquire into and decide a complaint promptly and, in any case, within seven working days. Provided that in cases of emergency, the Complaints Officer shall decide the complaint within one day.
- (f) The Complaints Officer, if satisfied that there has been an unfair/arbitrary refusal of services or deficiency in the services provided, shall (i) first direct second party to rectify the cause of the grievance, (ii) then counsel the person alleged to have committed the act and require such person to undergo training and social service. Upon subsequent violations by the same person, the Complaints Officer shall recommend to second party to, and the institution shall, initiate disciplinary action against such person.
- (g) The Complaints Officer shall inform the complainant of the action taken in relation to the complaint.

Assistance to ART Centres in various sectors under NACP

Component	Public Health Sector	Remarks
	Medical Colleges, Distt. Hosp.	
Land	Available	
Infrastructure Development	√	Under NACP-III
Equipment (CD4 machine)	√	
Additional Human Resources	√	
Diagnostic Kits (HIV/CD4)	√	
ARV Drugs (First Line)	√	
Drugs for Opportunistic Infections	Can be done as per cost effective/ Govt rates	
Training of key personnel	√	TA/DA by sponsoring agency
IEC material	√	
Operational Costs	√	