

Agreement

VC:-385083

This agreement made and entered into at Mumbai on 01st day of September 2019 (Effective Date), between **Reliance Life Sciences Pvt. Ltd.**, a Company incorporated under the Company's Act, 1956 having its registered office at Dhirubhai Ambani Life Sciences Centre, R - 282, TTC area of MIDC, Thane - Belapur Road, Rabale, Navi Mumbai 400 701, Maharashtra, India. (Hereinafter referred to as "RLS") which expression shall unless repugnant to the context shall mean and include its successors and assigns of the ONE PART.

AND

Mahatma Gandhi Mission Medical College & Hospital a Registered Blood Bank having its office at Kamothe, Sector-18, Navi Mumbai, Dist. Raigad - 410209, Maharashtra (Hereinafter referred to as "MGMMCH") which expression shall unless repugnant to the context shall mean and include its Board of Directors, Officers and its medical staff of the OTHER PART.

Whereas:

- A. **MGMMCH** has represented to **RLS** that **MGMMCH** is registered, as a Private blood bank and is located at Navi Mumbai, Maharashtra.
- B. **MGMMCH** has represented to **RLS** that they possess necessary and valid license in form 26G to separate human plasma from human whole blood, as prescribed in Drugs & Cosmetics Act 1940 and Rules thereafter, as amended and applicable from time to time. A copy of the valid license in Form 26G is provided to **RLS** and is attached hereto to this Agreement as Annexure 4.
- C. **MGMMCH** has represented to **RLS** that they possess expertise, adequate resources, manpower and infrastructure in collection, processing and storing plasma.
- D. **RLS**, inter alia, is engaged in research and development in biotechnology and Plasma products.
- E. **MGMMCH** separates blood components from donated blood and has offered to supply to **RLS** surplus plasma to enable **RLS** to carry out research, product development and commercial initiative using plasma.
- F. Based on the representations made by **MGMMCH**, **RLS** has agreed to procure surplus fresh frozen plasma or stored plasma from **MGMMCH** on the terms and conditions as stated hereunder.



IN CONSIDERATION OF THE COVENANTS AND CONDITIONS SET FORTH HEREIN, THE PARTIES AGREE TO THE FOLLOWING:

1. Definitions

The following terms shall unless the context otherwise requires, have the meaning ascribed to them below

| | | | |
|----|-----------------|----|---|
| 1 | Plasma | :- | Plasma is liquid portion separated from human Blood. |
| 2 | FFP | :- | FFP (Fresh frozen plasma) is plasma separated from whole blood and stored and frozen at or below -30°C within 6 hrs of blood collection. |
| 3 | SP | :- | SP (stored plasma) is plasma separated from whole blood after 6 hrs and within 72 hrs of blood collection which is stored at or below -20°C . |
| 4 | "Elisa" | :- | Enzyme linked immunosorbent assay |
| 5 | Anti-"HIV" test | :- | Testing of HIV 1 and 2 (Human Immunodeficiency Virus) antibodies in plasma/serum. |
| 6 | Anti-"HCV" Test | :- | Testing of HCV (Hepatitis C Virus) antibodies in Plasma/serum |
| 7 | HbsAg | :- | Testing of Hepatitis B surface antigen in plasma/serum |
| 8 | VDRL | :- | Testing of Sexually Transmitted Diseases. |
| 9 | Unit | :- | Blood bag containing Plasma from one donor. |
| 10 | CDP | :- | Cryo Deficient Plasma – Plasma remaining after separation of cryoprecipitate and stored at -30°C |

2. Responsibilities

a. **MGMMCH** shall separate plasma from blood collected from voluntary non-remunerated donors as per the Part XB of Drugs and Cosmetics Act, 1940 as amended from time to time and as per the establishment of National Blood Policy.

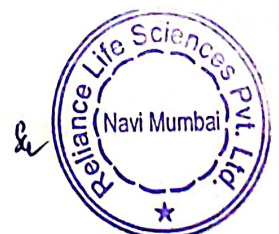
b. **MGMMCH** represents and warrants that **MGMMCH** has obtained and ensures the validity and effectiveness of all approvals, licenses, permits, permissions, sanctions applicable for collection, storage, processing, distribution of Human Blood, Human Blood components & Blood Products.

c. **MGMMCH** shall supply Fresh frozen plasma (FFP) to **RLS** of such quality and quantity (in units) as agreed under in this Agreement.

d. **MGMMCH** shall perform the anti- HIV, HBsAg, HCV and VDRL and certify that the plasma supplied to **RLS** are tested negative by Elisa for HIV, HBsAg, HCV and VDRL tests on the plasma before supplying it to **RLS**.

e. **MGMMCH** shall be responsible for labeling and packing of Units to be supplied to **RLS**, as per the guidelines laid down by FDA. **MGMMCH** shall certify that the minimum requirements with regard to the regulations on labeling, packing and dispatch have been observed in accordance with Drugs and Cosmetics Act 1940 and rules prevailing from time to time.

f. **MGMMCH** shall ensure the validity and effectiveness of all approvals, licenses, permits permissions applicable for collection, storage, processing, distribution of human blood, human blood components and blood products till the term of this



Agreement and shall provide copies of the same to **RLS**. **MGMMCH** also undertakes to renew the license from time to time prior to expiry

g. **MGMMCH** warrants that the plasma shall be supplied to **RLS**, within 12 months of its date of manufacture.

h. **MGMMCH** shall be responsible to provide the list of units supplied with each consignment. Certificate of Testing and the list of plasma units supplied will be provided as per the format given in Annexure 1 and Annexure 2.

i. **MGMMCH** shall supply Plasma solely to **RLS** during the term of the Agreement.

j. **RLS** should inform **MGMMCH** forthwith regarding any cancellation or suspension of the license or consent issued by authority for collection, transportation and manufacturing / research of life-saving plasma proteins from Fresh Frozen Plasma.

k. **MGMMCH** should inform **RLS** forthwith regarding any cancellation or suspension of the license or consent issued by authority for blood collection, component separation and other related activities.

3. Vendors Audit

Without prejudice to the contents of Article 2, **RLS** shall be entitled, but not obliged, to conduct audit of the facility of **MGMMCH** for verification of the quality or quantity of the plasma agreed to be supplied by **MGMMCH** to **RLS**.

4. Financial Arrangements

a. **RLS** shall from time to time coordinate with **MGMMCH** for supply of plasma.

b. **MGMMCH** shall charge **RLS @ Rs. 2200/- per liter for FFP** supplied to **RLS** in accordance with this agreement.

c. **MGMMCH** shall raise invoice on **RLS** for the said supply hereto, and shall be mailed to **RLS** at the address mentioned in article 16 herein.

d. The volume of plasma in each bag will be calculated by the following formula

Volume of Plasma in bag = (Weight of filled plasma bag – weight of empty plasma bag) / 1.03

5. Logistics

The parties shall mutually decide as to the logistics of the Units to be delivered from **MGMMCH** to **RLS**'s site. **RLS** would supply the necessary secondary packing materials free of cost and also bear the cost of transportation of Plasma from **MGMMCH** to **RLS**.

6. Representations and Warranties by **MGMMCH**

a. **MGMMCH** is a valid and subsisting duly registered Blood Bank and is not extinguished either by the Settlor or by any other statutory authority.

b. **MGMMCH** is entitled and has authority to enter into this Agreement.



c. **MGMMCH** has not done anything or omitted to do anything which would in any manner affect or prejudice the rights and obligations of **RLS** under this Agreement.

d. **MGMMCH** has obtained all the necessary Licenses, clearances, and permissions from the authorities concerned as are required for entering this Agreement and shall maintain valid throughout the Term of this Agreement, and all the requisite approvals, licenses, permissions, etc., as may be required under law for the time being in force.

e. Plasma supplied to **RLS** shall meet the specifications attached hereto as Annexure 3 (Specifications) and made a part hereof. If Specifications are revised during the term of this agreement both parties will agree to all revisions prior to implementation.

f. Plasma provided to **RLS** hereunder is not adulterated or misbranded within the meaning of Drugs and Cosmetics Act as amended from time to time.

7. Representations and Warranties by RLS

a. **RLS** is a corporation duly organized and existing under the laws of its incorporation.

b. **RLS** is entitled and has authority to enter into this Agreement.

c. **RLS** has not done anything or omitted to do anything which would in any manner affect or prejudice the rights and obligations of **MGMMCH** under this Agreement.

d. **RLS** has obtained all the necessary clearances and permissions from the authorities concerned as are required for entering this Agreement.

8. General Provisions

All consignments of plasma shall be accompanied by the following:

a. Batch release certificate to the effect that they were prepared in accordance with the local regulatory requirements for Blood and Blood Banks. The Protocol and its annexes may be amended or supplemented by the Parties to this Agreement.

b. List of plasma units supplied to **RLS** on letterhead of **MGMMCH** duly signed by the authorized person as per format in Annexure 2.

c. **RLS** is entitled to retest the plasma in minipools each comprising 10-12 individual plasma units for HIV – I & II antibodies, HBsAg, and HCV- PCR.

d. In the case of discrepancy between the physical units received and the list of plasma units provided by **MGMMCH**, **RLS** shall be entitled to reject the plasma units with discrepancy if appropriate clarifications are not received from **MGMMCH** within two weeks from intimation by **RLS**, without any costs or consequences.

e. Neither party will be liable to the other party for any indirect, incidental, consequential, special or punitive damages including but not limited to loss of production, loss of income or loss of profits arising out of claims brought by the other party to this agreement.



9. Indemnification

Each party agrees and undertakes to indemnify and keep the other party harmless from and against all costs, expenses, claims, liabilities, penalties etc., which the other party might incur on account of a breach of the representation and warranties furnished by each party under this agreement or any act of gross negligence and / or willful misconduct in performance of its obligations hereunder.

10. Intellectual Property Rights and confidentiality.

- a. All rights to inventions or discoveries arising from the use of plasma supplied by **MGMMCH** to **RLS** shall solely vest with **RLS**.
- b. **RLS** and **MGMMCH** shall maintain utmost secrecy about all data, particular methods, recipes, formulas, details, drawings and other confidential proprietary information exchanged between them (all this information is called confidential information).
- c. This confidential information shall be used by the parties for purpose of this agreement only and the same shall not be divulged, disclosed or communicated to any third party without prior written permission of **RLS** or **MGMMCH** as the proprietors of such confidential information as the case may be.
- d. However, restrictions as to confidentiality shall not be applicable to such information which are:
 - i. In a public domain without any breach on the part of any of the parties to this agreement.
 - ii. The receiving party is already in possession of such information.
 - iii. Is independently developed by such party.
 - iv. Is required to be disclosed under the applicable laws or under statutory requirements.

11. Term

This Agreement shall commence on the date of signing by both the parties and shall continue for a period of Two (2) years from the Effective Date. The parties have the option to extend the Agreement at terms mutually agreed upon by both the parties unless earlier terminated.

12. Termination

- a. Either party may terminate this Agreement with or without giving any reasons whatsoever by giving 30 days prior written notice of to the other party.
- b. In the event of breach non defaulting party shall be entitled to terminate the agreement by providing written notice, of 30 days to the defaulting party. If defaulting party fails to remedy the breach within 30 days of receiving notice, this agreement shall terminate immediately upon expiry of the aforementioned 30 days period.
- c. Either party may terminate the agreement immediately in the event any law or government-enacted regulation or decree renders the performance by a Party of its



obligations hereunder onerous or otherwise inexpedient; or as mutually agreed by both the parties.

d. Upon expiry of the Agreement for any reason, **MGMCH** shall promptly return to **RLS** all the written instructions, if any, issued by **RLS**.

13. Amendments

Any amendments or modifications of this Agreement may only be made upon mutual consent and have to be made in writing.

14. Arbitration

The parties shall attempt in good faith to resolve promptly any dispute arising out of or relating to this Agreement by negotiation. If the matter cannot be resolved in the normal course of business any interested party shall give the other party written notice of any such dispute not resolved, after which the dispute shall be referred to more senior executives of both parties, who shall likewise attempt to resolve the dispute. In case an amicable settlement of disputes arising in connection with the present Agreement or further agreements resulting thereof is not possible within 30 days of the arising of dispute, such disputes shall be referred to a sole Arbitrator acceptable to both parties under the provisions of the Arbitration and Conciliation Act, 1996. The place of arbitration shall be Mumbai and language of the arbitration shall be English.

15. Governing Law & Jurisdiction

This Agreement shall be governed by and construed in accordance with Indian Law. It is mutually agreed by and between the parties hereto that only an appropriate court of jurisdiction in Mumbai shall be entitled to entertain and try any disputes arising out of or in connection with the Arbitration under Article 14 hereto.

16. Notices

All notices in context of this Agreement will be served to the following persons as per the address detailed.

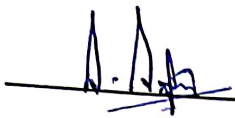
Dr. Seema Gupta (Medical Officer)
Mahatma Gandhi Mission Medical College & Hospital
Kamothe,
Sector-18,
Navi Mumbai,
Dist. Raigad - 410209,
Maharashtra.

Mr. Sasi Kumar
Reliance Life Sciences Pvt. Ltd.
R – 282, TTC area of MIDC,
Thane Belapur Road,
Rabale,
Navi Mumbai 400 701.



IN THE WITNESS WHEREOF THE PARTIES hereto, have subscribed their hands to this Agreement on the day and year first here in above written,

Reliance Life Sciences Pvt. Ltd.

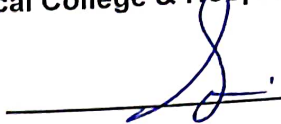
By: 

Name: Mr. Sasi Kumar

Title: Head – Plasma Proteins



**Mahatma Gandhi Mission
Medical College & Hospital**

By: 

Name: Dr. G. S. Narshetty

Title: Dean **Dean.**

**M.G.M Medical College & Hospital
Kamouli, Navi Mumbai - 410209**

