L#:

PUBLIC HEALTH SERVICE
BIOLOGICAL MATERIALS LICENSE AGREEMENT

This **Agreement** is entered into between the National Institutes of Health ("**NIH**") or the Food and Drug Administration ("**FDA**"), hereinafter singly or collectively referred to as "**PHS**", agencies of the United States Public Health Service within the Department of Health and Human Services ("**HHS**") through the Office of Technology Transfer, **NIH**, having an address at 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, U.S.A. and _____ ("**Licensee**"), a corporation of _____, having an office at _____.

1. Definitions:

(a) "**Materials**" means the following biological materials including the **Progeny** and **Unmodified Derivatives** thereof: _____(" **Original Material**", as described in _____ _____ and developed in the laboratory of _____.

(b) "**Licensed Products**" means the **Materials** and the **Pluripotent Modifications, Non-Pluripotent Modifications, Modified Derivatives** of the **Materials** _____.

(c) "**Net Sales**" means the total gross receipts by **Licensee** for sales of **Licensed Products** or from income from leasing, renting, or otherwise making **Licensed Products** available to others without sale or other dispositions transferring title, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by **Licensee**, or for the cost of collections.

(d) **"Licensed Field of Use**" means the use, sale, lease, rent, or making available of **Licensed Products** as research reagents only. For avoidance of doubt, the **Licensed Field of Use** specifically excludes the use, sale, lease, rent, or making available of **Licensed Products** for clinical or diagnostic uses _____.

(e) **"iPSCs"** means induced pluripotent stem cells derived from non-embryonic cells but which are "reprogrammed" to assume an embryonic stem cell-like state, by being forced to express genes and factors important for maintaining the defining properties of embryonic stem cells.

(f) **"Progeny"** means unmodified descendants from the **Original Material**.

(g) **"Unmodified Derivatives"** means substances which constitute an unmodified functional subunit or product expressed by the **Original Material**.

(h) **"Non-Pluripotent Modifications"** means cells created by **Licensee** which contain or incorporate the **Materials** or which are created through the use of the **Materials**, but only if such substances do not remain capable of self renewal in culture and cannot differentiate into various cell types from each of the three embryonic germ layers (endoderm, ectoderm, mesoderm).

(i) **"Pluripotent Modifications"** means cells created by **Licensee** that contain or incorporate the **Materials**, but only if such substances are capable of self-renewal in culture and can differentiate into various cell types from each of the three embryonic germ layers (endoderm, ectoderm, mesoderm), including genetically modified and cloned cell lines.

(j) **"Modified Derivatives**" means substances that are isolated or derived from **Non-Pluripotent Modifications** and **Pluripotent Modifications** by **Licensee** and that could not have been isolated or derived from **Original Material** or **Progeny**.

2. **Licensee** desires to obtain a license from **PHS** to use the **Materials** provided under this **Agreement** in its commercial research or product development and marketing activities. **Licensee** represents that it has the facilities, personnel, and expertise to use the **Materials** or the **Licensed Products** for commercial purposes and agrees to expend reasonable efforts and resources to develop the **Materials** or the **Licensed Products** for commercial use or commercial research.

3. **PHS** hereby grants to **Licensee**:

(a) a worldwide, non-exclusive license to make, have made, and use the **Materials** or the **Licensed Products**; and

(b) a worldwide, non-exclusive license to sell and have sold, to offer to sell the **Licensed Products** in the **Licensed Field of Use**.

4. In consideration of the grant in Paragraph 3, **Licensee** hereby agrees to make the following payments to **PHS**:

(a) Within sixty (60) days of its execution of this **Agreement**, a noncreditable, nonrefundable license issue royalty of _____ dollars ($X).

(b) A nonrefundable minimum annual royalty of _____ dollars ($X) which shall be due and payable on January 1 of each calendar year and may be credited against earned royalties for sales made in that year. The minimum annual royalty for the first calendar year of this **Agreement** is due and payable within sixty (60) days from the effective date of this **Agreement** and may be prorated according to the fraction of the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1.

(c) An earned royalty of _____ percent (X%) of **Net Sales**, which shall be due and payable within sixty (60) days of the end of each calendar year.

(d) All payments required under this **Agreement** shall be paid in U.S. dollars and payment options are listed in Appendix C. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due.

i) Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by **Licensee**; and

ii) Additional royalties may be assessed by **PHS** on any payment that is more than ninety (90) days overdue at the rate of one percent (1%) per month. This one percent (1%) per month rate may be applied retroactively from the original due date until the date of receipt by **PHS** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent **PHS** from exercising any other rights it may have as a consequence of the lateness of any payment.

5. Upon receipt by **PHS** of the license issue royalty and the prorated first year minimum annual royalty and verification of these royalties, **PHS** agrees to provide **Licensee** with samples of the **Materials**, as available, and to replace these **Materials**, as available, at reasonable cost, in the event of their unintentional destruction. **PHS** shall provide the **Materials** to **Licensee** at **Licensee's** expense and as specified in Appendix A.

6. **Licensee** agrees to make written reports to **PHS** within sixty (60) days of December 31 for each calendar year. This report shall state: the number, description, and aggregate **Net Sales** of **Licensed Products** made, sold, or otherwise disposed of; the total gross income received by **Licensee** from leasing, renting, or otherwise making **Licensed Products** available to others without sale or other disposition transferring title, during the calendar year; and the resulting calculation of earned royalties due **PHS** pursuant to Paragraph 4(c) and as shown in the example in Appendix B. The report shall also include the name, address and contact information of the individuals and/or entities to which **Licensee** has made available the **Materials** and **Licensed Products**. **Licensee** shall submit each report to **PHS** at the Mailing Address for **Agreement** notices indicated on the Signature Page.

7. **Licensee** agrees to lease, sell, license, rent or make available the **Materials** or **Licensed Products** to third parties only after such third parties agree, in writing that:

(a) the **Materials** or **Licensed Products** shall be used as research reagents only;

(b) the **Materials** or **Licensed Products** shall be used in compliance with all applicable statutes, regulations, and guidelines, including **PHS** and **HHS** regulations and guidelines, or if the use is in a location outside of the United States, the use shall be in compliance with the applicable laws and regulations of that country;

(c) the **Materials** or **Licensed Products** shall be used only in compliance with the most current U.S. National Institutes of Health guidelines on human stem cell research;

(d) the **Materials** or **Licensed Products** shall not be used in research in which human iPS cells or derivatives thereof are introduced into non-human primate blastocysts;

(e) no ownership rights to the **Materials** or **Licensed Products**, including to any of the **Materials** contained or incorporated in **Non-Pluripotent Modifications** or **Pluripotent Modifications** are conveyed;

(f) not to identify or contact the donor subject from whom the **Materials** or the **Licensed Products** were derived;

(g) notify **PHS** (at the address provided) of any transfer or distribution of the **Materials** or **Licensed Products;** and

(h) not to use the **Materials** or the **Licensed Products** for research involving human subjects or clinical trials in the United States without complying with 21 C.F.R. Part 50 and 45 C.F.R. Part 46.

8. **Licensee** agrees to supply the laboratory of Dr. _____, at **PHS**, at no charge, reasonable quantities of the **Licensed Products** that **Licensee** makes, uses, sells, or offers for sale or otherwise makes available for public use. **Licensee** also agrees to supply, to the Mailing Address for **Agreement** notices indicated on the Signature Page, the Office of Technology Transfer, **NIH** with inert samples of the **Licensed Products** or their packaging for educational and display purposes only.

9. This **Agreement** shall become effective on the date when the last party to sign has executed this **Agreement**, unless the provisions of Paragraph 25 are not fulfilled, and shall expire _____ (X) years from this effective date, unless previously terminated under the terms of Paragraphs 16 or 17.

10. As part of **Licensee's** performance under this **Agreement**, **Licensee** agrees to make the **Licensed Products** available to the public within _____ (X) months from the effective date of this **Agreement**.

11. **Licensee** agrees to retain control over the **Materials** and the **Licensed Products**, and not to distribute them to third parties without the prior written consent of **PHS** except as provided in Paragraph 3.

12. This **Agreement** does not preclude **PHS** from distributing the **Materials** or the **Licensed Products** to third parties for research or commercial purposes.

13. **Licensee** agrees not to identify or contact the donor subject from whom the **Materials** or the **Licensed Products** were derived.

14. By this **Agreement**, **PHS** grants no patent rights expressly or by implication to any anticipated or pending **PHS** patent applications or issued patents.

15. Exclusive of any **PHS** or any third-party rights therein, **Licensee** retains ownership of: (a) **Non-Pluripotent Modifications**, (b) **Pluripotent Modifications,** and (c) those substances created through the use of the **Materials**, **Non-Pluripotent Modifications** or **Pluripotent Modifications** of the **Materials**.

16. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE **MATERIALS** PROVIDED TO **LICENSEE** UNDER THIS **AGREEMENT**, OR THAT THE **MATERIALS** OR THE **LICENSED PRODUCTS** MAY BE EXPLOITED WITHOUT INFRINGING THE PATENT RIGHTS OF ANY THIRD PARTIES. **Licensee** accepts license rights to the **Materials** and the **Licensed Products** "as is", and **PHS** does not offer any guarantee of any kind.

17. **Licensee** agrees to indemnify and hold harmless the United States Government from any claims, costs, damages, or losses that may arise from or through **Licensee's** use of the **Materials** or the **Licensed Products**. **Licensee** further agrees that it shall not by its action bring the United States Government into any lawsuit involving the **Materials** or the **Licensed Products**.

18. **Licensee** may terminate this **Agreement** upon sixty (60) days written notice to **PHS**.

19. **PHS** may terminate this **Agreement** if **Licensee** is in default in the performance of any material obligation under this **Agreement**, and if the default has not been remedied within ninety (90) days after the date of written notice by **PHS** of the default.

20. Within thirty (30) days of the termination or expiration of this **Agreement**, **Licensee** agrees to return all **Materials** and the **Licensed Products** to **PHS**, or provide **PHS** with written certification of their destruction.

21. Within ninety (90) days of termination or expiration of this **Agreement**, **Licensee** agrees to submit a final report to **PHS**, and to submit to **PHS** payment of any royalties due. **Licensee** may not be granted additional **PHS** licenses if this final reporting requirement is not fulfilled.

22. **Licensee** is encouraged to publish the results of its research projects using the **Materials** or the **Licensed Products**. In all oral presentations or written publications concerning the **Materials** or the **Licensed Products**, **Licensee** shall acknowledge the contribution of Dr. _____ and the **PHS** agency supplying the **Materials**, unless requested otherwise by **PHS** or Dr. _____.

23. This **Agreement** shall be construed in accordance with U.S. Federal law, as interpreted and applied by the U.S. Federal courts in the District of Columbia. Federal law and regulations shall preempt any conflicting or inconsistent provisions in this **Agreement**. **Licensee** agrees to be subject to the jurisdiction of U.S. courts.

24. This **Agreement** constitutes the entire understanding of **PHS** and **Licensee** and supersedes all prior agreements and understandings with respect to the **Materials** or the **Licensed Products**.

25. The provisions of this **Agreement** are severable, and in the event that any provision of the **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, the invalidity or unenforceability of any provision of this **Agreement**, shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

26. Paragraphs 7, 13, 16, 17, 20, 21 and 22 of this **Agreement** shall survive termination or expiration of this **Agreement**.

27. The terms and conditions of this **Agreement** shall, at **PHS'** sole option, be considered by **PHS** to be withdrawn from **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by **PHS** within sixty (60) days from the date of **PHS** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

PHS BIOLOGICAL MATERIALS LICENSE AGREEMENT

SIGNATURE PAGE

In Witness Whereof, the parties have executed this **Agreement** on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For **PHS**:

_____**DRAFT**_____ _____
Richard U. Rodriguez Date
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

Mailing Address or E-mail Address for **Agreement** notices and reports:

Chief, Monitoring & Enforcement Branch
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

E-mail: LicenseNotices_Reports@mail.nih.gov

For **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of **Licensee** made or referred to in this document are truthful and accurate.):
by:

_____ **DRAFT** _____ _____
Signature of Authorized Official Date

_____
Printed Name

_____
Title

I. Official and Mailing Address for **Agreement** notices:

_____
Name

_____
Title

Mailing Address

_____

_____

_____

_____

Email Address: _____

Phone: _____

Fax: _____

II. Official and Mailing Address for Financial notices (**Licensee's** contact person for royalty payments)

_____
Name

_____
Title

Mailing Address:

_____

_____

_____

_____

Email Address: _____

Phone: _____

Fax: _____

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) and/or imprisonment).

APPENDIX A – SHIPPING INFORMATION

Licensee's Shipping Contact: information or questions regarding shipping should be directed to Licensee's Shipping Contact at:

_____ _____

Shipping Contact's Name Title

Phone: () _____ Fax: () _____ E-mail: _____

Shipping Address: Name & Address to which Materials should be shipped (please be specific):

_____

Company Name & Department

Address:

_____

_____

_____

_____

Licensee's shipping carrier and account number to be used for shipping purposes:

_____

APPENDIX B – EXAMPLE ROYALTY REPORT

Required royalty report information includes:

- OTT license reference number (L-XXX-200X/0)
- Reporting period
- Catalog number and units sold of each Licensed Product (domestic and foreign)
- Gross Sales per catalog number per country
- Total Gross Sales
- Itemized deductions from Gross Sales
- Total Net Sales
- Earned Royalty Rate and associated calculations
- Gross Earned Royalty
- Adjustments for Minimum Annual Royalty (MAR) and other creditable payments made
- Net Earned Royalty due

Example

Catalog Number	Product Name	Country	Units Sold	Gross Sales (US$)
1	A	US	250	62,500
1	A	UK	32	16,500
1	A	France	25	15,625
2	B	US	0	0
3	C	US	57	57,125
4	D	US	12	1,500

Total Gross Sales	153,250
Less Deductions:	
Freight	3,000
Returns	7,000
Total Net Sales	143,250
Royalty Rate	8%
Royalty Due	11,460
Less Creditable Payments	10,000
Net Royalty Due	**1,460**

APPENDIX C – ROYALTY PAYMENT OPTIONS

The OTT License Number MUST appear on payments, reports and correspondence.

Automated Clearing House (ACH) for payments through U.S. banks only

The NIH encourages our licensees to submit electronic funds transfer payments through the Automated Clearing House (ACH). Submit your ACH payment through the U.S. Treasury web site located at: **https://www.pay.gov.** Locate the "NIH Agency Form" through the Pay.gov "Agency List".

Electronic Funds Wire Transfers

The following account information is provided for wire payments. In order to process payment via Electronic Funds Wire Transfer sender MUST supply the following information within the transmission:

Drawn on a **U.S. bank account** via FEDWIRE should be sent directly to the following account:

Beneficiary Account:	Federal Reserve Bank of New York or TREAS NYC
Bank:	Federal Reserve Bank of New York
ABA#	021030004
Account Number:	75080031
Bank Address:	33 Liberty Street, New York, NY 10045
Payment Details:	License Number (L-XXX-XXXX) Name of Licensee

Drawn on a **foreign bank account** should be sent directly to the following account. Payment must be sent in **U.S. Dollars (USD)** using the following instructions:

Beneficiary Account:	Federal Reserve Bank of New York/ITS or FRBNY/ITS
Bank:	Citibank N.A. (New York)
SWIFT Code:	CITIUS33
Account Number:	36838868
Bank Address:	388 Greenwich Street, New York, NY 10013
Payment Details (Line 70):	NIH 75080031 License Number (L-XXX-XXXX) Name of Licensee
Detail of Charges (line 71a):	Charge Our

Checks

All checks should be made payable to "NIH Patent Licensing"

Checks drawn on a **U.S. bank account** and sent by US Postal Service should be sent directly to the following address:

National Institutes of Health (NIH)
P.O. Box 979071
St. Louis, MO 63197-9000

Checks drawn on a U.S. bank account and sent by **overnight or courier** should be sent to the following address:

US Bank
Government Lockbox SL-MO-C2GL
1005 Convention Plaza
St. Louis, MO 63101
Phone: 314-418-4087

Checks drawn on a **foreign bank account** should be sent directly to the following address:

National Institutes of Health (NIH)
Office of Technology Transfer
Royalties Administration Unit
6011 Executive Boulevard
Suite 325, MSC 7660
Rockville, Maryland 20852