

Combined Limited Use License and Statement of Use

Combined Limited Use License
and Statement of Use
Document 14-22 REF V-05

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Combined Limited Use License and Statement of Use

BEFORE PLACING AN ORDER OR USING THIS PRODUCT, PLEASE READ THE TERMS AND CONDITIONS SET FORTH BELOW. BY USE OF THE PRODUCT, USER AGREES TO BE BOUND BY THE TERMS OF THIS COMBINED LIMITED USE LICENSE AND STATEMENT OF USE AND THE STANDARD TERMS AND CONDITIONS OF SALE V-02 OR E-COMMERCE TERMS AND CONDITIONS OF SALE V-01.

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Definitions:

1. Commercial Use: any and all uses of the Product, Progeny, Modifications or Unmodified Derivatives thereof, by a party for monetary or other consideration and may include but is not limited to use in:
 - I. Manufacture of a product;
 - II. Sale of a product, Progeny, Modifications or Unmodified Derivatives thereof, whether or not such sale is limited for use in research;
 - III. Provision of a service to a third party*;
 - IV. Use in any diagnostic, preventative, or therapeutic application;
 - V. Use in any veterinary, livestock or agricultural application; and
 - VI. Use in later stage development of therapeutics, diagnostics, prophylactics (e.g., hit-to-lead, lead optimization).
2. Field: use of the Product for User's internal research use only. No "Commercial Use" is allowed.
3. Modification(s): any modifications of the Product.
4. Product: Cells which are differentiated from human induced pluripotent stem cells by or on behalf of Bit Bio Ltd., and which Bit Bio Ltd. sells, or are sold on behalf of Bit Bio Ltd. by a distributor.
5. Progeny: any unmodified descendant form of the Product.
6. Unmodified Derivatives: any substances created by the User which constitute an unmodified functional subunit or product expressed by the Product.
7. User: Person or entity who purchased Product(s) from Bit Bio Ltd. or a distributor.

* For services to a third party please contact Bit Bio Limited.

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Ethical considerations and donor protection:

The specimens used to generate the parental human induced pluripotent stem cell (hiPSC) lines used by Bit Bio Ltd. to generate the Product(s) were collected with the informed consent of both the collection site and the individual donor(s), under good clinical practice, and in accord with all applicable law. Any personally identifiable health information collected from the donor(s) during specimen collection was anonymized consistent with the provisions of the Health Insurance Portability and Accessibility Act (HIPAA) and/or the General Data Protection Regulation, as applicable, and in any case, has not been shared with Bit Bio Ltd.

Usage terms specifically applicable to ioMicroglia™:

By taking delivery of the ioMicroglia™ Product, the User agrees that:

- The User shall not make any attempt to identify the original donors of the Product(s) including by using Y-chromosome sequencing data. The User shall remove any data mapping to the Y chromosome (including sequencing reads, genotypes etc.) before making genetic or genomic data available to third parties, and such data shall be removed from publications or results; and
- In any publication in respect of the ioMicroglia™ Product, the User shall record the role of Genome Research Limited in developing and providing the parental cell line, with an appropriate acknowledgement in accordance with academic custom.

Usage terms applicable to all Products:

All Product(s) manufactured by or on behalf of Bit Bio Ltd. are produced according to strict aseptic bio-banking procedures. Each manufactured cell lot is tested for sterility and absence of mycoplasma infection, both at the cryopreservation and post-thawing stages, as well as for the presence of certain common pathogens (i.e., hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus-1 (HIV-1), human immunodeficiency virus-2 (HIV-2)). As a precaution, all Bit Bio Ltd. cell Products should be handled under biosafety level 1 (BSL1) containment at a minimum, as with all cells derived from human or other primate material.

By taking delivery of the Product(s), the User agrees:

- The Product(s) will not be used in human subjects, administered to human subjects in clinical trials, or administered for diagnostic purposes involving human subjects;
- The Product(s) will be used only in compliance with applicable laws and regulations, and in compliance with User's applicable policies on research involving human subjects;
- In the case of entities receiving funding from the United States federal government to conduct human stem cell research, the Product(s) will be used in compliance with all federal, state, and local laws and regulations and the NIH Guidelines on Human Stem Cell Research (available at <http://stemcells.nih.gov/policy>), each as applicable;

- The Product(s) will not be used in research in which they are introduced into blastocysts from non-human primates; and
- The Product(s) will not be used in research involving the breeding of animals where the introduction of the material may contribute to the germ line.

If you require more information, please Bit Bio Ltd. at info@bit.bio

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The use of this Product is strictly limited to User's own internal research as described and restricted in the iPS Academia Japan and ID Pharma Co. Ltd. User Restrictions Notice below.

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1. All Users may use the Product for internal research only including but not limited to screening potential drug compounds for efficacy and safety. No other right is granted to User whether expressly, by implication, by estoppel or otherwise. In particular, the purchase of the Product does not include nor carry any right or license to use, develop or otherwise exploit the Product commercially, and no rights are conveyed to User to use the Product for any other purpose other than specified in the Field.
2. User agrees to use the Product in compliance with all applicable statutes and regulations, but not to use the Product for any administration or application to humans. Moreover, User agrees not to use the Product in human subjects for human clinical use for therapeutic, diagnostic or prophylactic purposes, or in animals for veterinary use for therapeutic, diagnostic or prophylactic purposes, including but not limited to clinical applications, cell therapy, transplantation, and/or regenerative medicine without an appropriate license.
3. In the case that User transfers Product to a third party, User shall convey the User Restrictions set forth herein to such a third party.

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ERS Genomics Limited is an intended third-party beneficiary under this Combined Limited Use License and Statement of Use.

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