

Combined Limited Use License and Statement of Use

Combined Limited Use License
and Statement of Use
Document 14-22 REF V-06

bit.bio
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Customer support:
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Combined Limited Use License and Statement of Use

Before placing an order or using bit.bio Cells, please read the terms and conditions set forth below. By placing an order for, or use of bit.bio Cells, you agree to be bound by the terms of this (1) combined limited use license and statement of use (“**LUL**”); and (2) bit.bio’s standard terms and conditions of sale or e-commerce terms and conditions of sale.

bit.bio Cells are provided by Bit Bio Limited and/or its affiliates to the Purchaser under licensing rights from its licensors including ERS Genomics Limited, Cambridge Enterprise Limited, iPS Academia Japan, Inc., TET Systems GmbH & Co., and ID Pharma Co. Ltd. Use of bit.bio Cells is subject to the individual limited use license notices, terms of use and other license restrictions as set out in this LUL.

1. Definitions:

bit.bio Cells: cells which are differentiated from human induced pluripotent stem cells by or on behalf of Bit Bio Limited and purchased by the Purchaser from Bit Bio Limited, its affiliates, or its authorised distributor as identified in the Purchaser’s order confirmation.

Field of Use: Purchaser’s internal research, discovery and development use. Purchaser can use the Product for research including:

- (a) to support pre-clinical studies including target identification, validations, high-throughput screening, hit-to-lead, and lead optimisation;
- (b) to support drug discovery and drug development efforts; and
- (c) to evaluate features of the Product after stimulation with commercially available chemicals and share generated data with alliance partners.

The Purchaser can transfer the Product to a not-for-profit organisation or academic laboratory or any of its contractors for use intended for the benefit of the Purchaser.

The Purchaser can also transfer the Product to a third-party service provider to use the Product solely for the benefit of the Purchaser provided that no right is granted to the third-party service provider to conduct CRISPR-based screening unless such third-party service provider has a license directly from ERS Genomics Limited for such purpose.

Modified Product: any unmodified descendant form of bit.bio Cells, any modifications of bit.bio Cells, and any substances created by the Purchaser or on the Purchaser’s behalf which constitute an unmodified functional subunit or product expressed by bit.bio Cells.

Product: bit.bio Cells and Modified Product (as the case may be).

Purchaser: Person or entity who purchased bit.bio Cells from Bit Bio Limited, its affiliate, or its authorised distributor. “User”, “you” and “your” shall be construed accordingly.

Restricted Commercial Use: means to:

- (a) offer and provide commercial services using the Product;
- (b) sell the Product;
- (c) use the Product in clinical diagnostic, preventative, or therapeutic application; or
- (d) manufacture any product for commercial sale using the Product.

The Purchaser is not permitted to use the Product for Restricted Commercial Use.

2. Ethical considerations and donor protection:

The specimens used to generate the parental human induced pluripotent stem cell (hiPSC) lines used by Bit Bio Limited to generate bit.bio Cells 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 anonymised consistent with the provisions of the Health Insurance Portability and Accessibility Act (HIPAA) and/or the General Data Protection Regulation, as may be applicable, and in any case, has not been shared with Bit Bio Limited.

3. Usage terms applicable to all bit.bio Cells:

All bit.bio Cells manufactured by or on behalf of Bit Bio Limited 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 Cells should be handled under biosafety level 1 (BSL1) containment at a minimum, as with all cells derived from human or other primate material.

By purchasing the bit.bio Cells, the Purchaser agrees:

- the Product will not be used in human subjects, administered to human subjects in clinical trials, or administered for diagnostic purposes involving human subjects;
- the Product will be used in compliance with applicable laws and regulations, and in compliance with the Purchaser’s applicable policies on research involving human subjects;

- if the Purchaser is 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 will not be used in research in which they are introduced into blastocysts from non-human primates;
- the Product will not be used in research involving the breeding of animals where the introduction of the material may contribute to the germ line;
- that use of the Product shall be limited to the Field of Use (as defined above);
- the Product will not be used for Restricted Commercial Use (as defined above); and
- the Purchaser shall not make any attempt to identify the original donors of bit.bio Cells including by using Y-chromosome sequencing data. The Purchaser 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.

4. Usage terms specifically applicable to ioMicroglia™ | Male (io1021) and disease models of ioMicroglia™ | Male (io1021):

By purchasing the ioMicroglia™ | Male (io1021) or any disease models of ioMicroglia™ | Male (io1021), the Purchaser agrees that:

- in any publication in respect of ioMicroglia™ | Male (io1021) or any disease models of ioMicroglia™ | Male (io1021), the Purchaser 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.

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

5. Licensor Terms

(a) ERS GENOMICS Limited

CRISPR non-exclusive license agreement

bit.bio Cells are manufactured and supplied by Bit Bio Limited using technology covered by one or more issued patents within and outside the UK claiming priority to one or more of US Provisional Patent Application Numbers 61/652,086, 61/716,256, 61/757,640, and 61/765,576 provided under license from ERS GENOMICS Limited.

All Purchasers can use the Product for research including:

- (a) to support preclinical studies including high throughput screening, hit-to-lead and lead optimisation activities;
- (b) to support drug discovery and drug development efforts; and
- (c) to evaluate features of the Product after stimulation with commercially available chemicals and share generated data with alliance partners.

Purchaser can transfer the Product to a not-for-profit organisation or academic laboratory or any of its contractors for use intended for the benefit of the Purchaser.

Purchaser can also transfer the Product to a third-party service provider to use the Product solely for the benefit of the Purchaser provided that no right is granted to the third-party service provider to conduct CRISPR-based screening unless such third-party service provider has a license directly from ERS Genomics Limited for such purpose.

Purchaser may not use the Product for "Restricted Commercial Use". Restricted Commercial Use specifically means:

- (i) to offer and provide commercial services using the Product;
- (ii) sale of the Product;
- (iii) use of the Product in clinical diagnostic, preventative, or therapeutic application; or
- (iv) manufacturing of any product for commercial sale using the Product.

Except for the rights granted herein, any and all rights to the Product shall remain in Bit Bio Limited. No ownership rights are transferred.

Purchaser shall have no right to assign the rights granted herein to a third party.

Activities performed at commercial entities other than for internal research (for example, for the provision of contract research or contract screening services to a third party) may require additional contract rights from ERS Genomics Limited which are not granted through the purchase of bit.bio Cells. For additional information, please see: www.ersgenomics.com/research-products.php and contact Bit Bio Limited at info@bit.bio for more information.

ERS Genomics Limited is an intended third-party beneficiary under these terms.

(b) Cambridge Enterprise Limited

bit.bio Cells are manufactured and supplied by Bit Bio Limited based on a patent license from Cambridge Enterprise Limited. bit.bio Cells are covered by one or more claims in U.S. Granted Patent No. US20190338309A1 and pending foreign counterparts to U.S. Patent Application No. 16/463,829, including their divisions, continuations, extensions, substitutions, and those claiming priority therefrom or those claiming the same priorities therein.

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(c) iPS Academia Japan, Inc. and ID Pharma Co. Ltd.

bit.bio Cells are manufactured and supplied by Bit Bio Limited based on a patent license from iPS Academia Japan, Inc. bit.bio Cells are covered by one or more claims of issued patents and pending patent applications, including: U.S. Patent Nos. 8,048,999, 8,058,065, 8,129,187 and 8,278,104 and foreign counterparts thereof, including their divisions, continuations, extensions, substitutions, and those claiming priority therefrom or those claiming the same priorities therein.

bit.bio Cells are manufactured by Bit Bio Limited also using technology licensed from ID Pharma Co. Ltd. The Product is covered by one or more claims of issued patents and pending patent applications, including: U.S. Patent No. 9,127,256 and European Patent No. 1186667 and foreign counterparts thereof, including their divisions, continuations, extensions, substitutions, and those claiming priority therefrom or those claiming the same priorities therein.

The use of the Product is strictly limited to Purchaser restrictions as detailed below.

Purchaser Restrictions:

1. Purchaser may use the Product for internal research including but not limited to screening potential drug compounds for efficacy and safety, and for the provision of such services to third parties. No other right is granted to Purchaser 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 Purchaser to use the Product for any other purpose.
2. Purchaser 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, Purchaser 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 Purchaser transfers Product to a third party, Purchaser shall convey the Purchaser Restrictions set forth herein to such a third party.

(d) TET Systems GmbH & Co. KG

bit.bio Cells contain the Tetracycline controllable expression system (the "**Tet Technology**"). The Tet Technology IP portfolio is proprietary to TET Systems GmbH & Co. KG ("**Tet Systems**") and comprises a series of patents including U.S. patents 8,383,364, 9,181,556, European Patents EP 1954811, 2352833 and corresponding patent claims outside these regions. The Purchaser of the bit.bio Cells is granted an automatic license to use the Tet Technology only for the intended use of the Product and excludes the right to transfer or sell the Product, the Tet Technology, or its component parts to third parties. Purchaser whose research using the Product is sponsored by for-profit organisations, which shall receive ownership to any data or results stemming from the sponsored research, shall need a license agreement from Tet Systems in order to use the Product.

In accepting this license, all Purchasers of the bit.bio Cells acknowledge that the Tet Technology is experimental in nature. Tet Systems makes no warranties, express or implied or of any kind, and hereby disclaims any warranties, representations, or guarantees of any kind as to the Tet Technology, patents, or products.

All Purchasers of bit.bio Cells that do not have a license from Tet Systems will be restricted to the purchase of ten (10) or fewer units per annum. In case the Purchaser is purchasing more than ten (10) units per annum, a license will need to be obtained from Tet Systems.

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