Cell Line Information Pack (CLIP)

Cell line name	RCi001-B
ECACC Catalogue No.:	66540048

Purpose

The purpose of this Cell Line Information Pack (CLIP) is to communicate cell line specific information to potential users of the cell line, and to confirm that a User has received it upon the purchase of an EBiSC cell line.

Information

The CLIP may provide a variety of types of information related to an individual cell line. Of particular importance are Third Party Obligations (TPOs), which are ethical or legal obligations of a Depositor related to the use of the cell line. TPOs may impose ethical or legal limitations on the ability of a User to use the cell line, or require steps to be taken before it can be used. TPOs are likely to be:

- Obligations under license to an intellectual property rights (patent) holder, or
- Restrictions on use imposed by the donor of the primary tissue from which the cell line was made.

Third Party Obligations: donor consent provisions

Record of information provided to the donor of the primary tissue and the consent obtained

The standard terms used by the Pfizer under any research protocol are included below, which are each time independently reviewed and approved by a separate bioethics board per study.

12.2. Ethical Conduct of the Study

The study will be conducted in accordance with legal and regulatory requirements, as well as the general principles set forth in the International Ethical Guidelines for Biomedical Research Involving Human Subjects (Council for International Organizations of Medical Sciences 2002), Guidelines for GCP (ICH 1996), and the Declaration of Helsinki (World Medical Association 2008).

In addition, the study will be conducted in accordance with the protocol, the ICH guideline on GCP, and applicable local regulatory requirements and laws.

12.3 Informed Consent

All parties will ensure protection of subject personal data and will not include subject names or other identifiable data in any reports, publications, or other disclosures, except where required by law.

The informed consent documents must be in compliance with ICH GCP, local regulatory requirements, and legal requirements, including applicable privacy laws. The informed consent documents used during the informed consent process must be reviewed by the sponsor, approved by the IRB/EC before use, and available for inspection. The investigator must ensure that each study subject is fully informed about the nature and objectives of the study and possible risks associated with participation.

The investigator, or a person designated by the investigator, will obtain written informed consent from each subject before any study-specific activity is performed. The investigator will retain the original of each subject's signed consent document.

Cell Line Information Pack (CLIP)

Cell line name	RCi001-B
ECACC Catalogue No.:	66540048

Third Party Obligations: IP or license provisions

None

Technical information

None

Other information

None

User acknowledgement

Please sign below to indicate that you have read and acknowledge the information contained in this CLIP.

Name _____ **Position** _____

Signature _____ **Date** _____

SIGN AND RETURN THIS DOCUMENT WITH YOUR COMPLETED ACCESS AND USE AGREEMENT

www.ebisc.org

In case of queries, please contact European Collection of Authenticated Cell Cultures (ECACC),
Telephone: +44 (0) 1980 612512 Email: culturecollections@phe.gov.uk