POLICY STATEMENT:

Bioethics Policy – Center for Predictive Drug Discovery
(formerly Biopta*)

THIS POLICY SETS FORTH OUR COMMITMENT TO CONDUCT ACTIVITIES RELATED TO HUMAN TISSUE ASSAY SERVICE PROVISION, AND NON-CLINICAL AND CLINICAL RESEARCH, IN ACCORDANCE WITH THE HIGHEST LEGAL, ETHICAL, AND SCIENTIFIC STANDARDS, INCLUDING:

- International Conference on Harmonization (ICH) GCP and the ethical principles that have their origin in the World Medical Association Declaration of Helsinki
- Good Laboratory / Clinical / Practice
- International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS)
- The Human Tissue Authority Codes of Practice (UK)

Key Principles

- All REPROCELL employees understand that they are responsible for compliance with this Policy
- REPROCELL is committed to ensuring patient/donor rights and safety are safeguarded at all times
- Research activities will be performed in compliance with all local regulatory requirements, and quality and safety standards, in those countries in which we conduct research

Policy Statements

General

- A qualified Research Ethics Committee/Institutional Review Board (REC/IRB) will review and approve all REPROCELL sponsored/supported studies prior to initiation. Subjects must not be enrolled/approached until such approval is received, as well as, all local regulatory or governmental authorizations required in the country in which the study will be conducted.
- REPROCELL will carefully assess the type and degree of both risk and benefit for a given research population and seek to minimize risk to each subject. Study design must be adequate to achieve the stated aim of the research and the nature and likelihood of all benefits and risks should be clearly stated.
- Research subjects may only be enrolled in a study after providing their voluntary informed consent. Potential research subjects must be clearly and fully informed about the purpose, processes, risks/benefits and other critical factors regarding the study in which they may participate, and have the opportunity to request further information regarding their participation in the study. Subjects must be afforded the opportunity to provide or withhold their consent whenever possible.
- Research subjects are free to withdraw at any time without detriment to their ongoing medical care.
- REPROCELL is committed to maintaining the privacy of subjects by ensuring that all data is anonymised to conceal the subject's identity.

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* Biopta was acquired by the REPROCELL group in 2015 and subsequently formed the REPROCELL Center for Predictive Drug Discovery in 2017.

- The use of genomic information and human biological samples will be approved by appropriate ethical review. Subjects will be provided with information about the nature and purpose of the investigation and asked to provide consent. The genomic data may or may not be returned to the subject depending on the nature of the investigation and on the level of validation of the technology and reagents used to generate it. This will be clearly stated in the consent. If the data is returned to the subject we will specify, in the study protocol, a detailed process for handling such findings. We will communicate this process to the subjects, and they will acknowledge their acceptance when signing the consent form.
- REPROCELL support the investigation of human stem cell-derived cell lines for use in the laboratory, and we have a rigorous ethical framework that governs our work in this area. The majority of REPROCELL stem cell projects aim to investigate the research potential of human induced pluripotent stem cells (hiPSC) generated by 'reprogramming' adult cells to become more stem cell-like. hiPSC can be obtained safely from adult volunteers and do not involve embryos.
- All GMO work must be conducted under appropriate levels of biosafety containment and in compliance with relevant environmental, health and safety laws and regulations.
- Reimbursement or compensation to research subjects must be consistent with the principle of voluntary participation in the study i.e., no real/perceived coercion. Any such reimbursement or compensation should be appropriate to the local economy and must be reviewed by the REC/IRB.
- Compensation to researchers must not reward, or appear to reward, past use of REPROCELL products or induce future use of REPROCELL products. Payments must reflect fair market value for services rendered and be reasonable in light of the time and effort involved.
- Use of biological materials and technologies must be reasonable and ethical to ensure the safety and welfare of REPROCELL employees, the environment, and the communities in which we operate.
- All procedures involving the care and use of animals must comply with applicable laws and regulations.

Clinical Trials

- REPROCELL will conduct clinical studies/trials with human subjects in accordance with all regulatory requirements and the recognised international quality and safety standards in all countries in which we operate.
- The quality and safety standards applied include Good Manufacturing Practices, Good Laboratory Practices, and Good Clinical Practices.
- For First Time in Human (FTiH) studies, preclinical data must indicate the possibility of the trial drug/treatment delivering a clinical benefit with a favourable benefit/risk ratio.
- For clinical studies that include a control group, the standard of care provided to the control group(s) should be, at a minimum, equivalent to established and commonly employed treatments that are medically and ethically appropriate to treat the disease.
- Placebo controlled studies should only be utilized where there is a genuine uncertainty about the therapeutic merits of the proposed treatments being studied (clinical equipoise) and where doing so does not present an undue risk to the subject.

- REPROCELL is committed to global clinical trial transparency. We ensure transparency through appropriate registration of clinical trials and posting of clinical trial results on websites and peer reviewed publications. We will fully comply with laws, regulations and specific requirements for the registration and reporting of results.
- REPROCELL is committed to detecting any adverse events associated with investigational products and to providing updated information to investigators and research subjects as appropriate. All reports off adverse events will be scrutinised by medically qualified individuals. Cases judged to be of potential concern will result in further analyses of data and subsequent action.
- Our clinical trial protocols will be submitted externally to ethical committees and as required regulatory authorities in the countries where the study will take place.

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