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Document Type:	**Policy**	
Title:	**ETHICAL CLINICAL TRIALS**	

1. PURPOSE

1.1 The purpose of this Policy is to establish the principles and minimum standards under which Provention Bio, Inc. ("Provention") conducts ethical clinical trials.

2. SCOPE

2.1 This policy applies to all Provention personnel, including employees and consultants, as well as to any vendors, subcontractors and any others who may act on Provention's behalf in any country, worldwide (collectively, "Personnel").

2.2 Violations of this policy may result in disciplinary action up to and including termination of employment (for employees) and of contracts (for other Personnel).

3. GENERAL REQUIREMENTS

3.1 Conducting Clinical Trials

3.1.1 Provention is committed to adhering to internationally accepted principles for the ethical conduct of clinical trials, including those principles set forth in the Belmont Report and the World Medical Association Declaration of Helsinki. Therefore, Provention will sponsor only clinical research that is designed to adhere to Good Clinical Practices.

3.1.2 As part of its ethical conduct of clinical trials, Provention requires that there be appropriate ethical and scientific support for the involvement of any vulnerable populations in the clinical trials that it sponsors. Populations that are generally recognized as vulnerable in the context of clinical trials include pregnant women, human fetuses, neonates, children, and prisoners, as well as persons with diminished decision-making capacity.

3.1.3 Provention has adopted policies and procedures, which include periodic audits, to ensure that clinical trial sites carrying out Provention-sponsored studies do so in a manner that promotes patient safety, compliance, and data integrity. In all its clinical trials, Provention implements policies and requirements for timely and thorough receipt and review of reports of serious adverse events.

3.1.4 Provention, directly and/or with its clinical trial partners ("Partners"), reviews the capacity of its clinical trial sites to conduct the study successfully and in accordance with Provention's scientific and ethical norms, both before engaging the site and on an ongoing basis during the study. It is Provention's policy that sites for its sponsored studies be selected based on sites' qualifications, training, prior research, clinical expertise in relevant fields, potential to recruit eligible research participants, ability to conduct research in a manner that is consistent with Provention's principles and values, and other relevant factors including Good Clinical Practice guidelines.

3.1.5 In reviewing the study sites' abilities, Provention and its Partners take into account the risks presented by the particular clinical trial site (*e.g.*, the site's experience with similar trials as well as the expertise and track record of its senior leadership).

3.1.6 Provention will ensure that, if the research design calls for any genetic test results conducted in research to be returned to study subjects, such tests will be performed and returned to subjects in compliance with all applicable laws and regulations, including without limitation the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") and requirements relating to the pre-and post-test counseling of genetic test recipients.

3.1.7 Provention is committed to only using human biological samples or human embryonic stem cells in its research when Provention or its Partners have collected the samples or cells in compliance with, or obtained such cells or sample from, entities that follow all legal requirements related to the collection, storage and transport of such samples, as well as appropriate ethical and quality control standards.

3.1.8 Provention is committed to using animal subjects only when regulatory or scientific alternatives do not exist. For example, when possible, Provention strives to use computer models, cell culture techniques, and any other appropriate methods to minimize the need to use animals in research. When animals must be used in research, Provention is committed to adhering to all applicable laws and ethical standards, including a commitment to the 3Rs (replacement, reduction and refinement) for animal research.

3.2 Disclosure of Clinical Trial Results

3.2.1 Provention is committed to making results from its clinical trials available where and as required by applicable laws and regulatory standards.

3.2.2 It is Provention's policy that scientists publishing the results of any Provention-sponsored study in a scientific journal should disclose Provention's funding of the study as well as any financial or professional ties that the scientists themselves have with Provention. Papers describing Provention studies should only be submitted to reputable, peer-reviewed publications.

3.3 Supply Chain and Partners

3.3.1 Provention holds its suppliers and partners accountable for complying with all applicable laws, regulations and professional standards applicable to the work performed for Provention. Our Compliance and Quality teams periodically monitor these individuals and entities for compliance with this policy.

3.4 Training

3.4.1 Provention employees who participate in clinical trials shall receive training on this policy within 30 days of implementation. New hires shall receive training on this policy within 30 days of hire.

3.5 Reporting Violations

3.5.1 Personnel who become aware of a potential violation of this policy are required to report the matter immediately. Reports may be made to the Legal/Compliance department via email at compliance@proventionbio.com. Reports may also be made using the anonymous compliance hotline available at www.proventionbio.ethicspoint.com or (844) 449-7503.

3.5.2 Provention is committed to taking appropriate corrective action in response to any violation. No retaliatory action will be taken against any Personnel for raising concerns or claims in good faith under this Policy.

4. VERSION STATEMENT

4.1 This is an original Provention policy. There are no prior versions of this policy.

5. REFERENCES/RELATED DOCUMENTS

5.1 *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, US Department of Health, Education and Welfare (1979) available at https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html.

World Medical Association Declaration of Helsinki, available at https://www.who.int/bulletin/archives/79(4)373.pdf.

6. DOCUMENT HISTORY

#	Date	Version #	Revised By	Description of Changes