



Republic of the Philippines
Province of Cavite
CITY OF BACOR

Office of the Sangguniang Panlungsod

DISTRICT I

ABSENT
HON. CATHERINE SARINO-EVARISTO
City Councilor

HON. MICHAEL E. SOLIS
City Councilor

HON. ADRIELITO G. GAWARAN
City Councilor

HON. VICTORIO L. GUERRERO, JR.
City Councilor

HON. ALEJANDRO F. GUTIERREZ
City Councilor

HON. LEVY M. TELA
City Councilor

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City Councilor

HON. REYNALDO D. PALABRICA
City Councilor / President Pro-Tempore

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City Councilor

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HON. SIMPLICIO G. DOMINGUEZ
City Councilor

HON. RAMON N. BAUTISTA
Liga ng mga Barangay President

ABSENT
HON. MAC RAVEN ESPIRITU
SK Federation President

Attested by:
[Signature]

ATTY. KHALID A. ATEGA, JR.
Sangguniang Panlungsod Secretary

Certified by:
[Signature]

HON. REYNALDO D. PALABRICA
Acting Presiding Officer

Approved by:
[Signature]
HON. ROWENA BAUTISTA-MENDIOLA
Acting City Mayor

CITY ORDINANCE NO. 305-2023 Series of 2023

AN ORDINANCE REGULATING THE CONDUCT OF CLINICAL AND/OR RESEARCH TRIALS WITHIN THE CITY OF BACOR, CAVITE AND PROVIDING PENALTIES FOR VIOLATIONS HEREOF.

Sponsored by:

Hon. Reynaldo D. Palabrica and Hon. Alde Joselito F. Pagulayan

Co-Sponsored by:

Hon. Roberto L. Advincula, Hon. Ramon N. Bautista, Hon. Simplicio G. Dominguez, Hon. Reynaldo M. Fabian, Hon. Adrielito G. Gawaran, Hon. Alejandro F. Gutierrez, Hon. Rogelio M. Nolasco, Hon. Michael E. Solis and Hon. Levy M. Tela.

WHEREAS, it is the policy of the State under Republic Act No. 9711 (the "Food and Drug Administration (FDA) Act of 2009") and its Implementing Rules and Regulations to adopt, support, establish, institutionalize, improve, and maintain structures, processes, mechanism, and initiatives that are aimed, directed and designed to: (a) protect and promote the right to health of the Filipino people; (b) help establish and maintain an effective health products regulatory system; and (c) undertake appropriate manpower development and research responsive to the country's health needs and problems.

WHEREAS, the FDA is the National Regulatory Authority (NRA) and, as such, recognized that the conduct of clinical trials is beneficial to the country as a means of advancing the goal of Republic Act No. 11223, otherwise known as the "Universal Healthcare Act," which seeks to "ensure that all Filipinos are guaranteed equitable access to quality and affordable health care goods and services, and protected against financial risk."

WHEREAS, through the conduct of clinical trials, Filipinos can identify and have access to new treatment modalities which are crucial in addressing the high burden of communicable and non-communicable diseases.



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Acting City Mayor

WHEREAS, while many clinical trials are being conducted in other countries, the representation of Filipino patients is essential to account for race, genetic factors, and co-morbidity conditions that play pivotal roles in response to a drug or intervention.

WHEREAS, for the past 30 years, subsequent regulations and guidelines have been issued to expand the policies to approve, conduct, and monitor clinical trials. However, these issuances have to be rationalized to provide a clear framework of clinical trial regulation in the Philippines.

WHEREAS, the FDA primarily regulates the conduct of clinical trials in the Philippines.

WHEREAS, there has been a surge in the conduct of clinical trials in the Philippines.

WHEREAS, the City Government of Bacoor has been receiving letter requests for the conduct of clinical trials in the City of Bacoor involving its residents.

WHEREAS, some institutions and persons conduct clinical trials in the City of Bacoor involving its residents without the required and proper approval and certification from the FDA and other related national government agencies.

WHEREAS, the conduct of such unauthorized clinical trials pose a severe health concern for the City Government of Bacoor.

WHEREAS, Section 16, Chapter 1, Title, Book 1 of the Local Government Code provides that "Every local government unit shall exercise the powers expressly granted, those necessarily implied therefrom, as well as powers necessary, appropriate, or incidental for its efficient and effective governance and those which are essential to the promotion of the general welfare. Within their respective territorial jurisdictions, local government units shall ensure and support, among other things, the preservation and enrichment of culture, promote health and safety, enhance the right of the people to a balanced ecology, encourage and support the development of appropriate and self-reliant scientific and technological capabilities, improve public morals, enhance economic prosperity and social justice, promote full employment among their residents, maintain peace and order, and preserve the comfort and convenience of their inhabitants".



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WHEREAS, the local government of the City of Bacoor, Cavite, is legally mandated to preserve and enrich the health and lives of its residents.

WHEREAS, with the passage of this Ordinance, the City Government of Bacoor will be able to protect public health while providing an environment where scientific research involving clinical trials can be conducted safely.

NOW, THEREFORE, be it **ORDAINED** by the 5th Sangguniang Panlungsod of the City of Bacoor, Cavite, that:

Section 1. Title. – This Ordinance shall be known as the "**CLINICAL TRIALS REGULATION ORDINANCE OF THE CITY OF BACOR**".

Section 2. Objectives. – This Ordinance aims to achieve the following:

- 2.1 Regulate the conduct of clinical trials and research trials within the City of Bacoor;
- 2.2 Eliminate the conduct of unauthorized clinical trials and research trials within the City of Bacoor;
- 2.3 Assist institutions and persons in the conduct of clinical or research trials;
- 2.4 Avoid the duplication of the conduct of similar or related clinical or research trials;
- 2.5 Avoid duplicate enrollment of residents in similar or related clinical or research trials;
- 2.6 Ensure that the rights of the resident participants are upheld;
- 2.7 Ensure that the health and well-being of the resident participants are protected; and
- 2.8 Punish the violators of this Ordinance and other relevant laws and regulations.

Section 3. Coverage – This Ordinance shall cover all public and private institutions and/or individuals who will conduct clinical trials or research trials within the City of Bacoor or outside of the City but will use the participation of its residents by transporting these residents outside of the City to evade compliance with this Ordinance.

Section 4. Definition of Terms –

- 4.1 **Certification** – The required certification and/or authorization from FDA or other government agency mandated to give a certificate and/or license that states



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that the Sponsor, CRO, or Investigator is allowed to conduct clinical trials in the Philippines.

4.2 Clinical Trial/Research Trial - Any investigation involving human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial, research trial and clinical study are deemed synonymous.

4.3 Contract Research Organization (CRO) - A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

4.4 Institution - An established organization or corporation. This shall refer to private, public, semi-private, and semi-public.

4.5 Investigator - A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

4.6 Notice to Proceed - A document that the City of Government of Bacoor shall issue to the Sponsor, CRO, Investigator, or Individual authorizing them to proceed with the clinical or research trial.

4.7 Notice to Withdraw - A document that the City of Government of Bacoor shall issue to the Sponsor, CRO, Investigator, or Individual stating that they shall not



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continue with the clinical trial or research trial.

- 4.8 Sponsor** - An individual, company, institution, or organization that takes responsibility for initiating, managing, and/or financing clinical trials.

Section 5. Prohibited Acts – The following acts shall be prohibited:

- 5.1.** The conduct of clinical trials or research trials within the City of Bacoor without the required Certification and the required Notice to Proceed.
- 5.2.** The conduct of clinical trials or research trials within the City of Bacoor with the required Certification but without the required Notice to Proceed.
- 5.3.** The conduct of clinical trials outside of the City of Bacoor but uses/will use residents of the City of Bacoor by transporting these residents outside of the City of Bacoor to evade compliance with this Ordinance.
- 5.4.** Knowingly and willingly helping or assisting anyone who commits any of the prohibited acts under this Ordinance and relevant future issuances.
- 5.5.** Knowingly and willingly withholding information on any violation of this Ordinance and relevant future issuances; and
- 5.6.** Other analogous acts.

SECTION 6. Implementing Agency. – The City Health Board of the City of Bacoor shall lead in the strict implementation of this Ordinance. It shall be the duty of the implementing agency to:

- 6.1** Formulate and recommend additional guidelines, policies, rules, and requirements for the Local Chief Executive's approval to effectively implement this Ordinance.



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6.2 Disseminate the necessary information that will inform Sponsors, CROs, Investigators, City Government employees, and any person to comply with this Ordinance.

6.3 Collect all data related to the conduct of clinical trials in the City of Bacoor.

6.4 Prepare an annual report describing the progress in implementing the Ordinance; and

6.5 Coordinate with relevant national government agencies for the implementation of the Ordinance.

SECTION 7. Process for Application and Issuance of Notice to Proceed – The following shall be the process for the application and issuance of a Notice to Proceed:

7.1 Any Sponsor/CRO/Investigator/Institution/Individual who wants to conduct a clinical trial within the City of Bacoor must write a formal letter request addressed to the Office of the City Mayor and copy furnishing the City Health Board at least thirty (30) days before the conduct of the proposed clinical trial or research trial;

7.2 The letter request shall state the following information:

- Name of the Sponsor;
- Name of CRO, if different from the Sponsor;
- Name of the Investigator/s;
- Name of the Product subject of the clinical trial or research trial;
- Purpose of the clinical trial or research trial;
- Name of all the individuals who will conduct the clinical trial or research trial;



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- g. Period for the conduct of the clinical trial or research trial;
- h. Number of target participants within the City of Bacoor;
- i. Complete list of qualifications of participants within the City of Bacoor;
- j. Their policy on data and patient confidentiality;
- k. Their policy in case of adverse effects;
- l. Brief description of the participation of the participants in the study; and
- m. Summary of the help requested/needed, if any.

7.3 The letter request shall also be accompanied by the following attachments:

- a. Certified True Copy of the Certification issued by the FDA and other relevant government agencies;
- b. Copies of accreditation and other permits, if available; and
- c. Proof that the CRO/Investigator/Individual actually conducting the clinical trial or research trial is authorized and capable of doing the same (Ex: PRC ID for doctors/nurses).

7.4 The Local Health Board shall be convened to review and assess the Letter Request.

7.5 The Local Health Board may request additional documents or the attendance of the applicant/s.

7.6 After careful deliberation, the Local Health Board shall issue the necessary Resolution allowing or disallowing the conduct of the clinical trial or research trial and/or allowing or disallowing the help requested/needed, if any, providing justification for the said decision and submitting the Resolution to the Office of the City Mayor.

7.7 Upon recommendation from the Local Health Board, the Office of the City Mayor shall issue either a Notice to



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Proceed or a Notice to Withdraw to the applicant.

7.8 The Notice to Withdraw may not be appealed.

SECTION 8. Fees – A fee of Ten Thousand Pesos (Php 10,000.00) or Three Hundred Pesos (Php 300.00) per City of Bacoor resident as a participant, whichever is higher, shall be paid by the applicant to the Office of the City Treasurer within three (3) days from receipt of the Notice to Proceed. If the national government sponsors or conducts the clinical or research trial, the fees stated in this Section may be waived.

SECTION 9. Information and Education Campaign. – The City Health Office shall conduct a city-wide information and education campaign on the provisions of the Ordinance, with the assistance of concerned government agencies and Non-Government Organizations.

SECTION 10. Budgetary Requirement. – The funds needed to implement the Ordinance shall be taken from the Annual Development Fund or any Supplemental Budget that may be passed for the purpose.

SECTION 11. Penalties. – Any violation of this Ordinance shall be punishable as follows:

11.1. For first-time offenders: an administrative fine of Five Thousand Pesos (Php 5,000.00) per City of Bacoor resident who participated in the clinical/research trial shall be imposed on any juridical person or individual who shall violate any provision/s of this Ordinance.

11.2. For second-time offenders: the penalty of imprisonment of ten (10) to thirty (30) days and an administrative fine of Five Thousand Pesos (Php 5,000.00) per City of Bacoor resident who participated in the clinical/research trial shall be imposed on any juridical person or individual who shall violate any provision/s of this Ordinance.

11.3. For third-time and succeeding offenders: the penalty of imprisonment of six (6) months to one (1) year and an



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administrative fine of Five Thousand Pesos (Php 5,000.00) per City of Bacoor resident who participated in the clinical/research trial shall be imposed on any juridical person or individual who shall violate any provision/s of this Ordinance.

11.4. In case any violation of this Act is committed by a partnership, corporation, association, or any other juridical person, the partner, president, director, or manager who shall consent to or shall knowingly tolerate such violation shall be directly liable and responsible for the act of the employee and shall be criminally liable as a co-principal.

11.5. In case the offender is a government official or employee, in addition to the above penalties, a formal complaint shall be initiated before the Human Resources Development be deemed automatically dismissed from office and permanently disqualified from holding any elective or appointive position.

Section 12. Separability Clause. – If, for any reason, any provision or part of this Ordinance is declared invalid or unconstitutional, other provisions not affected thereby shall remain in full force and effect.

Section 13. Repealing Clause. – All Ordinances, Resolutions, local, Executive Orders, or Administrative Issuances or parts inconsistent with the Ordinance's provisions are hereby repealed, amended, or modified accordingly.

Section 14. Effectivity. – This Ordinance shall take effect fifteen (15) days after its publication in a newspaper of general circulation in the City of Bacoor, Cavite.

ENACTED, on the 11th day of September, 2023 by a unanimous vote of all the Members of the Sangguniang Panlungsod, there being a quorum.



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I hereby certify that the preceding City Ordinance is true and correct and that the same was duly approved in accordance with law.

Certified by:

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Date of Approval: 22 SEP 2023