Substantiated opinion of the CEP

RESEARCH PROJECT DATA

Research Title: Profile of cholecystectomy surgeries performed in a public hospital in the District.
Federal: Factors associated with the choice between open and videolaparoscopic techniques.

Researcher: MARINA FERREIRA DA SILVA

Thematic Area:

Version: 3

CAAE: 91880625.9.0000.5553

Proposing Institution: FOUNDATION FOR TEACHING AND RESEARCH IN HEALTH SCIENCES

Main Sponsor: Self-Funding

OPINION DATA

Opinion Number: 8.037.618

Project Presentation:

* According to the "SUBMISSION LETTER OF THE RESEARCH PROJECT TO CEP-FEPECS"

Posted on August 28, 2025, we have the following information:

1. Project Purpose: This is a postgraduate project in Medical Residency at the Higher School of Health Sciences in Surgery.

2. Proposing Institution:

Foundation for Teaching and Research in Health Sciences

3. Is this a multicenter study?

( ) Yes (x) No

4. If multicentric, what is the origin? Not applicable.

( ) National ( ) International

5. If international, what is the country of origin of the research? Not applicable.

6. Is the research sponsored or self-funded?

) Sponsored (x) Self-Funded

7. If this is sponsored research, cite the sponsor(s): Not applicable.

8. What is the sample size to be studied in the SES-DF?

315 participants will be selected from institutions within the SES-DF (Health Secretariat of the Federal District).

9. List ALL locations within the SES-DF (Health Secretariat of the Federal District) where the research

will be conducted: Taguatinga Regional Hospital.

10. What population will be studied?

( ) RNs

( ) Infants

( ) Children

( ) Teenagers (x)

Adults

( ) Elderly

11. Researcher training (Undergraduate level):

Medicine.

12. Supervisor's background, when applicable (Undergraduate):

Medicine.

* According to the "PB-BASIC PROJECT INFORMATION" posted on 11/20/2025, we have the

The following information:

13. Hypothesis(es):

H0: There is no significant difference between patients undergoing open cholecystectomy and those undergoing laparoscopy regarding sociodemographic, clinical, anatomical, institutional characteristics, postoperative complications, and length of hospital stay.

hospital.

H1: The sociodemographic, clinical, anatomical, and institutional characteristics of patients undergoing open cholecystectomy differ from those observed in patients undergoing videolaparoscopy, influencing the choice of surgical technique, the risk of complications, and the length of hospital stay.

14. Inclusion Criteria:

Patients over 18 years of age who underwent cholecystectomy surgery at a public hospital in the Federal District between March 2023 and February 2025; Complete and legible medical records containing sociodemographic, clinical, and surgical procedure-related information.

15. Exclusion Criteria:

Patients with a history of previous cholecystectomy performed at another facility; Cases in which contact with the patient is not possible to obtain the Informed Consent Form
(ICF).

16. Brief consideration of the methodology.

a) Proposed Methodology: This
study will be characterized as a descriptive cross-sectional study with a quantitative approach, with data collection carried out using the medical records of patients who underwent cholecystectomy surgery at a public hospital in the Federal District between March 2023 and February 2025. A retrospective analysis of the medical records will be performed. Data collection will be carried out through the analysis of the patients' medical records.
subjected to

These surgical procedures utilize information such as sociodemographic data (age, sex, race/ethnicity, geographic origin), clinical characteristics (clinical diagnosis, presence of comorbidities, duration of symptoms, prior antibiotic use), details of the surgical procedure (videolaparoscopic technique or open surgery, conversion), anatomical and intraoperative variables (presence of adhesions; perivesicular inflammation/infiltration; gallbladder wall thickening; difficulty visualizing Calot's triangle; biliary tract injury; need for drainage), and immediate
postoperative outcomes (complications, time to recovery).

Hospitalization, need for reintervention, clinical evolution, hospital readmission within 30 days). The estimated sample size is approximately 315 patients, corresponding to the total number of cholecystectomy procedures performed at the hospital between March 2023 and February 2025, according to previous records from the surgical statistics department. Therefore, this is a census sample, representing all available cases that meet the inclusion criteria, which ensures the robustness and representativeness of the results. Recruitment will be retrospective and non-invasive, based on the identification of the medical records of patients who underwent cholecystectomy during the study period. After screening, patients will be contacted individually by telephone (calls and WhatsApp messages) for clarification and invitation
to participate. Those who agree to participate will be informed about the purpose of the research, the confidentiality of the data, and the right to refuse or withdraw at any time, without prejudice to their follow-up or medical care. The Informed Consent Form (ICF) can be signed in person at the hospital or digitally via Google Forms, depending on the participant's availability.

b) Data Analysis Methodology: The
statistical analysis of the study will be descriptive in nature, aiming to characterize the epidemiological profile of patients undergoing cholecystectomy surgery in a public hospital in the Federal District between March 2023 and February 2025. The collected data will be organized into tables and graphs, allowing for a clear and informative presentation. Categorical variables will be described using absolute and relative frequencies (in percentage), while continuous variables will be analyzed
using measures of central tendency and dispersion, such as mean, median, standard deviation, minimum and maximum values.

Research Objective:
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According to the "PB - BASIC PROJECT INFORMATION" posted on 11/20/2025, we have:

I) Primary Objective:
- To analyze the profile of cholecystectomy surgeries performed in a public hospital in the Federal District, identifying the factors associated with the choice between the open and videolaparoscopic techniques.

II) Secondary Objectives:

- To describe the sociodemographic and clinical characteristics of patients undergoing cholecystectomy;
- To identify the frequency of surgeries performed using open surgery and video-laparoscopic techniques;
- To analyze the clinical, anatomical, and institutional factors related to the conversion of videolaparoscopy into open technique;
- To evaluate the main complications associated with each technique; -
To compare the length of hospital stay between patients undergoing open and laparoscopic surgery.

Risk and Benefit Assessment:

* According to the "PB - BASIC PROJECT INFORMATION" posted on 11/20/2025, we have:

I) Risks:

The potential risk associated with participation in the research is the possible accidental disclosure of the participants' identity. To mitigate this risk, we will adopt measures such as anonymizing the collected data through coding, without any nominal identification, and presenting it only in aggregate form in the results. Sensitive information such as name, address, telephone number, identity documents, medical record number, or any other data that could allow the direct identification of participants will not be collected. Furthermore, the data will be stored exclusively on a computer protected by a personal password, in a spreadsheet with encrypted protection, accessible only to the responsible researcher and the team directly involved in the research. This approach complies with Resolution No. 466/2012, which ensures the secrecy and confidentiality of research participants and their data.

II) Benefits:

This research offers public health benefits by contributing to the understanding of the epidemiological profile of cholecystectomy surgeries in a public hospital, allowing the identification of factors influencing the choice between the videolaparoscopic technique and open surgery. This analysis enables the identification of clinical, anatomical, and institutional patterns associated with technique conversion and...
postoperative complications,

supporting strategies to improve surgical decision-making and care planning. Furthermore, by providing data on outcomes and length of stay, the study can guide policies for more efficient resource allocation, optimize hospital flows, and contribute to the improvement of clinical practices, with a direct impact on the quality of care and patient recovery.

Comments and Considerations on the Research:
The following are the CONSIDERATIONS regarding this research project:

ITEM 1. Hypothesis Presentation: (x)
Adequate ( )
Needs adjustment ( ) Does
not apply to the proposed study

ITEM 2. Proposed Methodology (Type of Methodology, Recruitment Method, Obtaining Consent and Research Stages): (x) Adequate ( )
Needs
Adjustment

ITEM 3. Methodology for Data Analysis: (x)
Presented ( )
Not presented

ITEM 4. Research Objectives: (x)
Adequate ( )
Need adjustments

ITEM 5. Presentation of Risks and Methods of Mitigation: (x) Adequate ( )
Require
adjustments

ITEM 6. Presentation of Benefits: (x)
Adequate ( )
Need adjustments

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ITEM 7. Weighing the risks and benefits of the research: (x) The
expected benefits of the research outweigh the risks presented ( ) There are
significant risks in this research that outweigh the expected benefits

ITEM 8. Social relevance:

(x) The social relevance of the research was duly presented.
( ) The social relevance of this research was not clearly established.

ITEM 9. Criteria for inclusion of participant(s) in the research: (x)
Adequate ( )
Need Adjustments ( ) Not
presented

ITEM 10. Criteria for excluding participant(s) from the research: (x)
Adequate ( )
Need adjustments ( ) Not
presented

ITEM 11. Protection of research participants in vulnerable situations: ( ) The research
will involve person(s) with reduced capacity to give their consent AND/OR who are in situations that prevent(s)
them from resisting the taking of consent. (x) The research will not involve person(s) in
vulnerable situations. ( ) Not applicable, since free and informed consent
will not be obtained.

ITEM 12. Budget for conducting the research: ( )
Adequate ( )
Needs adjustment

ITEM 13. Research Execution Schedule: (x)

Adequate, with data collection scheduled to begin on 10/26/2025 and research completion scheduled for 06/11/2025.

( ) Needs adjustment

ITEM 14. Data collection instrument: (x)
Adequate ( )
Needs adjustment ( ) Not
applicable

ITEM 15. Consent Structure (ICF/ICF-R/TALE): (x) Adequate
( ) Needs
Adjustment ( ) Not applicable,
since the waiver of consent was granted

ITEM 16. Justification for Waiving Consent:
( ) Rejected
( ) Approved in accordance with the justifications presented
( ) May be granted provided that more adequate justifications are presented
(x) Not applicable, as consent will be required

Considerations regarding the mandatory submission terms:

After reviewing all the attached Mandatory Submission Terms, the following considerations apply.

CEP-FEPECS Collegiate Body:

(Note: If any of the documents below have not been submitted, leave the option blank and indicate the absence in the pending section.)

ITEM A. Project Cover Letter: (x) Submitted and
Adequate ( ) Submitted with
Inadequacies

ITEM B. Statement of Commitment from the Principal Investigator: (x)
Submitted and Adequate ( )
Submitted with Inadequacies

ITEM C. Title Page:

(x) Presented and Adequate

( ) Presented with Inadequacies

ITEM D. Consent Form OR Co-participation Form: (x)
Submitted and Adequate ( )
Submitted with Inadequacies

ITEM E. Lattes Curriculum of all those involved in the research:
(x) Presented and Adequate
( ) Presented with Inadequacies

ITEM F. Brochure Project.
When evaluating the Brochure, the rapporteur must verify if there are any DISPARITIES between the wording of the BROCHURE and the BASIC INFORMATION PB, mainly in the following items: Methodology, Objectives, Risks, Benefits, Schedule and Budget. The Brochure is a complement to the Basic Information PB so that the rapporteur can better understand the research proposal and thus issue their final opinion. Therefore, after the due evaluation of the BROCHURE PROJECT, it is considered to be: (x) Presented and Adequate ( ) Presented with
Inadequacies

ITEM G. TCLE/TCLE-R/TALE:
(x) Presented and Suitable
( ) Presented with Inadequacies
( ) Not applicable, since the waiver of consent WAS REQUESTED.

ITEM H. Waiver of Consent: ( )
Presented and Adequate ( )
Presented with Inadequacies (x) Not
applicable, since a waiver of consent was NOT REQUESTED.

Conclusions or Pending Issues and List of Inadequacies:
PROJECT APPROVED

The researcher's responsibility is non-delegable and non-waivable, encompassing ethical and legal aspects.

The researcher undertakes to guarantee confidentiality that ensures the anonymity and privacy of the research participants and that the data obtained will be used exclusively for the purpose foreseen in its protocol.

- The researcher is also responsible
for: a) developing the project as outlined; b) preparing
and submitting partial and final reports; c) submitting data requested
by the Ethics Committee (CEP) or the National Ethics Committee (CONEP) at any time; d) maintaining
the research data in a physical or digital file, under their custody and responsibility, for a period of 5 years after the end of the research; e) submitting the research results for publication, with due credit
to the associated researchers and the technical staff involved in the project; f) providing a well-founded justification to the Ethics Committee (CEP) or the National Ethics Committee (CONEP) for any interruption of the
project or non-publication.
of the results.

Final considerations at the discretion of the Ethics Committee:

This opinion was prepared based on the documents listed below:

Document Type File PB_INFORMAÇÕES_BÁSICAS_DO_P Basic		Posted	Author	Situation
Letter.pdf Previous Opinion	Information of the Project PROJECT_2605947.pdf Response	20/11/2025 00:04:04		Accepted
		20/11/2025 00:03:43	MARINA FERREIRA DA SILVA	Accepted
Detailed Project / Brochure Researcher	ProjectBrochure_MarinaFerreira.doc	20/11/2025 00:02:18	MARINA FERREIRA DA SILVA	Accepted
Informed Consent Form / Terms of Assent / Justification of Absence	Informed Consent Form (ICF).docx	28/08/2025 21:32:14	MARINA FERREIRA DA SILVA	Accepted
Others	ResearcherCurriculum.pdf	28/08/2025 21:31:43	MARINA FERREIRA DA SILVA	Accepted
Others	CurriculumAdvisor.pdf	28/08/2025	MARINA FERREIRA	Accepted

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Others	CurriculoOrientadora.pdf	21:31:17	DA SILVA	Accepted
Declaration of Researchers	TermoCompromisso.pdf	28/08/2025 21:30:29	MARINA FERREIRA DA SILVA	Accepted
Declaration of Researchers	ForwardingLetter.pdf	28/08/2025 21:30:16	MARINA FERREIRA DA SILVA	Accepted
Declaration of Institution and Infrastructure	Term of Agreement.pdf	28/08/2025 21:29:26	MARINA FERREIRA DA SILVA	Accepted
Title Page	FolhadeTratoMarinaFerreiradaSilvaassi nada.pdf	28/08/2025 21:29:07	MARINA FERREIRA DA SILVA	Accepted

Status of the Opinion:
Approved

Requires CONEP's approval:
No

BRASILIA, December 8, 2025

Signed by:
Estela Ribeiro Versiani
(Coordinator)