REVISTA TÓPICOS
ISSN 2965-6672 | Qualis A2

# ESTABLISHING A CLINICAL RESEARCH CENTER IN A TERTIARY HOSPITAL: A PRACTICAL MODEL BASED ON REAL-LIFE EXPERIENCE

## ESTABELECIMENTO DE UM CENTRO DE PESQUISA CLÍNICA EM UM HOSPITAL TERCIÁRIO: UM MODELO PRÁTICO BASEADO EM EXPERIÊNCIAS REAIS

Ciências da Saúde • 13/04/2026

REGISTRO DOI: 10.70773/revistatopicos/776021736

Roberta de Almeida da Silva[1,2]

Gustavo Monteiro Escott[2]

Antonio Nocchi Kalil[1,2]

Luis Fernando Ferreira[1,2,3]

**ABSTRACT**

Clinical research plays a fundamental role in advancing medicine, directly impacting quality of care provided to patients. Institutions with strong engagement in clinical studies demonstrate better outcomes, such as lower mortality and increased survival, even among patients not enrolled in research. There is a growing worldwide mobilization to promote clinical research, with emphasis on initiatives related to funding, regulation, and incentives for the establishment of Clinical Research Centers (CRCs) in hospitals. This article proposes a practical model for implementing a CRC based on the experience of a Brazilian hospital, aiming to offer structural, operational, and strategic guidelines that can be replicated worldwide, addressing topics such as essential regulations for the creation and maintenance of a CRC, including transparency and regulatory compliance; infrastructure; investment in human resources and multidisciplinary team; investment and action planning; strategies for relationship with industry, research organizations, and public agencies; and fee letters to support operational costs.

**Keywords:** Good Clinical Practice Guidelines; Clinical Research; Health Facilities; Health Services Administration; Hospital Administration.

**RESUMO**

A pesquisa clínica desempenha um papel fundamental no avanço da medicina, impactando diretamente a qualidade da assistência prestada aos pacientes. Instituições com forte envolvimento em estudos clínicos demonstram melhores resultados, como menor mortalidade e maior sobrevida, mesmo entre pacientes não incluídos em pesquisas. Há uma crescente mobilização mundial para promover a pesquisa clínica, com ênfase em iniciativas

relacionadas a financiamento, regulamentação e incentivos para o estabelecimento de Centros de Pesquisa Clínica (CPCs) em hospitais. Este artigo propõe um modelo prático para a implementação de um CPC baseado na experiência de um hospital brasileiro, visando oferecer diretrizes estruturais, operacionais e estratégicas que possam ser replicadas mundialmente, abordando tópicos como regulamentações essenciais para a criação e manutenção de um CPC, incluindo transparência e conformidade regulatória; infraestrutura; investimento em recursos humanos e equipe multidisciplinar; planejamento de investimentos e ações; estratégias de relacionamento com a indústria, organizações de pesquisa e órgãos públicos; e cartas de honorários para custear as despesas operacionais.
**Palavras-chave:** Boas Práticas Clínicas; Pesquisa Clínica; Serviços de Saúde; Administração Hospitalar.

## BACKGROUND

Clinical research is essential for advancing medicine, enabling the development of new therapies and treatments based on scientific evidence. It drives medical innovation and strengthens healthcare systems, with investments yielding benefits for both public health and scientific progress (1).

Studies show that in severe conditions such as cancer, greater research investment reduces mortality and increases five-year survival by up to two-thirds compared with low-investment contexts (2-4). From a hospital perspective, Hospitals more engaged in research also achieve lower postoperative mortality and better survival, even among patients not enrolled in trials, suggesting institutional involvement improves outcomes (5, 6).

Internationally, the United States and European Union lead in clinical research through major public and private investments. The NIH funds studies advancing treatments for cancer and neurodegenerative disorders (7, 8), while the EU's Horizon 2020 program invested billions in biomedical research, fostering public-private partnerships and strengthening healthcare systems(9).

In Brazil, Clinical Research Centers (CRCs) in private hospitals have expanded, particularly in large cities, aiming to improve patient care, strengthen ties with industry, and build a more innovative health system (10, 11), growth linked to increasing participation in multicenter and international studies, as noted by ABIMED (12). ANVISA's 2022 Annual Report highlights this trend as part of integrating Brazil into global research (13). Moreover, ANVISA and CONEP play a critical role in establishing ethical and regulatory guidelines to ensure the responsible conduct of research, as outlined in regulations RDC 9/2015 and CNS 466/2012 (14, 15).

The benefits of clinical research include new therapies for rare diseases, improved hospital quality, and greater patient access to experimental treatments. Hospitals engaged in research show higher survival and patient satisfaction, linked to innovative therapies and closer follow-up care (16, 17).

The following article explores the key aspects to be considered in the implementation and consolidation of a Clinical Research Center in a private hospital, focusing on regulations, necessary infrastructure, team development, investment, and relationships with stakeholders. This discussion is based on a successfully implemented project at a leading tertiary hospital in the city of Porto Alegre, Brazil.

## 1. ESSENTIAL REGULATIONS

To ensure compliance and safety in the operations of a Clinical Research Center (CRC), it is essential to adhere to both national and international regulations. Compliance with these regulations not only protects patients' rights but also ensures the integrity of the data produced and upholds the institution's reputation. An overview of these regulations in Brazil, and that shall serve as an example for other countries, is provided in Figure 1.

### 1.1. Brazilian Health Regulatory Agency (ANVISA)

RDC 9/2015 (15) establishes the guidelines for conducting clinical trials with pharmaceuticals in Brazil, ensuring that such trials are carried out ethically, safely, and efficiently. This regulation governs all stages of clinical trials, from protocol development to result evaluation, including the responsibilities of investigators, sponsors, and ethics committees.

RDC 9/2015 plays a crucial role not only within the Brazilian regulatory framework but also in aligning Brazil with international standards for clinical research. Its emphasis on ethical conduct, safety, and scientific rigor, reflecting global principles established by entities such as the International Council for Harmonisation (ICH) (18) and the Declaration of Helsinki (19). For CRCs operating in large hospitals, adherence to such regulations ensures credibility and facilitates collaboration with multinational studies and pharmaceutical sponsors. Globally, regulatory alignment is vital for mutual recognition of research data and for accelerating the development of new therapies. Thus, RDC 9/2015 (15) reinforces Brazil's capacity to contribute meaningfully to global clinical

research while safeguarding public health and upholding ethical standards.

Proper application of this regulation in the CRC ensures that investigational drugs are adequately evaluated for efficacy and safety, providing access to innovative and cutting-edge treatments. Failure to comply with RDC 9/2015, or similar laws, may result in legal and administrative sanctions and may also compromise the integrity of research data.

### 1.2. National Research Ethics Commission (CONEP)

Resolution CNS 466/2012 (14) defines the ethical guidelines for research involving human subjects, ensuring that studies are conducted according to bioethical principles, including respect for participants' dignity, safety, and rights.

Proper application of this resolution in the CRC ensures the protection of research participants' rights, guaranteeing that all studies are conducted in accordance with ethical standards. Non-compliance may result in study cancellation, financial losses, and damage to the institution's image.

Resolution CNS 510/2016 (20) must also be observed, as it governs research in the human and social sciences, providing specific guidelines for studies involving social, behavioral, or cultural aspects. This resolution allows for an expanded scope of research, especially for studies involving interventions in social and cultural contexts. However, failure to comply may compromise the credibility and ethical conduct of the study, particularly in research addressing sensitive issues.

Resolution CNS 466/2012 and Resolution CNS 510/2016 together form the ethical backbone of human subject research in Brazil, reflecting global commitments to uphold the dignity, autonomy, and safety of participants. Their emphasis on informed consent, risk minimization, and equitable subject selection is consistent with internationally recognized ethical frameworks, such as the Declaration of Helsinki (19) and CIOMS guidelines (21).

For CRCs, strict adherence to these resolutions ensures that studies are ethically grounded and socially responsible, fostering public trust and institutional credibility. Additionally, the inclusion of Resolution CNS 510/2016 (20) broadens the ethical oversight to research in the human and social sciences - a critical area often neglected in biomedical-centric regulations. In a global context, these resolutions demonstrate Brazil's comprehensive approach to ethics in research, and their application within CRCs strengthens international collaborations and safeguards against ethical breaches that could undermine both scientific validity and public confidence.

### 1.3. Good Clinical Practice (ICH-GCP)

The ICH-GCP (International Council for Harmonization – Good Clinical Practice) (18) guidelines are universally recognized as the gold standard for the ethical and scientific conduct of clinical trials. Their adoption ensures that research involving human participants is carried out with the highest degree of transparency, accountability, and respect for individual rights.

For CRCs, implementing ICH-GCP (21) principles not only improves the quality and consistency of data but also opens the door to global collaboration, regulatory approval in multiple regions, and

participation in multicenter international trials. Compliance with these guidelines signals a commitment to excellence and integrity, which is essential in today's globalized research environment. Conversely, failure to comply can result in data rejection by regulatory authorities, ethical violations, and reputational damage—consequences that compromise not only individual studies but also the credibility of the institution as a whole.

### 1.4. General Data Protection Law (LGPD)

Law No. 13.709/2018, the General Data Protection Law (LGPD) (22), establishes a robust legal framework for the collection, processing, storage, and sharing of personal data in Brazil, with a central focus on protecting individual privacy and autonomy. Globally, the LGPD aligns with international data protection standards, such as the European Union's General Data Protection Regulation (GDPR) (23), reflecting a broader trend toward stricter oversight of personal data use in research.

In clinical research, laws like LGPD (22) and GDPR (23) plays a critical role in regulating the handling of sensitive health information from participants, ensuring that data are managed with transparency, security, and ethical responsibility. For CRCs, compliance with these laws not only enhances participant trust and institutional integrity but also facilitates international collaboration by demonstrating adherence to globally recognized privacy norms. Conversely, failure to comply may result in significant financial penalties, loss of credibility, and barriers to participation in multinational studies, where data protection compliance is increasingly a prerequisite.


**Figure 1**. Key-point Regulations Implementing a Clinical Research Center: regulations in Brazil and its equivalents worldwide.

## 2. INFRASTRUCTURE AND LAYOUT

The physical structure of a clinical research center must be planned to meet the operational needs of clinical trial workflows and must comply with the regulations established by agencies such as ANVISA and CONEP, as well as with international guidelines like Good Clinical Practice (ICH-GCP), as previously mentioned.

Ideally, the clinical research center should be physically integrated into the hospital, ensuring easy access for patients, healthcare teams, and the technological and support services available on site. At a minimum, the structure should include the spaces listed below and must take into account the provisions of RDC 50 (24), which outlines the Technical Regulation for the planning, design, development, and evaluation of physical projects for healthcare facilities.

Figure 2 shows the actual layout of the CRC described in this article. With more than 90 square meter allocated to the CRC and an additional 80 square meter dedicated to the center's exclusive

pharmacy, the facility includes a reception area, waiting room, researcher workspaces, consultation rooms, laboratories, and state-of-the-art equipment, as detailed in the floor plan. The estimated investment in this center for the year 2025 is approximately 200 thousand United States dollars (USD), around a million Brazilian Reais (BRL). It has the capacity to support up to 100 simultaneous studies and to accommodate 25 patients per day.

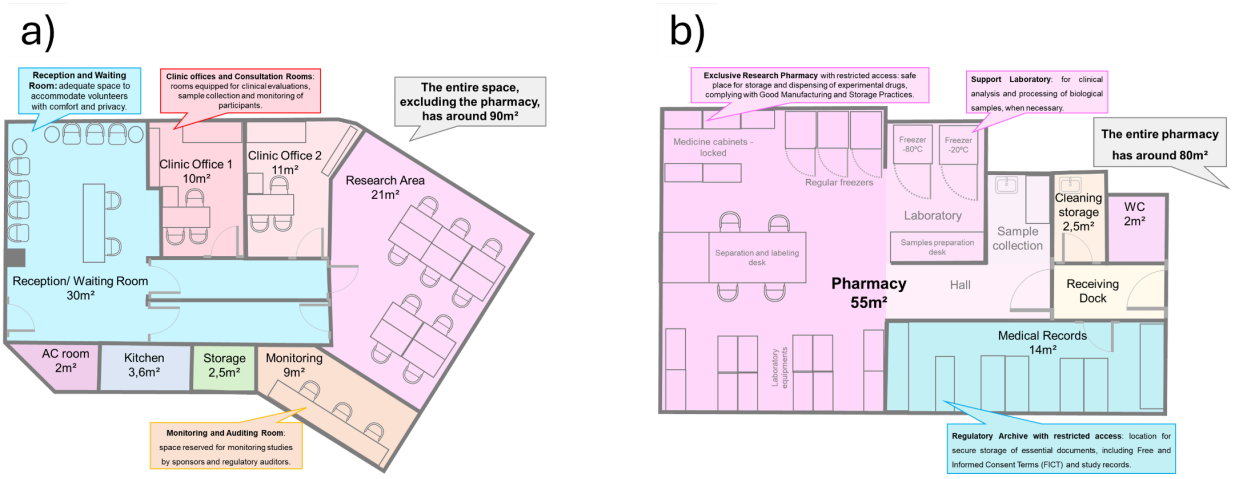


**Figure 2.** a) Physical space model of a Clinical Research Center – Excluding Research Pharmacy; b) Physical space model of a Research Pharmacy, attached to the Clinical Research Center.

## 3. MULTIDISCIPLINARY RESEARCH TEAM

The operation of a clinical research center requires a qualified and well-trained team composed of professionals from various healthcare fields, including physicians, nurses, pharmacists, biomedical scientists, professional researchers from other areas of knowledge, as well as administrative personnel. The center described in this article currently employs a team of 32 professionals, capable of providing safe and comfortable care to patients, while also meeting the demands of industry sponsors and other sectors involved in the research ecosystem.

Below is a description of the minimum team required to maintain a center of this scale, along with estimated year and monthly costs based on 2025 market averages. These estimates are based on our CRC, that, as said before, have the capacity to attend 100 projects, and an average of 25 patients per day.

### 3.1. Multidisciplinary Roles In a CRC Research Team

The principal investigator (PI) is responsible for leading the study, ensuring participant safety, and complying with the clinical protocol. This professional supervises the research team, reviews clinical data, and ensures ethical and regulatory compliance throughout the study process Ideally, a CRC should have a clinical research medical coordinator to ensure the quality of the PIs involved. In 2025 an average year-salary would be around 20-45 thousand USD for this the PI, and 60-72 USD.

Sub-investigators (SI) support the principal investigator in implementing the clinical protocol. Their responsibilities include conducting clinical assessments, collecting data, and monitoring participants' responses to treatment, contributing directly to the integrity and quality of the research. Ideally a CRC should have at least one SI for each 15 projects, at a year cost of approximately 50 thousand BRL (around 10 thousand USD).

The research coordinator (RC) oversees the day-to-day operational execution of the study, ensuring strict adherence to the protocols. This person serves as a liaison between the research team, sponsors, and ethics committees, while also coordinating site visits, regulatory documentation, and data management. Ideally a CRC should have

at least one RC for each 15 projects, at a year cost of approximately 100 thousand BRL (around 20 thousand USD).

**Table 1**. Team and average salary for maintaining a Clinical Research Center in Brazil in 2025.

| Position | Average Annual Salary* | Number of professionals** | Annual investment |
|---|---|---|---|
| **Clinical research medical coordinator** | 50.000,00 USD/ 250.000,00 BRL | 1 | 50.000,00 USD/ 250.000,00 BRL |
| **Principal Investigator** | 10.000,00 USD/ 50.000,00 BRL | 15 | 150.000,00 USD/ 750.000,00 BRL |
| **Sub-Investigator** | 10.000,00 USD/ 50.000,00 BRL | 15 | 150.000,00 USD/ 750.000,00 BRL |
| **Research Coordinator** | 20.000,00 USD/ 100.000,00 BRL | 15 | 300.000,00 USD/ 1.500.000,00 BRL |
| **Nurse** | 20.000,00 USD/ 100.000,00 BRL | 1 | 20.000,00 USD/ 100.000,00 BRL |
| **Pharmacist** | 20.000,00 USD/ 100.000,00 BRL | 1 | 20.000,00 USD/ 100.000,00 BRL |
| **Administrative** | 8.000,00 USD/ 40.000,00 BRL | 8 | 64.000,00 USD/ 320.000,00 BRL |
| **TOTAL** | | 41 | 754.000,00 USD/ 3.770.000,00 BRL |

**Where:** * Based on an average salary paid by the market in 2025, converted from Brazilian reais (BRL) to United States dollars USD). The values may vary depending on country and region economy; **

Number of professionals needed to serve 25 patients per day, on average.

Nurses and/or nursing technicians are responsible for collecting biological samples, administering investigational drugs, monitoring vital signs, and providing support to participants throughout the study period. Their clinical expertise plays a key role in ensuring participant safety and protocol adherence. As this team plays a crucial role in the day-to-day management of clinical trials, a number of 15 to 20 clinical research coordinators are needed in a CRC handling 100 studies, with an average monthly salary of 2,000 USD.

The research pharmacist is responsible for the proper storage, preparation, and dispensing of investigational products, ensuring traceability and compliance with safety and regulatory standards. This professional is essential to maintain the integrity of pharmaceutical interventions in clinical trials. Currently, it is recommended that a CRC have 1 pharmacist for every 100 studies, at an annual cost of approximately 24 thousand USD.

The administrative team manages contracts, budgeting, invoicing, and regulatory processes, ensuring the financial and legal sustainability of the research center's operations. Their work supports the seamless integration of research activities with institutional and sponsor requirements. This team includes, but is not limited to, receptionists, secretaries, financial analysts, and contract specialists, with salaries ranging from 800-2,000 USD, depending on the expertise required for each role.

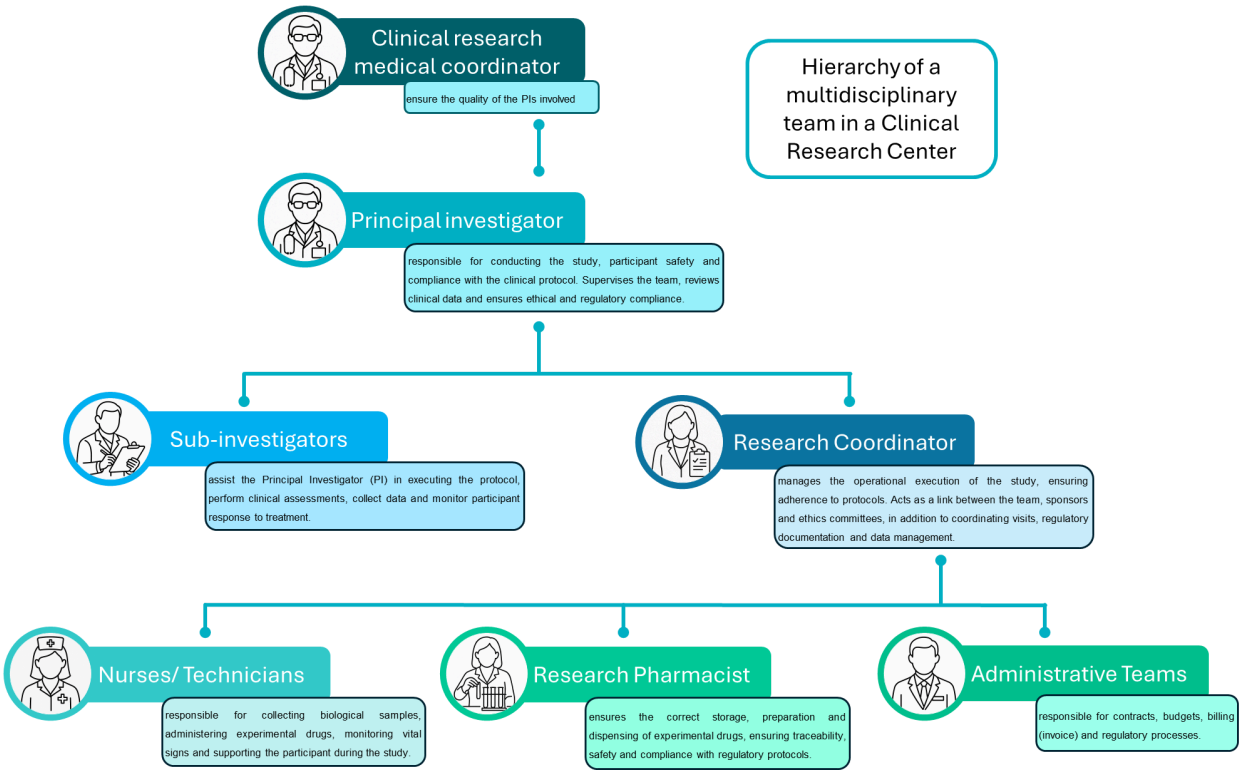


**Figure 3**. Proposed team for a multidisciplinary research center, along with its organizational hierarchy.

## 4. INITIAL INVESTMENT AND TARGETING OF ACTIONS

The implementation of a clinical research center within a hospital requires detailed financial planning. The initial investment may vary depending on the existing infrastructure of the institution and the specific needs of the studies to be conducted. However, the main cost categories generally include infrastructure and equipment, personnel, regulatory processes, technology, and study acquisition strategies.

Currently, the costs of implementing a CRC in a tertiary hospital in southern Brazil range from 2 to 2.2 million BRL (360 to 400 thousand USD), without the personnel (see personnel cost' details at chapter 3).

- **Infrastructure and equipment** costs cover the purchase of furniture, computers, medical and laboratory equipment, as well as storage facilities for supplies and biological materials.

These investments ensure that the center meets the operational and regulatory requirements for clinical research. As an initial investment for the implementation of a CRC suitable to attend the number of projects and participants detailed in this article, would be necessary to have a budget around 1 million BRL (around 200 thousand USD).

- The **hiring and training of the research team** represents another significant budget. This includes salaries, professional development, and certifications required by regulatory agencies. Investing in a well-qualified team is essential to ensure the quality and compliance of research activities. The annual and monthly investment in personnel are described in table 1, as well as the initial team for a CRC of this size. The costs for training the multidisciplinary research team will be described in details in the chapter 6.

- **Regulatory and approval costs** include fees for submissions to Ethics Committees (CEP/CONEP) and other regulatory bodies for clinical trial approvals. Proper budgeting for these processes is fundamental for the timely initiation of studies.

However, these costs may vary not only depending on the country where the center is located but also on the specific region within that country. Notably, regardless of location, the political interest of federal and local governments can significantly influence these expenses. For example, a government that prioritizes education and research may choose to reduce or even eliminate certain fees to encourage the establishment of a Clinical Research Center (CRC), seeing it as strategically aligned with its public health or economic development goals. Conversely, a government that does not

prioritize such initiatives may increase regulatory fees and create additional bureaucratic hurdles, potentially delaying the implementation process and raising overall costs.

- **Technology and data management** require investments in electronic document management software, electronic health records, and information security systems in compliance with the Brazilian General Data Protection Law (LGPD), or the local law to data protection. These tools are essential for ensuring data integrity, confidentiality, and regulatory compliance. A secure center of technology may need a budget of approximately 1 million USD.

- **Marketing and study acquisition strategies** involve actions aimed at attracting sponsors and securing new clinical trials. Developing visibility and credibility with industry partners is critical for the center's long-term sustainability. Marketing costs can vary widely depending on how aggressive you want your marketing to be. A budget between 5-25 thousand USD may be required. Nowadays our center charge around 3 thousand USD/ year for marketing in the target community, trying to attract patients.

To effectively guide these actions, it is recommended that institutions also define strategic objectives, setting short- and long-term goals with a focus on studies that offer the greatest scientific and financial impact. Establishing partnerships with academic institutions, the pharmaceutical industry, and funding agencies can help expand research opportunities and resources.

Developing a sustainability plan is essential to ensure economic viability. This includes maintaining an efficient cash flow and negotiating favorable contract terms. Additionally, investing in innovation, by adopting technologies that optimize processes, ensure regulatory compliance, and enhance the participant's experience, can further strengthen the center's operations.

The establishment of a clinical research center in a hospital setting enables the conduct of high-quality studies that meet ethical and regulatory standards. This initiative offers benefits not only to patients but also to scientific advancement and the professional development of the healthcare teams involved.

## 5. RELATIONSHIP STRATEGIES WITH THE PHARMACEUTICAL INDUSTRY AND CROS

The growth of a hospital-based clinical research center (CRC) depends on strong partnerships with the pharmaceutical industry and Contract Research Organizations (CROs). These collaborations enable high-quality trials while ensuring compliance with regulations and Good Clinical Practice (GCP). Based on five years of experience, our CRC has developed effective strategies that can guide other centers.

### 5.1. Building a Solid Reputation

Obtaining international certifications or accreditations can significantly enhance the hospital's credibility and the quality of its research processes. These recognitions serve as important indicators of compliance with international standards, making the center more attractive to sponsors and research partners.

Additionally, publishing study results in peer-reviewed scientific journals and presenting findings at international conferences are critical strategies for demonstrating the institution’s expertise and research quality. Such visibility helps build the center’s reputation within the global research community and can increase the likelihood of being selected for future clinical trials.

### 5.2. Active Prospecting Of Studies

Registering the center in global databases, such as ClinicalTrials.gov, ANVISA, and the World Health Organization's clinical trial registries, is essential for increasing its visibility to potential sponsors and research partners. Being listed in these platforms signals the center’s active participation in the clinical research landscape and enhances its chances of being selected for new studies.

Participation in national and international clinical research conferences and trade fairs is another key strategy. These events offer valuable networking opportunities with sponsors and CROs, allowing the center to showcase its infrastructure, expertise, and research portfolio, while also staying updated on emerging trends and opportunities in the field.

### 5.3. Developing Partnerships With Cros

Identifying and engaging regional CROs allows the CRC to present its infrastructure and compliance, positioning itself as a preferred site. Long-term agreements, such as master contracts, streamline processes and ensure prioritization in future trials.

### 5.4. Infrastructure And Operational Efficiency

Competitiveness depends on reducing approval times and streamlining ethics and contract processes. Clear responsibilities and agile negotiations are valued by sponsors. A well-trained team ensures compliance, patient care, and data quality, while continuous education strengthens performance.

### 5.5. Transparency And Regulatory Compliance

Performance reports demonstrating recruitment capacity, protocol adherence, and data quality build sponsor trust. Strict compliance with GCP and local regulations ensures ethical research and reinforces long-term partnerships.

### 5.6. Solid And Independent Ethics Committee

For a CRC of excellence, it is vitally important to establish a plural, efficient, and, above all, independent ethics committee (EC). Only with a solid EC, composed of independent and experienced researchers, can fundamental values for a CRC be ensured (25, 26).

An EC should be composed of researchers coming from different areas, such as social, health, biological and rehabilitation sciences, among others; and with different formations and knowledge, such as professionals, clinicians, researchers, professors and managers. It guarantees the plurality of ideas and backgrounds (25, 27).

From the perspective of the patients, an EC safeguard they rights and well-being, providing safety, ethical oversight to the research protocols and its applications, and offering support and consultations to the patients, family, caregivers and researchers involved (25, 27, 28).

The ISCMPA ethics committee works supported on 6 pillars: 1) Participant protection: ensuring that the rights, safety, and well-being of study participants are protected throughout the entire research process; 2) Ethical review: reviewing the research protocol to ensure that procedures are ethical, risks are minimized, and benefits are justified; 3) Legal and regulatory compliance: ensuring that the research complies with national regulations and international standards for ethics in clinical research; 4) Informed consent: evaluating the informed consent process, ensuring that participants receive all necessary information to make a fully informed decision about their participation; 5) Transparency and accountability: EC approval enhances the credibility of the research by ensuring transparency and accountability to sponsors, institutions, and the scientific community, and; 6) Ongoing monitoring: In addition to initial approval, the EC monitors the study's progress, evaluating any protocol modifications and investigating potential adverse events.

## 6. MULTIDISCIPLINARY TEAM TRAINING

To maintain regulatory compliance and ensure a high standard of quality, the multidisciplinary team must undergo regular training, following at least the schedule and content outlined below:

Annually, the team should receive updates on current legislation and new guidelines in clinical research. This training ensures that all professionals remain informed about regulatory changes that may affect the conduct of clinical trials.

Biannually, there should be reinforcement training on Good Clinical Practice (GCP), patient safety, and the data protection laws,

highlighting the ethical conduct of studies, protection of participant rights, and proper management of personal data.

Quarterly, operational training should be conducted focusing on study protocols, data collection procedures, and the management and reporting of adverse events. This ensures that all staff are prepared to handle the operational demands of ongoing studies.

Additionally, ad-hoc training sessions should be organized as needed, especially when new regulations are implemented or when new studies are initiated at the center.

Based on this schedule, the trainings should cover the following key areas:

- Good Clinical Practice (ICH-GCP), focusing on the ethical and regulatory conduct of clinical studies;

- Local and international regulations, including guidelines from ANVISA, FDA, or similar regulatory bodies; and national ethics committee (such as CONEP in Brazil);

- Data management and the laws that protect patients' data (e.g. LGPD), emphasizing the protection of sensitive participant information and compliance with data privacy standards;

- Patient safety and adverse event monitoring, ensuring accurate reporting and effective risk management;

- Internal center processes, with emphasis on workflow standardization and adherence to Standard Operating

Procedures (SOPs) for consistent and high-quality operational performance.

## 7. FEE LETTERS: SUBSIDY FOR OPERATING COSTS

To ensure financial sustainability, appropriate return on investment, and regulatory compliance, CRCs must establish a fee letter that clearly outlines the costs associated with all services and processes involved in conducting clinical trials. This document should align with current legislation and best practices, ensuring financial transparency while covering all operational expenses, from administrative to clinical activities. Additionally, the fee structure must comply with regulatory pricing guidelines, safeguarding the center from legal or ethical conflicts and contributing to its long-term financial health.

### 7.1. Model Of Initial Fees For Clinical Research Centers

Below is a list of possible fees that a clinical research center may adopt, following common market practices and regulatory guidelines. The summarized rates can be seen in Table 2.

a. The Initial Ethics Submission Fee is charged at the time of submission of the regulatory package to the Ethics Committee (CEP/CONEP in Brazil) and health surveillance agencies (e.g. ANVISA and FDA). It covers all initial communications, document review (such as the Informed Consent Form, Protocol, Investigator's Brochure, Diaries), preparation, and submission of documents for initial ethical and regulatory approvals. Even if the study is not initiated at the site for any reason, this fee remains due once these activities have been completed.

b. The Start-up Fee, payable at the beginning of the study and coinciding with the Site Initiation Visit (SIV), covers initial activities including budget and contract review, completion and submission of center service qualifications and equipment calibrations, the initiation visit itself (typically lasting 4 to 6 hours), training of support teams (infusion, radiology, among others), regulatory activities, and other administrative services required for study initiation.

c. The Amendment Submission Fee is charged whenever protocol amendments requiring regulatory approval are submitted.

d. The Initial Pharmacy Preparation Fee, due at the time of the SIV, covers the setup of the research pharmacy as well as training for both the pharmacy team and the nursing staff in the institution's chemotherapy outpatient clinic.

e. The Annual Pharmacy Maintenance Fee is charged yearly to cover ongoing maintenance activities of the research pharmacy.

f. The Annual Regulatory Maintenance Fee, also billed annually until the study's closeout visit, covers document organization and preparation for regulatory authorities, sponsor communications, and administrative expenses related to study management.

g. The Pharmacy Close-out Fee covers the final organization and review of investigational drugs at the research center.

h. The Document Reconciliation and Close-out Fee is charged alongside the contract retention fee, after the reconciliation of study documents and completion of the closeout visit.

i. The Re-consent Application Fee is billed quarterly, when applicable, at the same time as other study payments.

j. The Remote Monitoring Fee applies in exceptional cases and requires prior submission of a monitoring request letter at least 48 hours in advance. All remote monitoring, in our center, are conducted via Microsoft Teams video calls, hosted by the research center, with a maximum duration of one hour. This fee follows the study's payment schedule and is invoiced by the center.

k. The Ethics Committee Operationalization Fee is a one-time, non-refundable fee to cover the administrative costs of the Ethics Committee's operations. The full amount is retained by the institution and is payable within 30 days of invoice issuance, accompanying the submission of the draft contract.

l. The Post-study Document Archiving Fee refers to the storage of all study documents for five years, as required by Brazilian clinical research regulations. If other regulations bodies demands a different time of storage, this fee should be revisited. Payment is due at the end of the study upon presentation of the corresponding invoice.

m. The Annual Administrative Maintenance Fee is paid by the sponsor to the institution for administrative and financial activities related to the ongoing study.

n. The On-call Coordinator and Telehealth Availability Fee is a monthly fee covering the availability of the study coordinator for after-hours and weekend support. The multidisciplinary center operates Monday to Friday from 7:00 AM to 5:00 PM.

o. The Clinical Trial Recruitment Advertising Fee is a monthly fee payable by the sponsor during the study recruitment period. It covers the dissemination of study protocols on social media, corporate networks, media outlets, and institutional websites.

p. The Recruitment Support Fee is a one-time payment made to the institution to assist with patient recruitment for the study.

q. Finally, the Training Fee is a one-time charge paid to the institution for the training of the site team during the active period of the study.

**Table 2.** Model of Initial Fees for Clinical Research Centers

| Fee | Cost* | Details |
|---|---|---|
| a. Initial Ethics Submission | 2.000,00 USD/ 10.000,00 BRL | One-time fee |
| b. Start-up | 3.000,00 USD/ 15.000,00 BRL | One-time fee |
| c. Amendment Submission | 1.600,00 USD/ 8.000,00 BRL | Per submission |

| | | |
|---|---|---|
| d. Initial Pharmacy Preparation | 3.000,00 USD/ 15.000,00 BRL | One-time fee |
| e. Annual Pharmacy Maintenance | 2.000,00 USD/ 10.000,00 BRL | Annual |
| f. Annual Regulatory Maintenance | 2.000,00 USD/ 10.000,00 BRL | Annual |
| g. Pharmacy Close-out | 2.000,00 USD/ 10.000,00 BRL | One-time fee |
| h. Document Reconciliation and Close-out | 2.000,00 USD/ 10.000,00 BRL | One-time fee |
| i. Re-consent Application | 100,00 USD/ 500,00 BRL | Per application |
| j. Remote Monitoring | 500,00 USD/ 2.500,00 BRL | Monthly or per visit |
| k. Ethics Committee Operationalization | 2.000,00 USD/ 10.000,00 BRL | Annual or per study |
| l. Post-study Document Archiving | 1.000,00 USD/ 5.000,00 BRL | One-time fee or annual |
| m. Annual Administrative Maintenance | 2.000,00 USD/ | Annual |

| | | |
|---|---|---|
| | 10.000,00 BRL | |
| n. On-call Coordinator and Telehealth Availability | 1.000,00 USD/ 5.000,00 BRL | Monthly or anual |
| o. Clinical Trial Recruitment Advertising | 3.000,00 USD/ 15.000,00 BRL | Per campaign or monthly |
| p. Recruitment Support | 1.000,00 USD/ 5.000,00 BRL | Per study or monthly |
| q. Training | 3.000,00 USD/ 15.000,00 BRL | Per session or anual |

**Where:** * Rates charged by our center, based on the market average in Brazil in 2025.

## 8. FINAL CONSIDERATIONS

The implementation of a Clinical Research Center (CRC) within private hospitals in Brazil represents a significant milestone in expanding access to innovative treatments, strengthening scientific development, and enhancing the quality of patient care (10, 11). As discussed throughout this guide, building a successful research center requires strategic planning, professional training, and strict adherence to regulatory and ethical best practices.

It is also important to highlight that this article is based on a successful experience at a leading hospital in Brazil. According to

HospiRank 2024 (29), The Hospital Santa Casa de Porto Alegre is among the five best-equipped hospitals in the country, with infrastructure capable of handling a high volume of procedures. Each year, over 60,000 hospitalizations and nearly 70,000 surgical procedures are done, in addition to more than 1 million outpatient visits. The institution comprises nine hospitals specialized in different areas and is the only hospital in Brazil that performs all types of organ transplants. This gives us a solid starting point, with both expertise and strategic positioning.

Our research center, established in 2021, has naturally undergone adjustments in order to better serve the industry and CROs, researchers, and, most importantly, the patients involved in all clinical trials. These adjustments followed the execution of over 500 projects involving approximately 1,200 patients in the last 4 years. In 2024, we closed the year with 220 ongoing projects, carried out by a team of 35 professionals, including physicians, researchers, and support staff, attending a total of 304 patients during this period. This positions the Santa Casa' CRC as a large-scale center, ranking among the 10 largest and highest-rated in Brazil in terms of industry-sponsored studies.

The sustainability of the research center is also directly linked to the importance of studying Brazil's population diversity, a country with vast ethnic, cultural, and socioeconomic heterogeneity. This diversity is essential to generate clinical data that is representative and applicable to the local population, as well as to enhance the scientific robustness of studies. Furthermore, by meeting stringent international standards, the center attracts global health investments, as these resources are intended for research that can be applied in any country worldwide. Thus, the CRC not only

strengthens the national healthcare system but also positions Brazil as a strategic partner in conducting international clinical research, ensuring long-term financial and scientific sustainability.

Clinical research is an essential tool for the advancement of medicine and the expansion of therapeutic options available to patients. The dissemination of knowledge and sustained investment in this field have the potential to transform the healthcare landscape not only in Brazil, but in the world, with special attention to countries in development, like Brazil, fostering integration between the academic, medical, and business sectors (5, 10, 11, 21).

Through this guide, we encourage hospital administrators, healthcare professionals, and investors to explore this universe of opportunities, continually refining their practices and contributing to the growth of clinical research. The pursuit of knowledge and the ongoing improvement of these services should remain a continuous commitment, reflected in scientific advancement and better healthcare for the Brazilian population, or for the populations where those centers should be installed.

May this guide serve as just the starting point for a journey of innovation, learning, and contribution toward a more efficient and technologically advanced healthcare system.

**REFERENCES**

1. Ministry of Health. Secretariat of Science T, Innovation, Science SIiHDo, Technology. Clinical research action plan in Brazil. Ministry of Health, Brazil; 2020.

2. Cameron D, Stead M, Lester N, Parmar M, Haward R, Maughan T, et al. Research-intensive cancer care in the NHS in the UK. Annals of Oncology. 2011;22:vii29-vii35.

3. Petrelli NJ, Winer EP, Brahmer J, Dubey S, Smith S, Thomas C, et al. Clinical Cancer Advances 2009: major research advances in cancer treatment, prevention, and screening--a report from the American Society of Clinical Oncology. Journal of clinical oncology : official journal of the American Society of Clinical Oncology. 2009;27(35):6052-69.

4. Unger JM, LeBlanc M, George S, Wolmark N, Curran WJ, Jr., O'Dwyer PJ, et al. Population, Clinical, and Scientific Impact of National Cancer Institute's National Clinical Trials Network Treatment Studies. Journal of clinical oncology : official journal of the American Society of Clinical Oncology. 2023;41(11):2020-8.

5. Downing A, Morris EJ, Corrigan N, Sebag-Montefiore D, Finan PJ, Thomas JD, et al. High hospital research participation and improved colorectal cancer survival outcomes: a population-based study. Gut. 2017;66(1):89-96.

6. Rochon J, du Bois A, Lange T. Mediation analysis of the relationship between institutional research activity and patient survival. BMC medical research methodology. 2014;14:9.

7. Eichberg MJ. Public funding of clinical-stage antibiotic development in the United States and European Union. Health security. 2015;13(3):156-65.

8. Fajardo-Ortiz D, Thijs B, Glanzel W, Sipido KR, editors. Evolution of funding for collaborative health research towards higher-level patient-oriented research. A comparison of the European Union Framework Programmes to the program funding by the United States National Institutes of Health2023.

9. Gallo F, Seniori Costantini A, Puglisi MT, Barton N. Biomedical and health research: an analysis of country participation and research fields in the EU's Horizon 2020. European journal of epidemiology. 2021;36(12):1209-17.

10. Ribeiro EFO, Belmiro A, Boas LCV, Niemann CU. How to set up a clinical research center in Brazil, as an example of a middle-income country. Seminars in hematology. 2023;60(4):233-42.

11. 1Canedo JA, Rondao F, Ferreira CG, Ferrari B, Mathias CJASoCOebASoCOAM. Lessons From Implementing a Clinical Research Network in Brazil. 2022;42:1-10.

12. Interfarma. A importância da pesquisa clínica para o Brasil. Interfarma; 2022.

13. Sanitária. AANdV. Relatório Anual de Atividades 2022 [Available from: https://www.gov.br/anvisa/pt-br.

14. Saúde BCNd. Resolução n° 466, de 12 de dezembro de 2012. Resolução CNS 466/2012 ed. Brasília: Diário Oficial da União; 2012.

15. Sanitária BANdV. Resolução da Diretoria Colegiada – RDC n° 9, de 20 de fevereiro de 2015. RDC n° 9/2015 ed. Brasília: Diário Oficial da União; 2015.

16. Downing A, Morris EJA, Corrigan N, Sebag-Montefiore D, Finan PJ, Thomas JD, et al. High hospital research participation and improved colorectal cancer survival outcomes: a population-based study. 2016;66:89 - 96.

17. Rochon J, du Bois A, Lange TJBMRM. Mediation analysis of the relationship between institutional research activity and patient survival. 2014;14:9 -

18. Use ICfHoTRfPfH. ICH Harmonised Guideline: Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). Geneva: ICH; 2016.

19. Association WM. World Medical Association Declaration of Helsinki: Ethical principles for medical research involving human subjects %J JAMA. 2013;310(20):2191-4.

20. Saúde BMdSCNd. Resolução nº 510, de 7 de abril de 2016. Diário Oficial da União %J Conselho Nacional de Saúde; 2016. p. Seção 1:44-6.

21. 2Sciences CfIOoM. International Ethical Guidelines for Health-related Research Involving Humans. CIOMS/World Health Organization; 2016.

22. Lei nº 13.709, de 14 de agosto de 2018. Lei Geral de Proteção de Dados Pessoais (LGPD), (2018).

23. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (General Data Protection Regulation – GDPR), 119 (2016).

24. Sanitária BANdV. Resolução RDC nº 50, de 21 de fevereiro de 2002. Diário Oficial da União %J Agência Nacional de Vigilância Sanitária; 2002.

25. Moon MRJP. Institutional Ethics Committees. 2019;143.

26. Perin M, de Panfilis L. Clinical Ethics Committee in an Oncological Research Hospital: two-years Report. 2023;30:1217 - 31.

27. Hajibabaee F, Joolaee S, Cheraghi MA, Salari P, Rodney PPJJoME, Medicine Ho. Hospital/clinical ethics committees' notion: an overview. 2016;9.

28. Raoofi S, Arefi S, Khodayari Zarnaq R, Azimi Nayebi B, Mousavi MSSJJoME, Medicine Ho. Challenges of hospital ethics committees: a phenomenological study. 2021;14.

29. Intelligence GH. HospiRank 2024: Os hospitais mais bem equipados do Brasil. Global Health Intelligence; 2024. Contract No.: 1.

---

[1] Irmandade Santa Casa de Misericórdia de Porto Alegre.

[2] Universidade Federal de Ciências da Saúde de Porto Alegre.

[3] Queen’s University of Belfast.