



REPÚBLICA FEDERATIVA DO BRASIL
FEDERATIVE REPUBLIC OF BRAZIL
ANTONIO DARI ANTUNES ZHBANOVA

TRADUTOR PÚBLICO E INTÉRPRETE COMERCIAL-- *CERTIFIED PUBLIC TRANSLATOR*

Idioma/Language: Inglês - Português/*English - Portuguese*

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TRANSLATION No. WT- 30409

BOOK No. 214

PAGE No. 001

I, the undersigned Sworn Translator and Commercial Interpreter, hereby CERTIFY this is the description and faithful translation of a DOCUMENT written in Portuguese, which I translate as follows:

UFRN - FEDERAL UNIVERSITY OF RIO GRANDE DO NORTE - LAGOA NOVA

[Logo]

INFORMED OPINION OF THE REC [Research Ethics Committee]

RESEARCH PROJECT DETAILS

Research Title: COMPARATIVE STUDY OF HEAD ORIENTATION METHODS USING DIFFERENT SOFTWARE FOR VIRTUAL PLANNING OF ORTHOGNATHIC SURGERIES

Researcher: Adriano Rocha Germano

Subject Area:

Version: 2

CAAE: 12076519.0.0000.5537

Proposing Institution: Department of Dentistry

Main Sponsor: Own financing

OPINION DETAILS

Opinion number: 3.429.288

Project presentation:

This research project is associated with a master's degree linked to the postgraduate program in dental sciences at UFRN [FEDERAL UNIVERSITY OF RIO GRANDE DO NORTE]. This project will enroll 70 participants who have already been referred for orthognathic surgery by the UFRN clinic. These participants will be enrolled consecutively, of both sexes. Each participant will be subjected to all of the following protocols for acquiring the neutral head position: (A) The Procrustes Method; (B) The modified Charlotte Method; (C) The TVL Method (true vertical line); (D) The Universal Protocol Photographic Method.

Research Objective:

Primary Objective:

To evaluate the degree of three-dimensional positioning discrepancy between neutral head positioning methods in a virtual environment using different software.

Secondary Objectives:



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- To evaluate the linear and angular differences between composite skulls oriented using the recommended head positioning methods;
- To discuss the relationship and possible influence of the types of dentofacial deformity with the degree of accuracy of skull positioning;
- Discuss the reproducibility of skull positioning methods in clinical practice.

Risk and benefit assessment:

The risks are considered to be minimal, except for the radiation exposure caused by the CT scan, whose current dose is minimal and does not generate any major complications.

The benefits will be direct for the participants, as they will be assessed by different methodologies before their surgery.

Comments and Considerations on the Research:

The project is well structured and highly relevant.

Consideration of mandatory terms of presentation:

All the terms were presented: letter of consent, cover sheet, letter of non-initiation, REC form, research project, research instrument, timetable, term of concession for the use of medical records, ICF [Informed Consent Form], term of authorization for image recording.

Recommendations:

Submit partial and final research reports.

Conclusions or Pending Issues and List of Inadequacies:

The pending issues that were raised earlier have been answered and dealt with.

1) Both the research project and the REC form mention that 70 participants will be enrolled, but the methodology states that "10 patients of both sexes will be selected consecutively. Each patient will be subjected to all of the following protocols for acquiring the neutral position of the head: (A) The Procrustes Method; (B) The modified Charlotte Method; (C) The TVL Method (true vertical line); (D) The Universal Protocol Photographic Method." And what will be done with the other 60 participants? - answered and modified in the project and REC form.

2) When reading the ICF, it is suggested that it be written in simpler language, especially in the first paragraph, as it is still complex and, depending on the participant, can be difficult to understand. In addition, the ICF is not on pages and does not have a footer. It has been changed in the ICF.

3) Update the timetable, as we are assuming that the research has not yet started, although the form on the Brazil platform and the REC form state that the enrolment would be in March - it has been changed in the documents.

After ethically reviewing the responses to the issues raised in the previous opinion, we concluded that they have been properly fixed.



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This adequacy places the protocol in question within the basic precepts of ethics in research involving human beings, and it is therefore approved.

Final considerations at the discretion of the REC:

In accordance with Resolution 466/12 of the National Health Council (CNS) and the Operational Manual for Ethics Committees (CONEP), it is the responsibility of the researcher to:

1. prepare the Free and Informed Consent Form - ICF in two copies, initialed on all its pages and signed at the end by the person invited to take part in the research, or their legal representative, as well as by the researcher in charge, or the person(s) delegated by them, with the signature pages being on the same sheet (Res. 466/12 - CNS, item IV.5d);
 2. develop the project as outlined (Res. 466/12 - CNS, item XI.2c);
 3. submit any amendments or extensions to the REC with justification (Operational Manual for Ethics Committees - CONEP, Brasília - 2007, p. 41);
 4. discontinue the study only after the REC/CONEP/CNS/MS System that approved it has analyzed and expressed its reasons for discontinuing it, except in cases of justified urgency for the benefit of its participants (Res. 446/12 - CNS, item III.2u);
 5. prepare and submit partial and final reports (Res. 446/12 - CNS, item XI.2d);
 6. keep the research data in a physical or digital archive, under their custody and responsibility, for a period of 5 years after the end of the research (Res. 446/12 - CNS, item XI.2f);
 7. forward the results of the research for publication, with due credit to the associated researchers and technical staff who are part of the project (Res. 446/12 - CNS, item XI.
- 2g) and,
8. provide a reasoned justification to the REC or CONEP for interrupting the project or not publishing the results (Res. 446/12 - CNS, item XI.2h).

This opinion was prepared on the basis of the documents listed below:

Document Type	File	Posted on	Author	Status
Basic Project Information	PB_INFORMAÇÕES BÁSICAS DO PROJETO 1281919.pdf	12/JUN/2019 07:15:47		Accepted
Other	Modelo_10_Resposta_s_pendncias_Projeto Adriano CopiareColar.docx	12/JUN/2019 07:14:09	Adriano Rocha Germano	Accepted
Other	Modelo_10_Resposta_s_pendncias_Projeto Adriano.pdf	12/JUN/2019 07:13:39	Adriano Rocha Germano	Accepted
Researchers' Statement	FormularioCEPUFRNCopiarColar_Modificado.docx	12/JUN/2019 07:10:44	Adriano Rocha Germano	Accepted
Researcher's Statement	FormularioCEPUFRN.pdf	12/JUN/2019 07:10:09	Adriano Rocha Germano	Accepted
ICF / Terms of Agreement / Justification for Absence	TCLE_ProjetoAdrianoFelipe_Modificado.docx	12/JUN/2019 07:09:15	Adriano Rocha Germano	Accepted
ICF / Terms of Agreement /	TCLE_ProjetoAdrianoFelipe.docx	12/JUN/2019	Adriano Rocha	Accepted



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Justification for Absence		07:09:06	Germano	
Detailed Project / Investigator's Brochure	ProjetoMestradoAdrianoFelipe_Modifica do.docx	12/JUN/2019 07:07:55	Adriano Rocha Germano	Accepted
Detailed Project / Investigator's Brochure	ProjetoMestradoAdrianoFelipe.docx	12/JUN/2019 07:07:34	Adriano Rocha Germano	Accepted
Research Brochure	FormularioCEPUFRNCopiarColar.docx	30/MAY/2019 22:14:43	Adriano Rocha Germano	Accepted
Statement of Institution and Infrastructure	DeclaracaodeNaoIniciodaPesquisaCopia reColarNovo.docx	30/MAY/2019 22:11:47	Adriano Rocha Germano	Accepted
Statement of Institution and Infrastructure	DeclaracaodeNaoIniciodaPesquisaNovo. pdf	30/MAY/2019 22:11:29	Adriano Rocha Germano	Accepted
Declaration of Researchers	TermodeConfidencialidadeCopiarColar. docx	20/MAR/2019 09:22:14	Adriano Rocha Germano	Accepted
Statement of Institution and Infrastructure	TermodeConcessaoCopiarColar.docx	20/MAR/2019 09:21:56	Adriano Rocha Germano	Accepted
Declaration of Institution and Infrastructure	CartadeAnuenciaCopiarColar.docx	20/MAR/2019 09:18:38	Adriano Rocha Germano	Accepted
ICF / Terms of Agreement / Justification for Absence	Termodeautorizaoparausodeimagens.pd f	14/MAR/2019 22:42:13	Adriano Rocha Germano	Accepted
Other	InstrumentodePesquisaAnaliseFacial.pdf	14/MAR/2019 22:40:52	Adriano Rocha Germano	Accepted
Declaration of Institution and Infrastructure	TermodeConcessao.pdf	14/MAR/2019 22:27:54	Adriano Rocha Germano	Accepted
Declaration of Researchers	TermodeConfidencialidade.pdf	14/MAR/2019 22:26:23	Adriano Rocha Germano	Accepted
Declaration of Institution and Infrastructure	CartadeAnuenciaAssinada.pdf	25/FEB/2019 14:25:39	Adriano Rocha Germano	Accepted
Cover Sheet	FolhaDeRostoAssinada.pdf	20/JAN/2019 18:03:16	Adriano Rocha Germano	Accepted

Opinion status:

Approved

Needs CONEP assessment:

No

NATAL, July 01, 2019

Signed by:

LÉLIA MARIA GUEDES QUEIROZ

(Coordinator)

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Pages: 5

NOTHING ELSE was contained in said original, which I return with this faithful translation. In WITNESS WHEREOF, I have here set my hand and seal of office, this February 8, 2024.

Emoluments according to the law.



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**This document has been digitally signed by Antonio Dari Antunes Zhbanova.
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