

Ethical Review Report (CNS Resolution 466/2012)

Project: Observational Study on the Prevalence and Treatment of Tuberculosis in Indigenous Communities of the Metropolitan Region of Manaus

Ethical Review Outcome: Recommend with Revisions

Ethical Clarity: High

Informed Consent: Partial

Protection of Vulnerable Groups: Partial

Risk-Benefit Ratio: Adequate

Data Protection and Privacy: Partial

Feasibility: Strong

Key Ethical Weaknesses

Lack of clear informed consent process with voluntariness and withdrawal rights. Insufficient protections and justification for working with indigenous vulnerable groups. No mention of community participation or benefit-sharing plans. Partial description of data protection, lacking anonymization and storage details. Absence of plans for ethical monitoring, adverse event reporting, and staff training.

Recommendations to Reach Full Ethical Compliance

Develop comprehensive informed consent documents with clear language and processes adapted to indigenous languages/cultures. Justify and implement additional safeguards for vulnerable populations. Include community engagement and benefit-sharing plans. Explicitly describe data protection measures including anonymization and secure storage. Establish ethical monitoring protocols and provide training for research staff.

Ethical Review Report (CNS Resolution 466/2012)

Project: Evaluation of Telemedicine Implementation to Improve Hypertension Control in Primary Care in Manaus-AM

Ethical Review Outcome: Recommend with Revisions

Ethical Clarity: High

Informed Consent: Partial

Protection of Vulnerable Groups: Adequate

Risk-Benefit Ratio: Adequate

Data Protection and Privacy: Partial

Feasibility: Strong

Key Ethical Weaknesses

Partial informed consent lacking clear explanation of withdrawal rights and voluntariness. Insufficient data privacy details especially for telemedicine platform security. No plan for ethical monitoring, adverse event handling, or staff training. Lack of community involvement or dissemination and benefit-sharing plans. Digital divide and exclusion issues not addressed.

Recommendations to Reach Full Ethical Compliance

Improve informed consent procedures emphasizing voluntariness and rights to withdraw. Provide detailed data protection plans for telemedicine, including encryption and access controls. Implement ethical monitoring and adverse event reporting mechanisms. Develop community engagement and results dissemination strategies. Address potential exclusion of patients without digital access.