INFORMED CONSENT FORM – ICF

You are being invited to participate, as a volunteer, of the research entitled "**Prophylaxis for Primary Prevention of Tuberculosis in Prisoners**". My name is Roberto Dias de Oliveira, I am a doctorate student at the Federal University of Mato Grosso do Sul and, along with my advisor, Prof. Dr. Julio Croda, I am responsible for this research. After receiving the clarifications and the following information you will have an adequate time to reflect, consult with your relatives or other people you deem necessary, to decide on your participation in the study. If you agree to be a part of the study, collapse all the pages and subscribe to the end of this document, which is printed in two ways, one of which is yours and the other belongs to the researcher responsible. I clarify that in case of refusal to participate you will not be penalised in any way. But if you agree to participate, questions about the research may be clarified by the researchers responsible, by e-mail (roberto.dias@aluno.ufms.br and juliocroda@ufgd.edu.br) or in person in your sunny schedule. The Independent Research Bureau (IRB) of the State University of Mato Grosso do Sul (UEMS) is an interdisciplinary and independent collegiate, advisory, deliberative and educational, and aims to defend the interests of research participants in their integrity and dignity. When you persist your doubts about your rights as a participant of this research, you can also make contact directly with the UEMS's IRB, by phone (67) 3902-2699, from Monday to Friday, from 08:00 to 17:00h.

Tuberculosis is a major health problem for the prison population. We will develop this research to find out whether the use of a medicine called isoniazid prevents you from getting or having tuberculosis while fulfilling your sentence. This research is a double-blind, placebo-controlled clinical trial. This means that half of the participants will take the medicine (called the intervention group), the other half will have the placebo which is a pill equal to the medicine, but it does not effect (control group) and no one knows, until the end of the study, who is taking what. All this to reduce the psychological interference or alteration in the research data. Isoniazid is used both to treat who has tuberculosis and who has contacted the disease, but has no symptoms. This medicine should not be used by those who are allergic to isonicotinium acid (which makes up the remedy) and liver problems.

Your participation in this research predicts that you take three tablets with the medicine or with the placebo twice a week for one year, along with the clinical follow-up (consultations and interviews with the project team) and laboratory (blood and phlegm collection). Your participation in this research will have three phases:

In the first phase, we will have three steps.

Step 1: We will do an interview, which can take up to 10 minutes, in which we ask things about you, about your sentence, your current and past health, your habits inside and outside the prison, about exams you have already done, use of medications, among others.

Step 2: After the interview , we will collect about 9 ml (2 tablespoons) of your blood, as well as a sample of phlegm to perform the following exams, which do not cost you: Sputum culture, IGRA (Interferon Gamma Release Assay), HIV, Anti-HBC, HBsAg, Anti-HCV, aspartate aminotransferase (AST) and alanate aminotransferase (ALT). These exams are necessary to know if you have or have had tuberculosis, hepatitis B and C, plus HIV and if your liver is functioning properly. If your phlegm has a result that does not allow us to close a diagnosis, we may ask you to provide us with another sample. The same can happen with the blood test of interferon gamma.

Step 3: You will be placed one of the two study groups: intervention or control, through a draw, of which neither you nor the principal researchers participate, to ensure blindness.

In the second phase, two times a week, researchers will give you three (3) tablets for the next twelve (12) months. **Every three months** you will be attended by a team member, who will make a brief assessment of your health. During this care we will collect 5ml (about 1 tablespoons) of blood to repeat the liver tests (AST and ALT). It's very important that you report anything you're feeling to the professional that answers it. **In the sixth** and **twelfth month** of the study we will retake the sputum culture and the gamma interferon exam, to know if you have acquired tuberculosis during the time you took the medicine or if you were exposed to the disease.If your phlegm has a result that does not allow us to close a diagnosis, we may ask you to provide us with another sample. The same can happen with the blood test of interferon gamma.

In the third phase, after 1 year of the end of the study, we will re - test the gamma interferon and sputum culture, to verify if the treatment was able to prevent infection and active tuberculosis. If your phlegm has a result that does not

allow us to close a diagnosis, we may ask you to provide us with another sample. The same can happen with the blood test of interferon gamma.

At any time, you may withdraw the consent of custody and use of the blood stored in our laboratory (biorerepository) by means of a written and signed demonstration. Upon withdrawal of consent, your samples will be returned to you. Your samples will only be used in what is described in this term and in the project submitted to the IRB.

You may be withdrawn before the end of the search schedule for the following reasons:

- At your request, at any time;
- Not wanting to conduct any research procedure;
- Stop taking the remedy for more than 90 days or have several interruptions that vanish 90 days;
- If you are transferred or early released;
- If you experience any discomfort or have any alteration in your exam that the research physician finds better that you stop the medicine;
- If you use any other medicine that the research physician thinks may interfere in the medicine of this research;
- For another reason the research physician finds it better for his well-being and safety.

At the time of your withdrawal, we can take a blood test and get your phlegm to check your health, in addition to evaluating your condition and verifying that you have had some discomfort.

If you have been using the medicine for more than 6 months and want to leave the study or the doctor thinks it is best for your well-being to suspend your medicine, you have the option of continuing the study and doing the exams for 6 and 12 months. If you don't want to, you can leave the study without doing any more tests.

All of your clinical and laboratory data will be inserted into a secure database by a member of the study team. Data generated from analysis of sputum and blood samples will be associated only with a study number and no identification information will be provided in order to preserve its confidentiality. The results of this research can be presented in scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed.

The benefit of your participation in this research is the realization, at no cost to you, to the Brazilian Health System or to your private health plan, of the laboratory exams described below: sputum culture, IGRA (Interferon Gamma Release Assay), HIV, Anti-HBC, HBsAg, Anti-HCV, aspartate aminotransferase (AST) and alanate aminotransferase (ALT). These results will be made available to you.

Your participation may pose risks to your health, such as small purple, redness at the site of blood collection or liver problems arising from the use of the medication. In addition, questions asked in the questionnaire may bring some psychological damage due to the possibility of arouting negative memories. If you do not feel comfortable answering, you are free to refuse at any time and time. Our team will be on hand to assist you with whatever it takes to minimise the above risks. We will monitor your health condition and ensure full and free assistance to damage caused as a result of the study, when applicable, for an indefinite period.

Your participation in the study is voluntary. You can choose not to be part of the study, or you can quit at any time. You will not be forbidden to participate in further studies. You may be asked to leave the study if you do not comply with the prescribed procedures or meet the requirements stipulated. You have ensured by Resolution n^{o} 466/2012 of the National Health Council (CNS) the indemnity and reimbursement arising from the research. The main researchers are responsible for future indemnities and reimbursement that may occur due to this research.

All expenses incurred with the research will be the responsibility of the responsible researcher/sponsor, that is, you will not bear any costs relating to procedures and/or exams and no additional financial compensation associated with their participation. If during the application of the questionnaire and/or collection of the material or the intervention (use of the medication) you present some problem or detect that you need specialized monitoring, we will forward to medical care at Federal University of Grande Dourados's Hospital.

If you are not satisfied with the way this study is being conducted, or if you have any concerns, complaints or general questions about the search or your rights as a participant, please contact UEMS's IRB to talk to someone Independent of the search team on the phone (67) 3902-2699.

Researcher's Rubric: Participant's Rubric:

I declare that I understand the objectives, risks and benefits of my participation in the research and agree to participate.

_____, _____ of _____ of _____.
(Place) (dd). (month) (year)

_____ _____
Researcher's signature Participant's signature