Participant Information Sheet

Patient's Initials: ……. Patient No:…….. Date: ……..
Study Title: "**Cotrimoxazole in hospitalised patients with severe COVID-19 infection compared to the standard of care – an investigator-initiated, randomised controlled trial (CoTroxCov Study)"**
Principal Investigator: Prof Dr Udas Chandra Ghosh

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Dear Patient,

We would like to invite you to participate in study entitled "**Cotrimoxazole in hospitalised patients with severe COVID-19 infection compared to the standard of care – an investigator-initiated, randomised controlled trial (CoTroxCov Study)".**

Before you decide on participating in this research study, we would like to explain to you why we consider this research project as important and what it involves. Taking part in this study is entirely voluntary. Please take time to read the following information carefully and discuss with family members, relatives, friends or your doctor, if you wish. We urge you to seek clarification on any issues about this study with the investigator, if needed. Take your time to decide whether or not you would like to participate in this study. If you wish to participate, you must sign this form to document your consent.

Section 1: Purpose/ description of the study – The purpose of this study is to investigate if oral cotrimoxazole therapy instituted in hospitalized severe Covid-19 patients could prevent transition of the disease to a critical stage.

Section 2: Study procedures and intervention – The study shall include consenting COVID-19 in-patients. Participants will be randomized into either group. The intervention group will receive cotrimoxazole plus standard of care, while the control group will receive drugs or procedures in routine clinical practice according to the best standard of care as per local protocol.

Section 3: Duration of the engagement in the Study – Following your recruitment you would be closely monitored and followed up for the entire period of your hospital stay.

Section 4: Possible discomforts and risks – Co-trimoxazole is an old, time-tested, relatively well-tolerated drug that has been in clinical use for around five decades. Appropriate cautions shall be exercised by the investigators to guard against the known side effects of the drug. In case of any rare serious complication, urgent treatment shall be provided free of cost.

Section 5: Costs for participation – You need not have to incur any cost for participating in this study. There is however, no provision in this study to bear the cost to compensating for the loss in your daily wage/income. This is because in any case you an in-patient receiving treatment and care for Covid-19.

Section 6: Expected benefits – All participants in this study shall have the privilege of additional (beyond routine care) closer and more intense medical attention.

Section 6: Voluntary participation and freedom to refuse participation and to withdraw at anytime without disadvantages and/or prejudices – Taking part in this research study is absolutely voluntary. Besides, you are free to withdraw your participation at any time without giving any reason.

Section 7: Withdrawal from the study – Investigators and the ethics committee have the right to stop your participation at any time, in the best interest of yours as well as the research study.

Section 8: Statement of confidentiality – Your permission is a prerequisite for participating in the study. If the study results are published, confidentiality of the data will be ensured; particularly your name andidentity will not be mentioned anywhere in results. Your research records that are reviewed stored and analyzed at the study site will be archived in the department in a secure place. Representatives of the following persons within the institution may use your health information and share it with other specific groups in connection with this research study:a) the investigator and his research guides, b) the ethics committee c) your treating physician.

Section 10: Compensation for injuries – No harm/injury is envisaged. However, in case of a rare occasion of any *study-related* injury (as judged by the investigator and the ethics committee), you shall be entitled to some defined financial no-fault compensation as per the Project Steering Committee Policy (you can ask the Investigators for a copy of the same, for your perusal and understanding).

Section 11: Research funding – This study is an academic research project, with a modest research grant from Government of West Bengal. The investigators are not receiving any grant for the conduct of this study.

Section 12: Whom to contact for questions, problems – You have the right to ask any questions you may have about this research. If you have questions, complaints or concerns or believe related to this research, contact the Principal Investigator Prof Dr Udas Chandra Ghosh at 9433044237 or the Institutional Ethics Committee Chairperson Prof Nandita Basu at 9433090229.

Informed Consent Form

Study Title**: Cotrimoxazole in hospitalised patients with severe COVID-19 infection compared to the standard of care – an investigator-initiated, randomised controlled trial (CoTroxCov Study)**

Protocol Version: 01 Subject's Initials: ……Subject's Name:……
Subject No: …… Date of birth/ Age: ……..

Statement	**Subject's initial /LTI in each box**
I confirm that I have read and understood the information sheet dated …… for the above study and have had the opportunity to ask questions.	[ ]
I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reasons, without my medical care or legal rights being affected.	[ ]
I understand that the investigator, others working on the investigator's behalf, the Institutional Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I agree to this access. However, I understand that my identity will not be revealed in any information revealed to third parties or if published.	[ ]
I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).	[ ]
I agree to take part in the above study.	[ ]

_____ _____ _____
Name of Subject Subject's Signature (or Left Thumb Impression) Date

_____ _____ _____
Name of Legally Acceptable Representative (LAR) LAR's Signature (or Left Thumb Impression) Date

Investigator's statement / Statement of person administering Informed Consent

I, the undersigned, certify that I have fully and carefully explained all relevant aspects of this research study, to the subject signing this consent and it appears that he/ she has reasonably understood the nature, risks and potential benefits, if any, of his/ her participation in this study. If applicable, I confirm that I have explained the nature, purpose and foreseeable effects of the study to the subject's legally acceptable representative, whose name is documented above, and that he/ she has agreed on the subject's participation in this study. The LAR has confirmed to this by his/ her personally dated signature.

_____ _____ _____
Name/Signature of Investigator Name/Signature of Person administering IC Date

----------Use the following only if applicable----------
If this informed consent document is read to the subject because the subject is unable to read the consent form, an impartial witness must be present during the informed consent administration procedure and must sign the following statement: I confirm that the information in the consent form was accurately explained to, and apparently, understood by the subject. The subject consented free of will, to take part in this research study.

_____ _____ _____
Name of Impartial Witness Signature of Impartial Witness Date