INFORMED CONSENT FOR MEDICAL & CLINICAL STUDIES

KSU-IRB Form 005-E

King Saud University, Riyadh, Kingdom of Saudi Arabia

SECTION A:

STUDY INFORMATION

Study Title:	Recurrent ciprofloxacin induced hypoglycemia in a non-diabetic patient: Case Report
Protocol Number/Study Code:	
Principal Investigator:	
Principal Investigator Address:	
Telephone:	
Email:	
Sponsor/Non-Commercial Funding/NA:	None

INTRODUCTION

Dear Participant,

You are being invited to take part voluntarily in the local above-mentioned research study. A member of the research team will explain what is involved in this study and how it will affect you. Prior to signing this form, please read carefully all the study aspects to make an informed decision. This consent form describes the study procedures, the risks and benefits of participation, and how your confidentiality will be maintained. Please take your time to ask questions and feel comfortable making a decision whether to participate or not. This process is called informed consent. If you decide to participate in this study, you will be asked to sign this form and will be given a copy for your records. Throughout the course of this study, you will have the right to ask any questions regarding the study or your medical condition. As a part of the consenting process, we will keep you updated with any new findings that might affect your decision to continue with the trial.

SECTION B:

1. WHAT IS THE PURPOSE OF THE STUDY?

Case Report

2. **HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?**

The total number expected to participate in this study is *one* participants

3. **STUDY LOCATION?** A single center study at King Saud University Medial City, intensive care unit.
4. **WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?**

5. **WHAT IS EXPECTED OF ME DURING THE STUDY?**

5.1. **Baseline visit or/ Screening procedures:**

This will be a single visit study, if you decide to provide your consent, the clinician will be able to publish your case and help other physicians

5.2. **Study Procedures/Treatment period:**

5.3. **Follow up/Study end period**

At the end of the ciprofloxacin course, your participation in the study will end.

6. **HOW LONG WILL I BE IN THE STUDY?**

Your involvement will finish once you give us the agreement. It will be a case report study

7. **WHAT ARE MY RESPONSIBILITIES?**

Your participation in this study is totally voluntary, and you will always have the right to withdraw at any time without mentioning the reasons and without affecting your healthcare benefits or your relationship with the study staff. Signing this informed consent form does not mean that you waive your legal rights, yet you will still have the following responsibilities:

i) Read the informed consent form and seek understanding of the study.
ii) Ask questions and understand your rights.
iii) Inform your family physician or the emergency room physician that you are participating in this study
iv) As long as you are on this trial and for the follow up period, you cannot participate in other studies without getting back to the study investigator.

8. CAN I STOP BEING IN THE STUDY?

You can decide to stop taking part in the study at any time. If you decided not to take part in this study, you will be receiving the outmost standard of care utilized at our site to treat similar conditions. Please inform to the doctor/study investigator about your decision of stopping your study participation. Your doctor will guide you how to stop in the study, if there are any rules and guidelines, for your safety, with the alternate treatment for you or physician taking in charge for your illness treatment. No one will try or coerce you to continue the participation.

Once you are off the study you will not be allowed to take part in this study again. If your condition improved on the study medication and on the sponsor discretion you might continue to receive the study drug for free until the study drug is available on the market.

(**Note:** The procedures for safe and orderly termination of participation by the participant, should the participant decides to withdraw from the study before it is completed e.g. follow-up visits, etc. should be mentioned.)

9. ARE THERE RISKS IF I STOP BEING IN THE STUDY?

No risk .it is only for publication

10. WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?

None

11. ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Taking part in this study may not make your health better. While doctors hope that this study will help other physician to consider the side effect of ciprofloxacin in geriatric population in

12. WHAT IF I WILL TRAVEL OUTSIDE THE KINGDOM OR ABROAD WHILE IN THE STUDY?

Not applicable because it is a case report

13. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

You should inform your study investigator immediately about any discomforts/ illness / injuries during this study. Moreover, upon the principal investigator's decision that this injury / illness is study related, then all treating procedures, follow-ups, hospitalization will be covered by (
Not applicable because it is a case report
……). This information of your sickness/injury will be collected, documented and reported as adverse event(s) with confidentiality.

14. WHAT ARE THE COSTS OF TAKING PART IN THE STUDY?

You will not be asked to pay for participation or any procedure, drug, and laboratory test related to the study.

15. WILL I BE PAID FOR MY TAKING PART IN THIS STUDY?

Not applicable because it is a case report

16. WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?

All the information collected in subjects records belong to King Saud University, and the study Sponsor. Your records will remain strictly confidential and will not be made publicly available. However, in some situations as study requires, your information could be provided to the relevant personnel or permitted by the regulations of SFDA/FDA/KSU IRB or law within the limitations and boundaries of Saudi Arabia national, Sharia and ethical laws.
Scientific data from this research project may be presented or published in the journal but your personal identity will always remain protected.

SECTION C: Not applicable because it is a case report

NOTE: Fill this section in case subject's biospecimens are required as part of the study :

Not applicable because it is a case report

17. I am being asked to give my biosamples(s) as mentioned in the study procedure(s).
[Description of subject's biosamples required as part of research protocol. E.g. blood, urine, saliva, semen, ascites, stool, surgically resected/excised tissue, etc.]

18. I am asked for the biosamples(s) listed with the mentioned condition(s).
[Please mention the subject's biosamples required with their quantity, weight/volume and condition(s)]

19. Why I am asked to give my biosamples?
[Description mentioning the use and reasons of biosamples as part of study]

20. My biosamples will be sent to Central Laboratory/Company (Local// Abroad).
[*Please provide the name of affiliated laboratory/company, name of country to where samples are sent* as part of research study]

21. I hereby consent to provide my clinical data required with the biosamples. ☐ YES/ ☐ NO
[Please mention subjects clinical data required along with the biosamples, justifying the use, ensuring the limitations and privacy of subjects' data, with coding the identifiers. No national or government identity/database information could be allowed with the subject's data]

22. My biosamples will not be used for genetic testing. ☐ YES/ ☐ NO
[If yes, Please provide the Consent Form for Genetic testing KSUMC-IRB form # 06G-E and 06G-A along with this form]

SECTION D:

23. WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?
Taking part in this study is your choice. You may choose either to 'take part' or 'not to take part' in the study. You may leave the study at any time during your participation. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from KSUMC.

24. WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

Before you agree to be in this study, you will talk to a study team member qualified to tell you about this study. You can ask questions about any aspect of the research. If you have further questions about the study, you may ask them at any time. You may call *(PI Name at mobile number)*

SECTION E:

CONSENT

Subject:

The research and procedures have been explained to me. I have been allowed to ask any questions and all my questions have been answered. I have read the consent and have had time to think about participating. I can ask any additional questions I may think of later. I may refuse to participate in the study, and I may quit being in the study at any time without any penalty and without affecting my health care.

I have been given permission for the study doctor and sponsor to use and disclose my personal health information.

I will receive a signed copy of this consent form.

I agree to participate in this study. My agreement is voluntary. I do not have to sign this form if I do not want to be part of this research study.

Subject Signature:	The patient is not able to give the consent due to his illness
Date:	15/2/2021
Time: (AM ☒ PM ☐)	

Person Obtaining Consent: Mohammed Hamad

I have explained the nature and purpose of the study and the risks involved. I have answered and will answer questions to the best of my ability. I will give a signed copy of the consent form to the subject.

Signature of Person Obtaining Consent:	
Date:	15/2/2021
Time: (AM ☒ PM ☐)	
Principal Investigator:	Shereen Dasuqi
Signature of Principal Investigator:	
Date:	
Time: (AM ☒ PM ☐)	

SECTION F:

STOP! Do not use the following signature lines unless third party consent is being requested. (For subjects who are unable to give consent).

For subjects unable to consent:

Legally Authorized Representative:	
Date:	
Person Obtaining Consent:	
Date:	

For children who cannot give consent:

The person being considered for this study is unable to consent for himself/herself because he/she is a minor. By signing below, you are giving your permission for your child to be included in this study.

Parent or Legal Guardian:	
Date:	

IMPARTIAL WITNESS: In case when subject is unable to read and/or understand the text and nature of the ICF and the study, a witness is required.

Witness name:	
Relation, if any, with subject:	
Signature:	
Date:	
Person Obtaining Consent:	
Date:	

Principal Investigator:	
Signature	
Date:	
Time (AM ☑ PM ☐)	

*For more information, please visit the website of the Research Ethics Committee in King Saud University (*http://dsrs.ksu.edu.sa/ar/comm_Policies