INFORMATION SHEET: EXPERIMENTAL SAMPLE

EARLY IMMUNE RESPONSES IN ACUTE PANCREATITIS AND THEIR ROLE IN PREDICTING DISEASE SEVERITY

Good day,

We are researchers from the University of the Witwatersrand doing research on acute pancreatitis. Research is a process of learning and solving problems. In this research we want to find out what happens in the body when someone has this disease, why do other people stay in hospital for a shorter time and others go for surgery or they get released and come back with the same problem. Why is it a very serious disease for some people but not for others?

You are invited to take part in this study. This research study is looking for at least 15 participants diagnosed with acute pancreatitis of different severity to donate 2½ teaspoons (about 12 ml) of blood. The blood will be drawn from a vein in your arm using a syringe at the Hepatopancreaticobiliary Unit of the academic hospital in which you are admitted and transported safely protected in a secondary container to the University of the Witwatersrand where the research will be done. Transport will be by private means or through the NHLS transport services. From the blood, the liquid portion called plasma and cells will be separated and used for the study. Some of these samples such as the plasma cannot be used immediately and will be frozen at -20 or -80C until needed (within 2 months to 5 years). The results from these samples will be compared to those of participants who lack a history of pancreatic diseases.

Sampling will be part of routine management procedures and you may be subjected to some pain or discomfort caused by the needle, but a qualified and experienced medical practitioner (nurse or doctor) has been recruited to perform the procedure and to minimize the risks. The procedure will only take about 5 minutes and blood will be obtained from you once you consent and every 48 hours afterwards up to 7 days post admission.

Participating in this study might not benefit you now but we hope that the results from these studies will benefit patients in future. Significant new findings developed during the course of the research which may relate to your willingness to continue participating in the study will be provided to you.

Participating in this study will not result in any "out of pocket' expenses. Refusal to participate will involve no penalty or loss of benefits normally entitled to you. You may discontinue participation at any time without penalty or prejudice.

Blood samples will be collected anonymously to ensure confidentiality. At the end of the study, leftover blood will be discarded in 10% bleach, sterilized by heating to 120 degrees Celsius and disposed in bio-hazardous/ medical waste boxes.

For further information/ reporting study related adverse effects/complaints contact:

Researchers:
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Consent Form: Use of Clinical Sample and Information for Research

Dear Sir/madam,

You are currently admitted to a University of Witwatersrand affiliated academic hospitals. This hospital not only renders treatment but is also actively involved in conducting research aimed at improving the quality of care that is provided. From time to time such research involves the use of patient samples and records from which information is extracted. The use of such information is subject to the following:

1. Approval from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand.
2. Identity of a patient from whose file information is extracted is never revealed to anyone but the researcher unless specific consent is obtained to do so. The information gathered does not contain the name of the patient but only a coded number so as to maintain anonymity.

Whilst we are not currently involved in research that requires us to use any information now but rather are interested in collecting a blood sample from you, this may change in the future when you may have already been discharged. We would like to obtain your consent to use information from your file for the purpose of research, subject to the aforementioned conditions. We anticipate that such information will be accessed up to 5 years after sample collection. If you choose not to give consent, this will not compromise your treatment in any way. If at any time you choose to withdraw consent you are free to do so and will not be prejudiced in any way. Should you wish to contact us at any stage regarding consent, phone: Ms Mwangala Nalisa at (011) 717-2574, Dr Pascaline Fonteh at (011)717-2476. If you agree to participate please place your signature below under the participant section.

PARTICIPANT

[redacted]		22/08/19.
Print Name	**Signature**	**Date**

RESEARCHER

Mwangala Nalisa	Nalisa	22/08/19
Print Name	**Signature**	**Date**

WITNESS

Janet Mazibuko		22/08/19
Print Name	**Signature**	**Date**