Decreasing Leptospirosis Emergence through Prognosis and Treatment Optimization (DeLEPTO) Project 1: Preventive Strategies for Early and Late Complications of Leptospirosis

Informed Consent Form

Version 6

2025-04-23

APPENDIX A
INFORMED CONSENT
ENGLISH VERSION

INFORMED CONSENT FORM FOR PARTICIPANTS WHO CAN INDEPENDENTLY PROVIDE CONSENT

Patient ID: _____

This document will remain in the patient record.

You, _____, _____ years old, residing in _____ are being invited to participate in the study entitled "Preventive strategies for early and late complications of leptospirosis", under the direct supervision of Dr. Romina Danguilan of the National Kidney and Transplant Institute (NKTI) as the principal investigator. Dr. Romina Danguilan is the project leader. The principal site investigator for University of the Philippines Manila (UPM) is Dr. Jose Nevado Jr. The principal site investigator for San Lazaro Hospital (SLH) is Dr. Rontgene Solante. Other main co-investigators are Dr. Joselito Chavez and Dr. Mel-hatra I. Arakama of NKTI; Dr. Ana Ria Sayo-Abungan, Dr. Jeffrey Verona, Dr. Jaime Trifalgar-Arches and Dr. Nathaniel Lee of SLH. Drs. Danguilan, Chavez, Arakama, Solante, Sayo-Abungan, Verona and Trifalgar-Arches may serve as both investigators and attending physicians to the participants, but Dr. Nevado and Dr. Lee will not.

The study is funded and sponsored by the Department of Science and Technology (DOST), a government agency.

This study has been approved by the NKTI Research Ethics Committee (NKTI REC), University of the Philippines Manila Research Ethics Board (UPMREB), SLH Research Ethics Review Unit (SLH RERU), and Department of Health Single Joint Research Ethics Boards (DOH SJREB).

The following have been explained well to you and you fully understand them before you signed this consent form.

1. The study is experimental in nature.

2. This study will last for three (3) years.

3. The study aims to determine how the body responds to being affected by leptospirosis. Specifically, the study will try to search for indicators in the blood that can help in the prediction of the occurrence of pulmonary complications in leptospirosis and the benefit of early treatment, specifically plasma transfusion, hemoperfusion (HP), or the use of extracorporeal membrane oxygenation (ECMO) in case of life-threatening bleeding of the lungs.

4. This investigation will add to the current knowledge and understanding of leptospirosis and its complications. Results generated may also become important to medical doctors in dispensing medical advice and genetic counseling.

5. The study will recruit subjects who are 18-60 years of age from the emergency rooms, wards, and clinics of NKTI and SLH.

6. Only trained research personnel can and will interact with patients or their legal representatives for the recruitment process and the duration of the patient's participation in the study.

7. In the event that the patient is not physically or mentally capable of giving consent, a legally authorized representative or guardian may provide consent on their behalf.

8. The study will include 678 participants in the study, all with moderate to severe leptospirosis. Of these, 142 will receive plasma transfusion and another 142 without plasma transfusion for comparison. For hemoperfusion, 197 will receive hemoperfusion, while 197 will not for comparison. There will be 16 patients to undergo ECMO for the study to document, depending on the referral of attending physicians.

9. You will receive the standard care provided to leptospirosis patients regardless of your assignment. Standard care includes tests to confirm leptospirosis, blood tests to check kidney and liver function, chest x-ray to visualize any lung damage, antibiotics, intravenous fluids, and other interventions your attending physician deems necessary.

10. The assignment of experimental treatments (plasma transfusion or hemoperfusion) is random; that is, whether you receive plasma transfusion or hemoperfusion treatment or none of the above is not known at the start and will be determined by chance. For those who will be on ECMO, it will be for those with severe lung complications that will be decided by the attending physician for the procedure.

11. In this study, 12 ml of blood (about 2.5 tablespoons) will be collected from the participant. This will be stored in vials and kept in a refrigerator or in ice until processing. All of the blood will be used for chemical testing to determine changes in the blood with various conditions, including being affected with leptospirosis. The sample will be stored and analyzed at the NKTI, SLH, or at UPM and will be kept in freezers for storage. Samples will be coded and safeguarded such that the privacy and confidentiality of the participant will be protected. There will be no payment for this procedure. The samples will be stored for at most 20 years after blood collection.

12. If you have been assigned to the prophylactic plasma transfusion (PPT) group, the research staff will inform you whether the patient has been randomized to receive a plasma transfusion or receive standard care treatment only.

    - Plasma, the liquid component of blood, contains factors that help reduce inflammation. In leptospirosis, excessive inflammation within the body can damage vital organs like the kidneys and lungs, leading to serious complications. This study aims to evaluate the potential benefits of plasma transfusion in mitigating inflammation, removing harmful toxins, and preventing the development of complications in leptospirosis patients.

    - All expenses directly related to the use of fresh frozen plasma for the transfusion procedure under Objective 1 will be covered by the project budget.

13. If you have been assigned to be in the Hemoperfusion (HP) group, the research staff will inform you whether you have been randomized to undergo hemoperfusion or receive standard care treatment only.

    - Hemoperfusion is a method of filtering blood outside the body to remove toxins. The study aims to confirm the benefits of hemoperfusion in decreasing inflammation, removing harmful toxins, and preventing development of complications in leptospirosis patients.

- The study will cover the expenses for up to three (3) hemoperfusion cartridges. Any additional hemoperfusion cartridges used will be shouldered by the patient.

- Inflammatory marker blood tests, such as Interleukin-6 (IL-6), High-sensitivity C-reactive protein (hsCRP), Procalcitonin, TNF-alpha, and Gasdermin D will also be covered regardless if you are classified to receive hemoperfusion or receive standard of care only. These tests can show the extent of inflammation or damage caused by leptospirosis, and will also be used to assess the effectiveness of the treatments in reducing inflammation.

14. Should you develop severe pulmonary complications, your attending physician may employ any rescue treatment, such as Extracorporeal Membrane Oxygenation (ECMO), that he/she may deem necessary.

    - If the patient was initially randomized to receive plasma transfusion or not, they will have the option to undergo plasma transfusion and/or ECMO as a rescue treatment, if the disease progresses.

    - If the patient was initially randomized to receive hemoperfusion or not, they will have the option to undergo hemoperfusion and/or ECMO as a rescue treatment, if the disease progresses.

    - ECMO involves the use of a pump that circulates blood outside the human body to an artificial lung. This artificial lung oxygenates the blood, which is then pumped back into the body.

    - The study aims to confirm the potential benefits of ECMO in improving survival rates for leptospirosis patients with lung complications, and will cover the expenses for the ECMO device, cannulae, and insertion kits used in the procedure.

15. The participant's decision to allow or refuse rescue treatment will not affect the quality of care provided by their attending physician(s). Alternative treatment options will be provided and discussed by the healthcare team.

16. The study will also cover the expenses for the following interventions for all patients, regardless of treatment assignment:

    - Intravenous fluids and medications up to Php 2000.00.

    - Standard-of-care laboratory tests up to Php 2000.00 for participants without other available sources or medical insurance (such as PhilHealth), as applicable.

17. The following are possible risks for the procedures in the study:

    - For patients undergoing plasma transfusion, you may experience some side effects, such as difficulty in breathing, itchiness, rashes, swelling, lowering of blood pressure, and faster or slower beating of the heart.

    - For patients undergoing hemoperfusion, you may experience some side effects, such as bleeding in wound sites and other parts of the body, low blood pressure and palpitations. You may have temporary lowering of platelet count that may need monitoring.

- For patients undergoing ECMO, you may experience some side effects, such as bleeding in wound sites and other parts of the body, sudden changes in blood pressure and heart rate, and infection in areas where the body is attached to the machines. Moreover, there is also the possibility of the machine having some failure.

- There is minimal risk associated with blood extraction provided that the subjects are hemodynamically stable, without respiratory distress, and a hemoglobin level of not less than 90 g/li. These include bleeding from the site of injection, pain, local reaction to the tape or cotton, and infection.

- In most instances, most side effects are mild and serious occurrences are less than 5%.

18. If there is a persistence of symptoms (such as rashes and itchiness), sudden difficulty of breathing, new onset of pain, severe bleeding that will not stop with gentle pressure and worsening fever or weakness, it is advised that you contact Dr. Romina Danguilan of NKTI or Dr. Rontgene Solante of SLH. The participant can consult any emergency room/clinic/doctor (preferably NKTI or SLH) if any of the above occurs. Less serious adverse events can be consulted through out-patient consultation in clinics. A part of the project fund is committed for assistance to affected participants in case of admission and/or required treatment resulting from study-related adverse events or complications.

19. The research team understands that participation in this study may raise personal or emotional concerns. To support your well-being, the study offers access to psychosocial support services if needed. Your decision to utilize or decline these services will not affect your participation in the study.

20. You are expected to participate during your hospital stay or until the 30th day after inclusion in the study, whatever is shorter.

21. As the study will provide assistance to standard of care testing and treatment for all participants, there will be direct benefit for your condition.

22. The results of the study are still of unknown significance given the current scientific knowledge on leptospirosis. Hence, even though the results may show that you are susceptible to an increased risk of developing complications from leptospirosis which may increase your and your family's anxiety level if they are positive or provide a false sense of reassurance if they are negative; there is no significant basis to justify the dependability of the test during the study. Thus, you are also encouraged to communicate anytime with the primary investigator concerning the results of the study and their impact on your health.

23. You will receive a Php 1000 monetary remuneration for your participation in the study, If needed, you are still expected to spend for transportation on follow-up. Such expenses will not be directly reimbursed, but the study will provide compensation during follow-up to cover for food, transportation, and the possible loss of income. Furthermore, you will be supported for the following tests, if needed: test for leptospirosis, serum creatinine, blood urea nitrogen, chest X-ray, complete blood count with differential count, and urinalysis. If you prefer, you will also be offered health information regarding leptospirosis. The remaining expenses will be sourced from the participant.

24. All your records or personal information related to the study will be kept confidential. These will be coded and kept in secured/locked cabinets and computers such that confidentiality is maintained. However, the results of the study may be presented at scientific or medical meetings, conferences, or published in scientific articles. To maintain your privacy, there will be no mention of your name or

any information that can be traced directly to you. The study monitor(s), auditor(s), the institutional ethics review board of NKTI, UPM, SLH, or DOH SJREB, and regulatory authorities will be granted direct access to your medical records for purposes only for verification of clinical trial procedures and data. This also applies to future research/es in which your information is to be used and if you provide your consent.

25. There will be ways to ensure respect for your privacy and confidentiality in records in which you will be identified, such as coding of samples and keeping all records/ samples in secured/locked areas. All samples will be kept in freezers with the key kept by authorized personnel only.

26. In the event of a privacy breach, the principal investigator will promptly notify the Data Protection Officer (DPO) responsible upon knowledge of the breach. The notification will include a written summary of the incident and an action plan to prevent future occurrences.
    - The following are the corresponding Data Protection Officer (DPO) per implementing and cooperating site of this project:
        i. For UPM:
        Mr. Arturo M. Ongkeko Jr., MSc, RN
        Designation: Data Protection Officer
        Office: Data Protection Office
        Email: amongkeko@up.edu.ph, dpo.upmanila@up.edu.ph

        ii. For NKTI:
        Dr. Genlinus D. Yusi
        Data Privacy Officer for NKTI

        iii. For San Lazaro Hospital:
        Atty. Cherry Laine A. Derequito
        Attorney IV, Head, Legal Office, San Lazaro Hospital and
        Data Privacy Officer for SLH

27. You have the right to know the full results of this study and you can request the results of the study. And though you cannot have direct access to your records, you will maintain your right to know data relevant to yourself.

28. Any genetic, clinical, or personal information directly traceable to you will not be released to others, including family members, without a written consent from you.

29. Your participation in this study is voluntary and you can withdraw anytime, for any reason. This should not affect your treatment provided by your doctors. In case you withdraw permission, you will be withdrawn from the study, your record will be deleted from the database, and the sample collected from you will be properly disposed of.

30. You, as a participant, will be withdrawn in the following conditions: (1) if s/he withdraws from the study for any reason; (2) if the samples are not feasible for testing; and (3) the study is terminated prematurely by the sponsor, DOST. In these cases, you will be withdrawn from the study, your record will be deleted from the database, and the sample collected from you will be properly disposed of.

31. The results of this study are intended to develop products and/or services for commercial purposes, such as tests for leptospirosis. You might benefit from these testing, but you will not receive any direct commercial benefits from this.

32. If there will be new information that could affect your continuing and willing participation in the study, the study staff shall relay so in a timely manner to make you decide.

33. You will be informed if there are changes or amendments to the information you supplied in this study.

34. Consent for Storage of Biological Sample for Future Use (Optional)

    Please check box and put initial on the line of your choice below (choose only one):

    ☐ You are giving your consent to your biological samples being saved and used for future research. The excess samples from the study will be stored in a -20 °C to -80 °C freezer and will be kept at most for 5 years at the Institute of Human Genetics. If used for other relevant studies in the future, the samples will be decoded, de-identified and anonymized, except for age and sex. Only authors and research assistants involved in the current project are allowed to handle/use the samples.

    ☐ You do not consent to your biological samples being saved and used for future research. Samples will only be used for the present study. Sample collected from you will be properly disposed of 1 year after this study.

35. Before signing this informed consent, you are encouraged to ask further questions relevant to the study and indicate that you are satisfied with the responses. Should you have more questions later, you can call and ask Dr. Romina Danguilan of the National Kidney and Transplant Institute (NKTI) at 981- 0300 loc 4427, or email at radanguilan@gmail.com.

36. For any questions, concerns, or complaints, the participant may reach out to the following research ethics committees through their contact details:

Dr. Sigrid M. Agcaoili, Chair of NKTI REC
Address: NKTI, East Avenue, Quezon City
Telephone: + 981-0300 – 981-0400 Local 2158
Email: nktiresearchethics@gmail.com

Dr. Cecilia A. Jimeno, Chair of UPMREB Panel 1
Address: Room 126, Ground Floor, National Institutes of Health, UP Manila, 623 Pedro Gil Street, Ermita, 1000 Manila
Telephone: +63 2 85264346
Email: upmreb@post.upm.edu.ph

Dr. Ryan Jeanne V. Ceralvo, Chair of SLH RERU
Quiricada St, Santa Cruz, Manila, 1003 Metro Manila
Email: slh.iso.reru2@gmail.com

Secretariat Staff, DOH SJREB
Department of Health, Bldg. 3, San Lazaro Compound, Rizal Avenue, Sta. Cruz, Manila
Trunkline: (02) 651-7800 local 1328
Email: sjreb.doh@gmail.com

You are giving your consent subject to the above conditions, under the treatment assignment: _____

_____ _____
Name and Signature of Participant Date

_____ _____
Witness Witness

Informed consent obtained by: _____
Name and Signature

INFORMED CONSENT FORM FOR LEGALLY ACCEPTABLE REPRESENTATIVE OF PARTICIPANTS WHO CANNOT INDEPENDENTLY PROVIDE CONSENT

Patient ID: _____

This document will remain in the patient record.

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    - Hemoperfusion is a method of filtering blood outside the body to remove toxins. The study aims to confirm the benefits of hemoperfusion in decreasing inflammation, removing harmful

toxins, and preventing development of complications in leptospirosis patients.

- The study will cover the expenses for up to three (3) hemoperfusion cartridges. Any additional hemoperfusion cartridges used will be shouldered by the patient.

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    - If your patient was initially randomized to receive plasma transfusion or not, they will have the option to undergo plasma transfusion and/or ECMO, if the disease progresses.

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    - ECMO involves the use of a pump that circulates blood outside the human body to an artificial lung. This artificial lung oxygenates the blood, which is then pumped back into the body.

    - The study aims to confirm the potential benefits of ECMO in improving survival rates for leptospirosis patients with lung complications, and will cover the expenses for the ECMO device, cannulae, and insertion kits used in the procedure.

15. You or your patient's decision to allow or refuse rescue treatment will not affect the quality of care provided by their attending physician(s). Alternative treatment options will be provided and discussed by the healthcare team.

16. The study will also cover the expenses for the following interventions for all patients, regardless of treatment assignment:
    - Intravenous fluids and medications up to Php 2000.00.
    - Standard-of-care laboratory tests up to Php 2000.00 for participants without other available sources or medical insurance (such as PhilHealth), as applicable

17. The following are possible risks for the procedures in the study:

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    - For patients undergoing hemoperfusion, you may experience some side effects, such as bleeding in wound sites and other parts of the body, low blood pressure and palpitations. You may have temporary lowering of platelet count that may need monitoring.

    - For patients undergoing ECMO, you may experience some side effects, such as bleeding in

wound sites and other parts of the body, sudden changes in blood pressure and heart rate, and infection in areas where the body is attached to the machines. Moreover, there is also the possibility of the machine having some failure.

- There is minimal risk associated with blood extraction provided that the subjects are hemodynamically stable, without respiratory distress, and a hemoglobin level of not less than 90 g/li. These include bleeding from the site of injection, pain, local reaction to the tape or cotton, and infection.

- In most instances, most side effects are mild and serious occurrences are less than 5%.

18. If there is a persistence of symptoms (such as rashes and itchiness), sudden difficulty of breathing, new onset of pain, severe bleeding that will not stop with gentle pressure and worsening fever or weakness, it is advised that you contact Dr. Romina Danguilan of NKTI or Dr. Rontgene Solante of SLH. The participant can consult any emergency room/clinic/doctor (preferably NKTI or SLH) if any of the above occurs. Less serious adverse events can be consulted through out-patient consultation in clinics. A part of the project fund is committed for assistance to affected participants in case of admission and/or required treatment resulting from study-related adverse events or complications.

19. The research team understands that participation in this study may raise personal or emotional concerns. To support your patient's well-being, the study offers access to psychosocial support services if needed. Your decision to utilize or decline these services will not affect your patient's participation in the study.

20. Your patient-participant is expected to participate during his/her hospital stay or until the 30th day after inclusion in the study, whatever is shorter.

21. As the study will provide assistance to standard of care testing and treatment for all participants, there will be direct benefit for his/her condition.

22. The results of the study are still of unknown significance given the current scientific knowledge on leptospirosis. Hence, even though the results may show that your participant-dependent is susceptible to an increased risk of developing complications from leptospirosis which may increase your and your family's anxiety level if they are positive or provide a false sense of reassurance if they are negative; there is no significant basis to justify the dependability of the test during the study. Thus, you are also encouraged to communicate anytime with the primary investigator concerning the results of the study and their impact on your patient-participant's health.

23. You will receive a Php 1000 monetary remuneration for your patient-participant's participation in the study, and Php 2000 for intravenous fluids and medicine. If needed, you are still expected to spend for transportation on follow-up. Such expenses will not be directly reimbursed, but the study will provide compensation during follow-up to cover for food, transportation, and the possible loss of income. Furthermore, your patient-participant will be supported for the following tests, if needed: test for leptospirosis, serum creatinine, blood urea nitrogen, chest X-ray, complete blood count with differential count, and urinalysis. If you prefer, you will also be offered health information regarding leptospirosis. The remaining expenses will be sourced from the participant.

24. All your participant-dependent's records or personal information related to the study will be kept confidential. These will be coded and kept in secured/locked cabinets and computers such that confidentiality is maintained. However, the results of the study may be presented at scientific or

medical meetings, conferences, or published in scientific articles. To maintain his/her privacy, there will be no mention of his/her name or any information that can be traced directly to his/her or to you. The study monitor(s), auditor(s), the institutional ethics review board of NKTI, UPM, SLH, or DOH SJREB, and regulatory authorities will be granted direct access to your medical records for purposes only for verification of clinical trial procedures and data. This also applies to future research/es in which your information is to be used and if you provide your consent.

25. There will be ways to ensure respect for your patient-participant's privacy and confidentiality in records in which s/he will be identified, such as coding of samples and keeping all records/samples in secured/locked areas. All samples will be kept in freezers with the key kept by authorized personnel only.

26. In the event of a privacy breach, the principal investigator will promptly notify the Data Protection Officer (DPO) responsible upon knowledge of the breach. The notification will include a written summary of the incident and an action plan to prevent future occurrences.
    - The following are the corresponding Data Protection Officer (DPO) per implementing and cooperating site of this project:
        i. For UPM:
        Mr. Arturo M. Ongkeko Jr., MSc, RN
        Designation: Data Protection Officer
        Office: Data Protection Office
        Email: amongkeko@up.edu.ph, dpo.upmanila@up.edu.ph

        ii. For NKTI:
        Dr. Genlinus D. Yusi
        Data Privacy Officer for NKTI

        iii. For San Lazaro Hospital:
        Atty. Cherry Laine A. Derequito
        Attorney IV, Head, Legal Office, San Lazaro Hospital and
        Data Privacy Officer for SLH

27. You and your patient-participant have the right to know the full results of this study and you can request the results of the study. And though you cannot have direct access to his/her records, you will maintain your right to know data relevant to him/herself.

28. Any genetic, clinical, or personal information directly traceable to your patient-participant will not be released to others, including family members, without a written consent from you.

29. Your patient-participant's participation in this study is voluntary and s/he can withdraw anytime, for any reason. This should not affect his/her treatment provided by his/her doctors. In case you withdraw permission, your patient-participant will be withdrawn from the study, his/her record will be deleted from the database, and the sample collected from him/her will be properly disposed of.

30. Your patient-participant will be withdrawn in the following conditions: (1) if s/he withdraws from the study for any reason; (2) if the samples are not feasible for testing; and (3) the study is terminated prematurely by the sponsor, DOST. In these cases, your patient-participant will be withdrawn from the study, his/her record will be deleted from the database, and the sample collected from him/her will be properly disposed of.
31. The results of this study are intended to develop products and/or services for commercial purposes,

such as tests for leptospirosis. Your patient-participant might benefit from these testing, but you or your patient-participant will not receive any direct commercial benefits from this.

32. If there will be new information that could affect your patient-participant's continuing and willing participation in the study, the study staff shall relay so in a timely manner to make you decide.

33. You will be informed if there are changes or amendments to the information you supplied in this study.

34. Consent for Storage of Biological Sample for Future Use (Optional)
    Please check box and put initial on the line of your choice below (choose only one):

    ☐ You are giving your consent to the biological samples of the participant to being saved and used for future research. The excess samples from the study will be stored in a -20 °C to -80 °C freezer and will be kept at most for 5 years at the Institute of Human Genetics. If used for other relevant studies in the future, the samples will be de-coded, de-identified and anonymized, except for age and sex. Only authors and research assistants involved in the current project are allowed to handle/use the samples.

    ☐ You do not consent to the participant's biological samples being saved and used for future research. Samples will only be used for the present study. Sample collected from your patient-participant will be properly disposed of 1 year after this study.

35. Before signing this informed consent, you are encouraged to ask further questions relevant to the study and indicate that you are satisfied with the responses. Should you have more questions later, you can call and ask Dr. Romina Danguilan of the National Kidney and Transplant Institute (NKTI) at 981- 0300 loc 4427, or email at radanguilan@gmail.com.

36. For any questions, concerns, or complaints, the participant or legal representative may reach out to the following research ethics committees through their contact details:

Dr. Sigrid M. Agcaoili, Chair of NKTI REC
Address: NKTI, East Avenue, Quezon City
Telephone: + 981-0300 – 981-0400 Local 2158
Email: nktiresearchethics@gmail.com

Dr. Cecilia A. Jimeno, Chair of UPMREB Panel 1
Address: Room 126, Ground Floor, National Institutes of Health, UP Manila, 623 Pedro Gil Street, Ermita, 1000 Manila
Telephone: +63 2 85264346
Email: upmreb@post.upm.edu.ph

Dr. Ryan Jeanne V. Ceralvo, Chair of SLH RERU
Quiricada St, Santa Cruz, Manila, 1003 Metro Manila
Email: slh.iso.reru2@gmail.com

Secretariat Staff, DOH SJREB
Department of Health, Bldg. 3, San Lazaro Compound, Rizal Avenue, Sta. Cruz, Manila
Trunkline: (02) 651-7800 local 1328
Email: sjreb.doh@gmail.com

You are giving your consent on behalf of the patient-participant subject to the above conditions, under the treatment assignment: _____

_____ _____

Name of Participant Date

_____ _____

Name and Signature of Legal Representative Witness

Informed consent obtained by: _____

Name and Signature