STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

Evaluation of the Efficacy and Safety of Bladder Injection of Autologous Platelet-Rich Plasma for Refractory Overactive Bladder

Prepared for ClinicalTrials.gov PRS document upload review

Official Title	Evaluation of the Efficacy and Safety of Bladder Injection of Autologous Platelet-Rich Plasma for Refractory Overactive Bladder
Brief Title	Autologous Platelet-Rich Plasma Bladder Injection for Refractory Overactive Bladder
NCT Number	Pending assignment - replace before public upload
Document Type	Study Protocol and Statistical Analysis Plan
Document Date	July 1, 2026
Version / Source Version	Protocol source: V1.0 dated 2026-05-06; ethics resubmission form references Protocol V2.0 dated 2026-07-15
Principal Investigator	Gang Chen, MD
Institution / Department	The First Affiliated Hospital of Chongqing Medical University; Department of Urology
Study Design	Prospective, single-center, single-cohort observational study
Version-control note: This English draft was generated from the Chinese protocol supplied by the user and the ethics resubmission form. The ethics form references Protocol V2.0 dated 2026-07-15, while the supplied protocol text shows V1.0 dated 2026-05-06. Confirm the final approved protocol version, document date, and NCT number before public upload.	

Protocol Synopsis

Study title	Evaluation of the Efficacy and Safety of Bladder Injection of Autologous Platelet-Rich Plasma for Refractory Overactive Bladder
Study type	Investigator-initiated, prospective, single-center, single-cohort observational clinical study
Study population	Adults with refractory overactive bladder evaluated in the Department of Urology at The First Affiliated Hospital of Chongqing Medical University
Planned enrollment	Approximately 50 participants
Planned recruitment period	June 2026 to December 2026
Follow-up duration	Approximately 24 weeks after treatment
Intervention / exposure	Bladder injection of autologous platelet-rich plasma / autologous platelet concentrate as clinically arranged
Primary objective	To evaluate the efficacy and safety of bladder injection of autologous platelet-rich plasma for refractory OAB
Primary outcomes	Change from baseline in OABSS; incidence of adverse events and procedure-related complications

1. Background and Rationale

Overactive bladder (OAB) is a common lower urinary tract disorder characterized by urinary urgency, usually accompanied by urinary frequency and nocturia, with or without urgency urinary incontinence, in the absence of urinary tract infection or another obvious local pathologic, metabolic, or neurologic cause. OAB can substantially affect daily activity, sleep, social participation, and psychological well-being.

Standard treatment options include behavioral intervention, oral pharmacologic therapy, and third-line treatment such as intradetrusor botulinum toxin injection or sacral neuromodulation. A subset of patients continue to have bothersome symptoms despite first-line and second-line therapy, or cannot tolerate medication-related adverse effects. These limitations create a need for additional minimally invasive treatment strategies for refractory OAB.

Platelet-rich plasma (PRP), also described in the Chinese source documents as autologous concentrated platelets or autologous platelet concentrate, is prepared from autologous peripheral blood and contains

concentrated platelets, growth factors, and cytokines. The proposed biological rationale includes tissue repair, modulation of chronic inflammation, and local neural regulation. Preliminary urologic research has explored PRP in bladder-related disorders, including interstitial cystitis / bladder pain syndrome. Based on these properties, bladder injection of autologous PRP may have potential to improve refractory OAB symptoms by modulating the bladder wall microenvironment and lower urinary tract function.

2. Objectives

2.1 Primary Objective

To evaluate the efficacy and safety of bladder injection of autologous platelet-rich plasma / autologous platelet concentrate in adults with refractory OAB.

2.2 Secondary Objective

To explore broader clinical application of autologous platelet-rich plasma injection in lower urinary tract disease and provide clinical data to support future larger studies.

3. Study Design

This is an investigator-initiated, prospective, single-center, single-cohort observational clinical study conducted in the Department of Urology at The First Affiliated Hospital of Chongqing Medical University. Approximately 50 eligible adults with refractory OAB will be enrolled and followed for approximately 24 weeks.

ClinicalTrials.gov design classification: Study Type: Observational; Observational Model: Cohort; Time Perspective: Prospective; Number of Groups/Cohorts: 1; Sampling Method: Non-probability sample. If an institutional or PRS interpretation classifies the protocol-directed PRP procedure as a prospective treatment assignment, the registry record may need to be converted to an interventional single-group open-label treatment study. The supplied Chinese materials identify the study as a prospective observational IIT.

4. Study Population

Participants will be recruited from the urology outpatient clinic. All participants are patients who actively present for care; no additional recruitment advertisements are planned. Vulnerable populations, including minors, pregnant women, prisoners, illiterate individuals, and persons without full capacity for civil conduct, will not be enrolled.

5. Eligibility Criteria

5.1 Inclusion Criteria

1. Age 18 years or older, with full capacity to understand the study and provide written informed consent.
2. Diagnosis of OAB according to International Continence Society criteria: urinary urgency, usually with frequency and nocturia, with or without urgency urinary incontinence, and without urinary tract infection or another obvious local, metabolic, or neurologic cause.
3. Refractory OAB, defined as persistent bothersome symptoms after standard first-line behavioral therapy for at least 3 to 6 months and inadequate response or intolerance to at least two oral medications with different mechanisms, such as antimuscarinic agents and beta-3 adrenergic agonists, after adequate treatment duration.
4. Other possible causes of OAB-like symptoms have been excluded by appropriate clinical evaluation, such as urinalysis, urine culture, ultrasound, urodynamic testing, and cystoscopy when clinically indicated.
5. Participant is unwilling, unsuitable, contraindicated, or has inadequate response to existing third-line treatments such as intradetrusor botulinum toxin injection or sacral neuromodulation, as determined by the investigator and final approved protocol.
6. General condition permits local anesthesia and cystoscopic bladder injection.
7. No absolute contraindication to autologous PRP treatment.
8. Willingness and ability to comply with scheduled visits and follow-up assessments.

5.2 Exclusion Criteria

9. Platelet dysfunction syndrome or platelet count below 50 x 10^9/L.
10. Coagulation disorder or current anticoagulant therapy judged to increase bleeding risk.
11. Active systemic infection or local infection at the planned injection site.
12. Active malignancy or history of malignancy within the past 5 years, especially urinary tract malignancy, or hematologic malignancy such as leukemia or lymphoma.
13. Active autoimmune disease judged by the investigator to increase risk or affect interpretation of study results.
14. Pregnancy or lactation.
15. Known allergy to any component used in PRP preparation.
16. Untreated urinary tract infection.
17. Bladder stone, bladder tumor, bladder outlet obstruction, neurogenic bladder, interstitial cystitis / bladder pain syndrome, or another organic disease that explains OAB-like symptoms.
18. Severe cardiac, hepatic, or renal insufficiency; uncontrolled diabetes; severe anemia; or another systemic condition that may affect safety or wound healing.
19. Psychiatric illness, cognitive impairment, or other condition that prevents understanding of informed consent or reliable follow-up.
20. Recent nonsteroidal anti-inflammatory drug or corticosteroid use when judged by the investigator to interfere with PRP effect, unless discontinued for an appropriate washout period.
21. Expected survival shorter than the study period.

22. Refusal to sign informed consent or inability/unwillingness to comply with follow-up.

Eligibility note for finalization: The supplied Chinese V1.0 protocol contains a potential inconsistency regarding prior intradetrusor botulinum toxin injection or sacral neuromodulation. The final approved Chinese protocol should be checked before public upload so the English eligibility criteria match the approved version exactly.

6. Study Procedures

6.1 Screening and Baseline Assessment

Screening will include review of OAB history and refractory status, prior and current medications, medical history, pregnancy/lactation status when applicable, and physical examination. Symptom and quality-of-life assessments include OABSS, ICIQ-OAB, OAB-q SF, and a continuous 3-day 24-hour bladder diary. Laboratory evaluation may include blood routine testing with platelet count, coagulation function, liver and kidney function, blood chemistry, blood glucose, blood type, urinalysis, and urine culture. Imaging and functional evaluation may include urinary tract ultrasound and urodynamic testing. Cystoscopy will be performed when clinically indicated.

6.2 Treatment / Exposure

Eligible participants will undergo bladder injection of autologous platelet-rich plasma / autologous platelet concentrate as clinically arranged. PRP is prepared from the participant's own peripheral blood. The supplied two Chinese source documents do not specify a detailed injection volume, injection-site map, or preparation device; these operational details should be inserted only after confirmation from the final approved institutional protocol or standard operating procedure.

6.3 Perioperative Recording

The study team will record procedure name, date, operator, procedure duration, blood loss, transfusion if any, intraoperative complications, technical details, vital signs, urination frequency, urine volume, wound or procedure-site status, complications, and all adverse events.

6.4 Follow-up

Participants are expected to participate for approximately 24 weeks. Follow-up visits are scheduled before treatment and at 1, 3, and 6 months after treatment. Follow-up may include outpatient visits and WeChat-based follow-up registration according to local clinical practice.

Assessment / Procedure	Screening / baseline	Treatment day / perioperative	1 month	3 months	6 months
Eligibility review and informed consent	X				
Medical history and physical examination	X		As needed	As needed	As needed

OABSS	X		X	X	X
ICIQ-OAB / OAB-q SF	X		X	X	X
ICIQ-SF, if applicable	X		X	X	X
Three-day 24-hour bladder diary	X		X	X	X
Blood, urine, imaging, urodynamic tests	X	As clinically indicated	As clinically indicated	As clinically indicated	As clinically indicated
PRP preparation and bladder injection		X			
Procedure details and vital signs		X			
Adverse events / complications		X	X	X	X
Participant satisfaction			Optional	Optional	X

7. Outcome Measures

Outcome	Measure	Time frame	Analysis
Primary efficacy	Overactive Bladder Symptom Score (OABSS), total score; minimum 0, maximum 15; higher scores indicate worse OAB symptom severity	Baseline (pre-procedure), 1 month after procedure, 3 months after procedure, and 6 months after procedure	Repeated-measures ANOVA or linear mixed-effects model; paired post-baseline comparisons as appropriate
Primary safety	Incidence and type of adverse events and procedure-related complications	From the start of the procedure through 24 weeks after the procedure	Descriptive summary; event counts and proportions; Fisher exact or chi-square tests for exploratory comparisons if applicable
Secondary efficacy	24-hour micturition frequency from a 3-day bladder diary	Baseline (pre-procedure), 1 month after procedure, 3 months after procedure, and 6 months after	Repeated-measures or paired analyses as appropriate

		procedure	
Secondary efficacy	Urgency urinary incontinence episodes from a 3-day bladder diary	Baseline (pre-procedure), 1 month after procedure, 3 months after procedure, and 6 months after procedure	Repeated-measures or paired analyses as appropriate
Patient-reported outcomes	International Consultation on Incontinence Questionnaire - Overactive Bladder (ICIQ-OAB), total score 0-16, higher scores indicate worse symptoms; Overactive Bladder Questionnaire Short Form (OAB-q SF), Symptom Bother scale 0-100 with higher scores indicating worse symptom bother, and health-related quality-of-life scales 0-100 with higher scores indicating better quality of life; International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF), total score 0-21, higher scores indicate worse symptom impact	Baseline (pre-procedure), 1 month after procedure, 3 months after procedure, and 6 months after procedure	Repeated-measures or paired analyses as appropriate
Exploratory clinical outcomes	Urodynamic parameters such as maximum bladder capacity and detrusor function when available	Baseline (pre-procedure) and 6 months after procedure, when clinically indicated	Descriptive and paired analyses as data allow
Satisfaction	Local participant satisfaction assessment; not a validated numeric scale and summarized as recorded	1 month, 3 months, and 6 months after procedure	Descriptive statistics; rank-based analysis if ordinal

8. Safety Assessment

Safety will be assessed from treatment through the end of follow-up. All adverse events and procedure-related complications will be recorded, including relationship to the procedure or PRP when assessable, severity, seriousness, action taken, outcome, and need for treatment.

- Risks related to blood collection: puncture-site pain, hematoma, vasovagal reaction, and rare infection.
- Risks related to PRP preparation: preparation failure or inability to reach the expected platelet concentration.
- Risks related to cystoscopy and bladder injection: urethral or bladder pain, burning sensation, discomfort, transient hematuria, urinary tract infection, bladder injury or perforation, bladder spasm, dysuria, urinary retention, and worsening irritative symptoms.
- Risks related to PRP and its biological action: uncertain efficacy, rare allergy to preparation components, unknown long-term risks, and theoretical concerns related to growth factors in abnormal tissue environments.
- Psychological risks: disappointment if treatment is ineffective and anxiety related to receiving an investigational treatment.

Participants who experience study-related harm will receive appropriate medical treatment. According to the Chinese protocol, free treatment and corresponding compensation for study-related injury will be provided by the project team.

9. Data Management and Confidentiality

Data sources include medical records, laboratory results, questionnaires, bladder diary records, procedure records, and other clinical information collected during the study. Data will be entered into an encrypted electronic database. A double-check process will be used for data entry. Completeness and consistency checks will be performed regularly, and abnormal data will be traced and corrected when needed.

Participant data and biological samples will be used only for this study. Data and samples will be anonymized or coded using unique identifiers. Access will be limited to study team members, data analysts, and ethics committee reviewers authorized for study oversight. Public reports and publications will present aggregate or de-identified results only.

The ethics resubmission form states that participants may provide approximately 20 mL of blood, approximately 50 mL of urine, and some diseased bladder tissue according to study arrangements. Before registry upload, confirm whether specimens are retained for future analysis, destroyed after testing, or used only for routine clinical testing.

10. Statistical Analysis Plan

10.1 Sample Size

This study is a prospective observational study of a relatively uncommon clinical population, refractory OAB. The planned enrollment of approximately 50 participants is based on the site's historical clinical volume, with an expected recruitment rate of approximately 1 to 2 participants per week and a planned recruitment period of approximately 6 months. No formal hypothesis-driven power calculation is specified in the Chinese source protocol.

10.2 Analysis Sets

- Full Analysis Set: all enrolled participants who receive PRP bladder injection and have at least one post-baseline efficacy assessment, analyzed according to the intention-to-treat principle as far as the observational design permits.
- Safety Set: all participants who undergo any study-related PRP preparation or bladder injection procedure, analyzed according to treatment received.
- Per-Protocol Set: participants without major eligibility or follow-up deviations, used for supportive analyses if needed.

10.3 General Statistical Principles

Statistical analyses will be performed using SPSS, SAS, R, or equivalent validated statistical software. Continuous variables will be summarized by mean, standard deviation, median, interquartile range, minimum, and maximum as appropriate. Categorical variables will be summarized by counts and percentages. Two-sided P values less than 0.05 will be considered statistically significant where formal testing is performed. Because this is an early observational single-cohort study, statistical inference will be interpreted as exploratory.

10.4 Primary Efficacy Analysis

The primary efficacy endpoint is change from baseline in OABSS total score over follow-up. OABSS at baseline, 1 month, 3 months, and 6 months will be analyzed using repeated-measures analysis of variance or a linear mixed-effects model, depending on data distribution, missingness, and model assumptions. Paired t tests or Wilcoxon signed-rank tests may be used for within-participant comparisons between baseline and specific follow-up time points.

10.5 Secondary Efficacy Analyses

Secondary outcomes, including 24-hour micturition frequency, urgency urinary incontinence episodes, ICIQ-OAB, OAB-q SF, ICIQ-SF when applicable, and available urodynamic parameters, will be analyzed using repeated-measures models, paired tests, or descriptive methods as appropriate. Participant satisfaction will be summarized descriptively and analyzed using chi-square tests, Fisher exact tests, or rank-based tests if exploratory group comparisons are applicable.

10.6 Safety Analysis

Adverse events and procedure-related complications will be summarized by event type, severity, seriousness, relationship, timing, action taken, and outcome. Incidence proportions will be calculated for all adverse events and selected event categories. Chi-square or Fisher exact tests may be used for exploratory comparisons if clinically meaningful subgroups are defined.

10.7 Missing Data

The amount and pattern of missing data will be summarized. Linear mixed-effects models may accommodate missing observations under appropriate assumptions. Sensitivity analyses may be performed using complete-case analysis or other clinically justified approaches if missingness is substantial.

10.8 Protocol Deviations

Major protocol deviations, including eligibility violations, missed key assessments, or follow-up outside the defined window, will be recorded and reviewed before database lock. The impact of major deviations may be explored through per-protocol supportive analyses.

11. Ethics and Informed Consent

The informed-consent process will be conducted by the principal investigator and study assistant according to ethics requirements. After screening, the investigator or study assistant will explain the study purpose, procedures, potential risks, potential benefits, alternative treatments, voluntary participation, and the right to withdraw without affecting subsequent medical care. Participants will receive a written informed-consent document in understandable language and will have sufficient opportunity to ask questions before signing.

To reduce potential conflict of interest or perceived pressure, the participant's treating physician will not directly conduct the informed-consent discussion when feasible. If new information arises that may affect participant rights, safety, or willingness to continue, the study team will communicate it promptly and re-consent participants as required.

12. Costs, Compensation, and Dissemination

According to the Chinese source protocol, this clinical observational study collects clinical and biochemical data related to the disease during the normal diagnosis and treatment process. Routine examinations and procedures required for clinical care are borne by the participant and are not intended to create additional economic burden because of research participation. If a participant experiences study-related injury, free treatment and corresponding compensation will be provided by the project team.

Study findings may be published in scientific journals and presented at academic conferences. Results will be reported in aggregate or de-identified form and will not include participant names or identifying information.

13. References

23. Peyronnet B, Mironska E, Chapple C, et al. A Comprehensive Review of Overactive Bladder Pathophysiology: On the Way to Tailored Treatment. Eur Urol. 2019;75(6):988-1000. doi:10.1016/j.eururo.2019.02.038.
24. Therapeutic Efficacy of Intravesical Platelet-Rich Plasma Injections for Interstitial Cystitis/Bladder Pain Syndrome - A Comparative Study of Different Injection Number, Additives and Concentrations. Source listed in the supplied Chinese protocol.
25. Effects of Therapeutic Platelet-Rich Plasma on Overactive Bladder via Modulating Hyaluronan Synthesis in Ovariectomized Rat. Source listed in the supplied Chinese protocol.

INFORMED CONSENT FORM

Evaluation of the Efficacy and Safety of Bladder Injection of Autologous Platelet-Rich Plasma for Refractory Overactive Bladder

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Document Type	Informed Consent Form
Document Date	July 1, 2026
Version / Source Version	Informed Consent Form V2.1 dated 2026-07-30
Principal Investigator	Gang Chen, MD
Institution / Department	The First Affiliated Hospital of Chongqing Medical University; Department of Urology
Study Design	Prospective, single-center, single-cohort observational study
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Participant Information Sheet

Study title	Evaluation of the Efficacy and Safety of Bladder Injection of Autologous Platelet-Rich Plasma for Refractory Overactive Bladder
Principal investigator	Gang Chen, MD
Institution	The First Affiliated Hospital of Chongqing Medical University, Department of Urology
Study duration	Approximately 24 weeks
Visits	Before treatment and at 1, 3, and 6 months after treatment
Study contact	[Insert public study contact and telephone number approved for public use]

1. Invitation to Participate

You are being invited to take part in this clinical research study because you have refractory overactive bladder, meaning that your urinary urgency, frequency, nocturia, or urgency urinary incontinence has not improved adequately after standard treatment or you could not tolerate treatment-related side effects. Please read this form carefully and ask the study doctor or study assistant any questions before you decide whether to participate.

2. Purpose of the Study

The purpose of this study is to evaluate the efficacy and safety of bladder injection of autologous platelet-rich plasma (PRP), also called autologous platelet concentrate, for refractory overactive bladder. PRP is prepared from your own blood and contains concentrated platelets and biological factors that may support tissue repair, regulate inflammation, and influence local nerve function. The effect of PRP for refractory overactive bladder is still being studied, and benefit cannot be guaranteed.

3. Voluntary Participation

Taking part in this study is entirely voluntary. You may choose not to participate, or you may withdraw from the study at any time, without giving a reason. Refusing to participate or withdrawing from the study will not affect your future medical care or your relationship with your doctors or the hospital.

4. What Will Happen If You Participate

If you agree to participate, the study team will first confirm whether you meet the study criteria. This may include review of your medical history, physical examination, urine and blood tests, ultrasound, urodynamic testing, cystoscopy when clinically indicated, symptom questionnaires, and a 3-day bladder diary.

If you are eligible, PRP will be prepared from your own peripheral blood and injected into the bladder as clinically arranged. During and after the procedure, the study team will record procedure details, urination symptoms, urine volume, vital signs, complications, and adverse events.

Study schedule in plain language: Your participation will last about half a year, or 24 weeks. You will complete 4 visits: before treatment, 1 month after treatment, 3 months after treatment, and 6 months after treatment. You will be asked to cooperate with symptom assessment, clinical data recording, and study-arranged specimen collection.

- Approximately 20 mL of blood may be collected.
- Approximately 50 mL of urine may be collected.
- Some diseased bladder tissue may be collected if this is part of the study arrangement and clinically indicated.
- Your study data will be managed using a unique code to protect your identity.

5. Questionnaires and Follow-up

You may be asked to complete symptom and quality-of-life assessments such as OABSS, ICIQ-OAB, OAB-q SF, ICIQ-SF when applicable, and a 3-day bladder diary. Follow-up may be conducted through outpatient visits and local follow-up tools used by the Department of Urology.

6. Possible Risks and Discomforts

All medical procedures and research participation can involve risks. The possible risks of this study include:

- Blood collection risks, such as puncture-site pain, bruising, hematoma, dizziness or fainting, and rare infection.
- PRP preparation failure, which may occur if the blood sample is insufficient or the expected platelet concentration cannot be obtained.
- Cystoscopy and bladder injection discomfort, including urethral or bladder pain, burning sensation, bladder irritation, or temporary worsening of urinary symptoms.
- Hematuria, which may be visible or microscopic and is usually temporary.
- Urinary tract infection, with possible symptoms such as urinary frequency, urgency, painful urination, or fever.
- Bladder injury, bladder perforation, bladder spasm, dysuria, or temporary urinary retention, which are uncommon but may require medical treatment.

- Allergic reaction to preparation components, although PRP is prepared from your own blood and the risk is considered low.
- Uncertain efficacy. Your symptoms may not improve, or may improve less than expected.
- Unknown long-term risks, because PRP treatment for refractory OAB is still under clinical investigation.
- Psychological discomfort or disappointment if the treatment does not work as expected.

The study doctor will monitor your safety. If you experience discomfort or adverse symptoms, please contact the study team promptly.

7. Possible Benefits

You may or may not benefit directly from participating in this study. If the treatment is effective for you, your urinary urgency, frequency, nocturia, or urgency urinary incontinence may improve, and your quality of life may improve. Information from this study may also help doctors better understand PRP treatment and may support future studies for patients with refractory OAB.

8. Alternatives to Participation

You do not have to take part in this study to receive medical care. Alternative options may include continued behavioral therapy, oral medications such as antimuscarinic agents or beta-3 adrenergic agonists, intradetrusor botulinum toxin injection, sacral neuromodulation, other treatments recommended by your doctor, or no study treatment.

9. Costs and Compensation

According to the Chinese source protocol, this study collects disease-related clinical and biochemical data during the normal diagnosis and treatment process. Routine examinations and procedures required for clinical care are borne by you and are not intended to create additional economic burden because of research participation. If you experience injury related to this clinical research study, you may receive free treatment and corresponding compensation provided by the project team according to applicable institutional and regulatory requirements.

10. Privacy and Confidentiality

Your personal information, medical records, and biological samples will be used only for this study. Your data and samples will be coded using a unique identifier so that your name is not used in the research database. Access to identifiable information will be limited to authorized study team members, data analysts, and ethics committee or regulatory reviewers when required for oversight.

Study results may be published in scientific journals or presented at academic meetings, but your name and identifying information will not be included. Uploaded public documents for ClinicalTrials.gov must not contain participant names.

11. Use of Samples and Data

Blood, urine, and bladder tissue specimens collected according to the study arrangement will be used for this study and managed according to the approved protocol and institutional requirements. Before any public registry upload or final English release, the study team should confirm whether specimens are retained for future analysis, destroyed after testing, or used only for routine clinical testing.

12. New Information

If new information becomes available during the study that may affect your rights, safety, or willingness to continue, the study team will inform you promptly. You may be asked to sign an updated consent form if required.

13. Withdrawal

You may withdraw from the study at any time. If you withdraw, the study team will provide necessary medical advice and help arrange appropriate follow-up care. The handling of information and samples already collected will follow the ethics-approved study policy and applicable regulations.

14. Questions and Contacts

If you have questions about this study, your rights as a research participant, or any research-related injury, please contact the study doctor or the responsible ethics office using the contact details approved by the institution for public and participant-facing use.

Consent Statement

Please read each statement carefully. By signing below, you confirm that:

- The study purpose, procedures, possible risks, possible benefits, alternatives, costs, compensation, confidentiality protections, and voluntary nature of participation have been explained to you.
- You have had enough time to read this form and ask questions.
- Your questions have been answered to your satisfaction.
- You understand that you may withdraw from the study at any time without affecting your future medical care.
- You voluntarily agree to participate in this study.

Signatures

Participant name	

Participant signature	
Date	
Person obtaining consent name	
Person obtaining consent signature	
Date	
Principal investigator signature, if required	
Date	