Informed Consent Form of Autologous Platelet-rich Plasma Injection for Androgenic Alopecia (Original in Chinese)

This single-center, single-arm trail was reviewed and approved by the Ethics Committee of the General Hospital of Western Theater Command. The original documents are in Chinese. Provided as follows are: (1) the cover page of the ethical approval letter, which includes the study title, approval number (2023xjsxxm-28), and approval date (14 August 2023); and (2) the English translation of the original Chinese informed consent form.

中国人民解放军西部战区总医院伦理委员会

伦理审查批件

<table>
<tr><td>受理编号</td><td colspan="2">2023xjsxxm-28</td><td>批件编号</td><td colspan="2">2023xjsxxm-28</td></tr>
<tr><td>项目名称</td><td colspan="5">自体富血小板血浆头皮注射治疗雄激素源性脱发</td></tr>
<tr><td>项目负责人</td><td colspan="2">谭强</td><td>所在科室</td><td colspan="2">输血医学科</td></tr>
<tr><td>审查文件</td><td colspan="5">1. 新技术新项目方案
2. 知情同意书</td></tr>
<tr><td rowspan="3">审查类别</td><td colspan="5">☒初始审查</td></tr>
<tr><td>☐跟踪审查</td><td colspan="4">☐年度/定期跟踪审查
☐修正案审查
☐严重不良事件和非预期事件报告审查
☐不依从/违背方案事件审查
☐暂停或终止已批准研究审查
☐结题审查
☐受试者抱怨
☐实地访查</td></tr>
<tr><td colspan="5">☐复审</td></tr>
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<tr><td>会议日期</td><td colspan="2"></td><td>审查会议地点</td><td colspan="2"></td></tr>
<tr><td>投票结果</td><td colspan="5"></td></tr>
<tr><td rowspan="2">审查意见</td><td colspan="5">审查决定：/</td></tr>
<tr><td colspan="5">1. 已批准项目应遵循伦理委员会批准的方案执行，需符合伦理原则；
2. 对已批准的新技术新项目方案、知情同意书等材料的任何修改及项目负责人更换等，须及时通知本伦理委员会重新审查，获得批准后执行；
3. 发生严重不良事件及影响风险受益的非预期事件，须及时报告本伦理委员会；
4. 根据伦理委员会对跟踪审查频度的意见，无论项目开始与否，请在跟踪审查日期到期前一个月提出跟踪审查的申请；
5. 方案违背/偏离，暂停/提前终止，需及时通知本伦理委员会。</td></tr>
<tr><td colspan="2">年度定期/跟踪审查频率</td><td>1年</td><td>批件有效期</td><td colspan="2">1年</td></tr>
<tr><td>联系人</td><td colspan="2">高瑞雪</td><td>联系电话</td><td colspan="2">570216</td></tr>
<tr><td>主任委员（被授权者）签名</td><td colspan="5">西部战区总医院伦理委员会（盖章）
2023年8月14日</td></tr>
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内部 医疗管理科 田沛 20230814

This is the ethical committee-approved informed consent form (original in Chinese) for the single-arm trial of autologous apheresis platelet-rich plasma (PRP) injection for androgenetic alopecia (AGA). It details the procedures (including PRP preparation via apheresis and scalp injection protocol), potential risks (e.g., discomfort at injection site, infection, procedural risks), benefits, alternative treatments, voluntary nature of participation, and the right to withdraw. The study was conducted in full compliance with the principles outlined in this document.

Informed Consent Form of Autologous Platelet-rich Plasma Injection for Androgenic Alopecia
Patient Name Gender Age ID Number
Part 1: Condition Introduction and Treatment Recommendation My physician has informed me that I have been diagnosed with androgenetic alopecia. It is recommended that I undergo Autologous Platelet-Rich Plasma (PRP) Scalp Injection Treatment under topical anesthesia. Autologous Platelet-Rich Plasma (PRP) is a plasma product with a high concentration of platelets, obtained from autologous whole blood via density gradient centrifugation. It can release various growth factors and bioactive proteins, promoting cell proliferation and migration, and facilitating tissue regeneration and healing. Its use is supported by evidence-based medicine for conditions such as chronic musculoskeletal pain, wound repair, and androgenetic alopecia. Prior to treatment, the physician will strictly disinfect the skin at the injection site(s). Following topical anesthesia, a 1 mL syringe will be used to perform subcutaneous or intradermal injections in the alopecic areas of the scalp. Approximately 0.05 mL of PRP will be injected per point, with injection points spaced 0.5 cm apart. The injections will be administered once per month for a total of 3 to 5 consecutive sessions. Efficacy and safety will be assessed monthly during the treatment period and at a final follow-up visit one month after the last injection, resulting in a total of 4 to 6 evaluations. The entire procedure will be performed under strict aseptic technique, and all treatment details will be documented promptly.

Part 2: Available Treatment Options

For your condition, the following treatment options are currently available at our hospital. Your physician will explain the nature, relative advantages and disadvantages, potential harm, and estimated costs associated with each option. Please consider carefully and make your choice. After listening to your physician's detailed explanation of the following treatment methods and their pros and cons, please select your preferred treatment method (check the box as instructed):

□ Autologous Apheresis Platelet-Rich Plasma (PRP) Scalp Injection Treatment

□ Oral Finasteride

□ Topical Minoxidil

□ Hair Transplantation

□ Other: _____

Part 3: Potential Risks and Countermeasures

My physician has explained to me the potential risks associated with autologous PRP treatment. I understand that some less common risks may not be listed here. The specific treatment approach may vary depending on individual patient circumstances. I have been advised that I can discuss the specifics of my treatment with my physician and address any particular concerns I may have.

1. I understand that any surgical anesthesia carries risks.
2. I understand that any medication used may produce side effects, ranging from mild symptoms such as nausea and rash to severe anaphylactic shock, or even life-threatening situations.
3. I understand the potential risks of this treatment and the physician's countermeasures:
    1) During PRP Apheresis: Vasovagal syncope (fainting), fear of blood, hypoglycemia, hypocalcemia, etc., may occur, potentially leading to failed PRP collection and requiring a repeat procedure.
    2) Due to factors such as lipemic (fatty) blood or equipment issues, the collected PRP may not reach the therapeutic concentration or may contain excessive other cellular components, rendering it unusable and requiring a repeat collection.
    3) Localized bleeding, hematoma, swelling, or pain at the injection site. Symptomatic management such as compression or cold application may be

applied.

4) Infection at the injection site, requiring anti-infective treatment.
5) Injury to local nerves, requiring specialized treatment.
6) Other unknown or currently unpredictable complications.

4. I understand that the medical staff will closely monitor my condition and strive to prevent or minimize the aforementioned situations. Should any of these adverse reactions occur, the medical staff will actively implement appropriate countermeasures, and my and my family's cooperation will be required.

Part 4: Patient's Informed Choice

My physician has explained to me the planned treatment method, the potential complications and risks associated with this treatment and its aftermath, as well as other available treatment methods, and has answered my questions regarding this treatment.

I understand the potential benefits and risks of the PRP treatment as explained. My participation in this study is entirely voluntary. I have the right to refuse to participate or to withdraw my consent and discontinue participation at any time, for any reason, without any penalty or loss of benefits to which I am otherwise entitled.

I choose <u>Autologous Apheresis Platelet-Rich Plasma (PRP) Scalp Injection Treatment</u>.

I agree that during the treatment, the physician may adjust the predetermined treatment plan based on my condition.

I understand that my treatment may require the involvement of multiple physicians.

I acknowledge that I have not been given a guarantee of 100% treatment success.

I authorize the physician to handle any diseased tissue or specimens obtained during the treatment, including but not limited to pathological examination, cytological examination, and disposal as medical waste.

Patient Signature and Thumbprint: _____

(□ Right Index Finger □ Left Index Finger) **Date:** _____

Part 5: Physician's Statement

I have informed the patient of the planned treatment method, the potential complications and risks associated with this treatment and its aftermath, other available treatment methods, and have answered the patient's questions regarding this treatment.

Physician Signature: _____ Date: _____