[Institution Name] Obstetrics and Gynecology Hospital of Fudan University, Shanghai
[Investigator Name] Professor Zhang Wei
[Dec 19, 2013]
[机构名称] 上海复旦大学附属红房子医院
[研究者姓名]张炜教授
[12月/19日/2013年]

研究者发起的研究协议 [提供资金]	**INVESTIGATOR INITIATED STUDY AGREEMENT [FUNDS]**
雅培医药贸易（上海）有限公司（"雅培"） 希望向复旦大学附属妇产科医院 （"研究机构"）提供资金仅为实施研究者发起研究（"研究"）的有限目的。本研究协议（"本协议"）自完全签署之日起生效（"生效日期"）。鉴于相互约定，各方达成协议如下：	Abbott Pharmaceutical Trading (Shanghai) Co., Ltd. ("Abbott") desires to provide funding to Obstetrics and Gynecology Hospital of Fudan University, Shanghai, China ("Institution") for the restricted purpose of Institution's conduct of an investigator initiated study ("Study") effective as of the date this Investigator Initiated Study Agreement (the "Agreement") is fully executed (the "Effective Date"). In consideration of the mutual promises set forth herein, the parties hereto agree as follows:
1. 申办者和研究的执行。研究机构应遵循本协议条款，严格遵守附于本协议并作为本协议组成部分的**附录A**规定之雅培编号为A14-390，标题为**"地屈孕酮调整异常子宫出血-排卵障碍患者的不规则月经周期：一项基于门诊病人的前瞻性，自身对照观察性研究"** 的方案（"方案"）及，附于本协议并作为本协议组成部分的**附录B**规定之预算概况及付款计划（"预算"） 进行申办和研究。研究机构应对本研究的各个方面负全部责任。如法律和/或法规要求，研究机构应向适当的监管机构提交方案和其他规范性文件。如方案经过修改，研究机构须将修改后的方案交至雅培，并取得雅培继续提供资金和/或提供研究药物的书面同意。如果修改后的方案需要变更研究预算或者本协议的其他条款，双方应签署书面的修订文件，其中纳入修改后的方案以及对本协议进行的任何必要变更。	1. Sponsor and Conduct of Study. Institution will sponsor and conduct the Study pursuant to the terms of this Agreement and in strict adherence to Protocol No. A14-390, entitled "**Dydrogesterone in Cycle Regularization in Abnormal Uterine Bleeding – Ovulation Dysfunction (AUB-O) Patients: A Prospective, Observational Study**" (the "Protocol") attached hereto and incorporated herein by reference as ***Exhibit A*** and Budget Summary and Payment Schedule ("Budget") attached hereto and incorporated herein as ***Exhibit B***. Institution shall have complete responsibility for all aspects of the conduct of the Study. If required by law and/or regulation, Institution shall submit the Protocol and any other required regulatory documents to the appropriate regulatory authority for review. In the event that the Protocol is modified, Institution must provide such modified Protocol to Abbott and obtain Abbott's written approval of continued funding and/or provision of the Study Product(s). If the modified Protocol requires changes to the Budget or other terms of this Agreement, a written amendment signed by the parties shall be made incorporating the modified Protocol and any necessary changes to this Agreement.
2. 研究者；联络人。张炜教授（"研究者"）代表研究机构负责实施研究，如该研究者因任何原因无法实施该研究，雅培有权立即终止本协议。研究机构在雅培的联络人是葛怡琳，其地址为上海南京西路388号仙乐斯广场32楼，电话/传真号为8602123204040，或者雅培书面指定的任何其	2. Investigator; Contacts. Professor Zhang Wei ("Investigator") will be responsible on Institution's behalf for the conduct of the Study. If Investigator is not available to conduct the Study for any reason, Abbott may terminate this Agreement immediately. Institution's contact(s) at Abbott will be Ge

他人。雅培在研究机构的联络人是葛怡琳, 地址为上海南京西路388号仙乐斯广场32楼, 电话/传真为862123204040，或研究机构书面指定的其他人。研究机构陈述并保证研究者是研究机构的雇员。如果研究者在本协议期间（见下文定义）于研究机构离职，研究机构将立即书面通知雅培。	Yilin, 32/F, 388 Nanjing West Road, Shanghai, 862123204040 or whomever Abbott may designate in writing. Abbott's contact(s) at Institution will be Ge Yilin, 32/F, 388 Nanjing West Road, Shanghai, 862123204040, or whomever Institution may designate in writing. Institution represents and warrants that Investigator is an employee of Institution. If Investigator leaves Institution's employment during the Term (as defined below), then Institution will promptly notify Abbott Laboratories in writing.
3. 遵守法律。 a) 研究机构和研究者声明，其在履行本协议义务时应遵守所有适用法律，特别是，在不限制前述一般性原则的情况下，研究机构及研究者在开展研究时应遵循所有适用医疗保健计划的中华人民共和国法律、规定、准则和条例。研究机构或研究者均不得向任何人或公司或从任何人或公司寻求、接受、提供、许诺、给予报酬、费用、贷款、服务或礼品，作为开展与雅培间业务的条件或目的。另外，在履行本协议下义务时，研究机构和研究者或者代表其行事的人员均不得直接或间接提供、许诺、授权贿赂、回扣、好处或其他形式的报酬、礼品，以不恰当地影响代理商、政府官员、政党或者公职候选人对其裁量权或影响力的运用。为促进前述之义务，研究机构应确保依据适用法律和法规设立和组建的独立伦理委员会（"IEC"）对研究的执行予以批准和监督。研究机构应遵守IEC就研究做出的指令，并且如果任何此等指令与方案有差异，研究机构应通知雅培。如当地监管机构或其他代理人有任何影响或可能会影响推广本研究药物或持续实施本研究的行为，研究机构应立即告知雅培。	3. Compliance with Law. (a) Each of Institution and Investigator represent that each shall comply with all applicable laws in performing its obligations under this Agreement. In particular, but not to limit the generality of the foregoing, Institution and Investigator shall conduct the Study in compliance with all applicable People's Republic of China's laws, regulations and guidelines and rules governing healthcare programs. Institution and Investigator must not seek, accept, offer, promise or give any payments, fees, loans, services or gifts from or to any person or firm as a condition or result of doing business with Abbott. In performing its obligations under this Agreement, neither Institution nor any person acting on its behalf shall make, directly or indirectly, any offer or promise or authorization of a bribe, kickback, payoff or any other payment or gift intended to improperly influence an agent, government official, political party or candidate for public office to exercise their discretionary authority or influence in their performance of their obligations under this Agreement. In furtherance of the foregoing obligations, Institution will further ensure that an Independent Ethics Committee ("IEC") established and constituted in accordance with applicable laws and regulations, approves and oversees the conduct of the Study. Institution will comply with the directives of the IEC respecting the conduct of the Study, and will notify Abbott to the extent any such directives vary from the Protocol. Institution will promptly disclose to Abbott, any action or threatened action by the local regulatory authority or other agency that may

	affect marketing of the Study Product(s) or continuation of the Study.
b) 研究机构和研究者同意，如果研究药物或其他研究材料是由雅培免费提供的，和/或其他工作是由雅培付款的，则研究机构、其代理人或研究者均不得从任何第三方（包括但不限于从受试者、任何私营保险提供方、政府项目或社会保险等）单独就此等研究药物、其他研究材料和第三方服务收取费用或寻求补偿。如果项目涉及的受试者的研究药物、其他研究材料和/或研究机构和研究者提供的工作被纳入全球支付体系如诊断相关组别（"DRGs"），研究机构将把该等由雅培免费提供的研究药物或其他研究材料，或由雅培付款的工作作为在该等支付体系所适用的开票程序下研究的一部分。如法律要求，研究机构将向联邦、国家或私立保险项目进一步报告该等研究药物的收到情况。	(b) Institution and Investigator agree that, if Study Product(s) or other Study materials are provided without charge by Abbott, and/or work performed by Institution or Investigator is paid for by Abbott, none of Institution, its agents or Investigator shall separately bill or seek reimbursement for such Study Product(s), other Study materials and/or work from any third party including, without limitation, a subject, any private provider of insurance, or governmental program. If the Study involves subjects whose Study Product(s) or other Study materials and/or work performed by Institution or Investigator are covered under global payments systems, such as Diagnosis Related Groups ("DRGs"), Institution will treat any such Study Product(s) or other Study materials that are provided without charge by Abbott, or work that is paid for by Abbott as part of the Study, under the billing procedures applicable to such payment system. Institution will further report receipt of such Study Product(s) to any federal, state or private insurance program, as may be required by law.
c) 研究者理解和同意，除依据预算中规定支付给研究机构的资金以外，研究者或任何协同研究者均不会就其与研究相关的任何工作从雅培处再行收取任何额外资金。	(c) Investigator understands and agrees that none of Investigator or any subinvestigator will receive any funds from Abbott in connection with the Study other than the funds paid to Institution according to the Budget.
不良事件。研究者/研究机构确保符合任何适用主管当局的报告要求。此外，如果研究者/机构 获悉一下药物安全相关信息，需要向雅培报告： a) 不良反应。（不良反应的定义是指：对医疗产品有害的和非预期的反应。上述这种反应是不良事件与医疗产品之间存在因果关系，这种因果关系至少具有合理的可能性。不良反应可能是由于职业暴露或者市场授权内或外的产品使用。市场授权外的使用包括超适应症使用，过量使用，错误使用，滥用和治疗差错） b) 怀孕期的药物暴露（包括母亲，父亲或者胎儿的药物暴露），有或没有不良反应 c) 通过母乳的婴儿药物暴露（通过母乳喂	4. Adverse Events. Investigator / Institution shall comply with all applicable regulatory reporting obligations. In addition, Investigator / Institution shall report to Abbott the following Pharmacovigilence-relevant information relating to the Abbott product(s), if Investigator / Institution become aware of it: • adverse reactions (An adverse reaction is defined as: A response to a medicinal product which is noxious and unintended. Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility. Adverse reactions may arise from use of the product within or outside the terms of the marketing

养），有或没有不良反应 d) 药物过量（即单次或者累计的医疗产品给药剂量超过了授权产品信息的最大推荐剂量（注：通常需要临床判断），有或没有不良反应 e) 药物滥用或错误使用（即非临床原因使用），有或没有不良反应 f) 超适应症使用，有或没有不良反应 g) 疏忽或者意外药物暴露，有或没有不良反应 h) 职业药物暴露，有或没有不良反应 i) 治疗差错（即当在医疗工作者，病人或者消费者控制下使用药物，任何导致或引起不适当的药物使用或者病人伤害），有或没有不良反应 j) 治疗效果缺乏（即“缺乏疗效”报告） k) 可疑的传染源传播，并将会被归为严重不良反应 l) 产品使用导致的意外治疗效果或临床获益 上述信息，要求主要研究者/机构在获悉后 2 个日历日内报告给雅培。主要研究者/机构应当立即使雅培可以获得可能必须的记录并进行相关的事件调查。 进一步，主要研究者/机构需要立即向雅培通知或者提供： a) 任何危及研究的安全性问题 b) 任何与雅培产品相关的安全信号 c) 中期研究报告，如果适用 d) 最终研究报告或至少相应的出版物 e) 最终研究报告或至少相应的出版物，需要在研究数据关闭后 12 个月内提供 上述所有与雅培产品相关的药物安全信息应当报告给以下联系人是赵璐，地址为上海南京西路 388 号仙乐斯广场 32 楼，电话/传真号为 86 21 63345041	authorization or from occupational exposure. Conditions of use outside the marketing authorization include off-label use, overdose, misuse, abuse and medication errors) • product exposure (including maternal, paternal or fetal exposure) associated with a pregnancy with or without an adverse reaction • a trans-mammary exposure of an infant (transmission via breastmilk) to a product with or without an adverse reaction • overdose (i.e. administration of a quantity of a medicinal product given per administration or cumulatively which is above the maximum recommended dose according to the authorized product information (Note: Clinical judgment should always be applied) with or without an adverse reaction • abuse or misuse (e.g. use for non-clinical reasons) with or without an adverse reaction • off-label use with or without an adverse reaction • inadvertent or accidental exposure with or without an adverse reaction • occupational exposure with or without an adverse reaction • medication errors (i.e. any event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer) with or without an adverse reaction • lack of therapeutic efficacy (i.e., “lack of effect” reports) • suspected transmission of an infectious agent, which will be classified as a serious adverse reaction • an unexpected therapeutic or clinical benefit from use of the product Such information shall be reported by Investigator / Institution to Abbott within 2 calendar days of becoming aware of such occurrences. Investigator / Institution shall promptly make available to Abbott such records as may be necessary and pertinent to investigate such occurrences. Further, Investigator / Institution shall promptly inform Abbott about/provide Abbott with: • any safety issues in relation with the study at stake

	• any safety signal associated with the Abbott product(s) • interim study reports, if applicable • the final study report or at least the corresponding publication The final study report or the corresponding publication is due at the latest within 12 months as of closure of the study database. All Pharmacovigilence-relevant information mentioned above relating to the Abbott product(s) shall be reported to the following contact: Zhao Lu, 32/F, 388 Nanjing West Road, Shanghai, Fax 86 21 63345041.
5. 研究供给。雅培将无偿提供足量的研究药物，但仅供研究机构和研究者实施研究所用。研究机构和研究者都不得将研究药物用于依据方案实施研究以外的目的。如果研究药物属管制药物，该药物应运送到 DEA 登记表格或相应表格上列明的地址。所有研究药物、研究材料和其他雅培提供的与本协议相关的信息均始终为雅培单独所有。研究者和研究机构承诺并保证： a) 保证研究药物供给充足，并按照雅培的书面指示，相关研究药物的标签说明及相关规范性要求始终妥善储存和处理研究药物； b) 在标明的有效期后不再使用研究药物； c) 研究完成或终止时，雅培提供的研究药物和材料应依据研究机构的政策和流程予以销毁，并且研究机构应对该等销毁情况作记录，或依照雅培的指示归还该等研究药物和材料。研究者应保存研究药物处理的详细记录，包括日期、数量及受试者的使用情况。	5. Study Supplies. Abbott will provide sufficient quantity of the Study Product(s) at no cost solely for use by Institution and Investigator in the conduct of the Study. Neither Institution nor Investigator will use any of the Study Product(s) for any purpose other than to conduct the Study pursuant to the Protocol. If the Study Product(s) is a controlled substance, it will be shipped to the address listed on the DEA Registration or equivalent form. All Study Product(s), materials and other information provided by Abbott in connection with this Agreement are and will remain the sole property of Abbott. Each of Investigator and Institution represents, warrants and covenants that: (a) it will ensure the supply of Study Product(s) is adequate and that the Study Product(s) is and will be stored and handled in accordance with Abbott's written instructions and as set forth in the labeling of the applicable Study Product(s) and in accordance with applicable regulatory requirement(s); (b) the Study Product(s) will not be used past the labeled expiration date; and (c) upon conclusion or termination of the Study, the Study Product(s) and materials provided by Abbott will be either destroyed in accordance with Institution's policies and procedures and Institution will document such destruction, or returned pursuant to Abbott's direction. Investigator shall maintain adequate records of the disposition of Study Product(s) including dates, quantity, and use by subjects.

6.递交进展报告。研究机构应按雅培要求向雅培递交口头或书面的研究进展情况的报告。在完成或终止研究后的四十五（45）日内，研究机构应向雅培递交最终报告，详细说明研究成果。	6. Delivery of Progress Reports. Upon the request of Abbott, Institution will submit oral or written reports on the progress of the Study. Within forty-five (45) days following the completion or termination of the Study, Institution will furnish Abbott with a final report detailing the results of the Study.
7.研究记录及数据审计。雅培有权在正常营业时间内定期对与本研究有关的记录和其他数据进行审计。研究机构有权修改该等记录、源文件和其他法律要求的数据，以保护受试者在本协议**第 10 条**下的保密性。研究机构应依据适用法律、法规或方案保存研究文件。	7. Auditing of Study Records and Data. Abbott reserves the right to periodically audit records and other data related to the Study during normal business hours. Institution may redact such records, source documents, and other data as may be legally required to protect subject confidentiality, consistent with **Section 10** of this Agreement. Institution shall retain the Study documents in accordance with the applicable laws, regulations and the Protocol.
8.资助。 a) 雅培应按**附录 B** 规定的预算向研究机构支付其所进行研究的资助款。经双方同意，预算中规定的资助金额代表了所提供之工作的公平市场价值，并且预算中规定的费用是合理的并且符合惯例的。差旅相关费用应依照雅培差旅政策相关规定，包括乘坐经济舱，依照地域差别核定的、合理的且符合惯例的食宿标准。 b) 如本协议由雅培因研究机构违约以外的任何原因提前终止，则雅培根据预算规定的金额向研究机构支付其已履行的工作的费用。 c) 所有付款都应在雅培批准账单后的三十（30）日内并且仅在本协议全部签署后作出，账单应列明研究机构依据本协议提供之工作或发生垫付的费用。 d) 对于本协议下的最终付款，应随附账项调整单，且应考虑依据**第 8 条**所做的付款。如果在做最终账项调整时，雅培业已支付的总款项低于研究机构于本协议项下的应	8. Funding. (a) Abbott shall fund Institution's Study per the Budget, set forth in **Exhibit B**. The parties agree that the amount for funding set forth in the Budget represents the fair market value for the work to be performed, expenses contained in the Budget are reasonable and customary, and expenses related to travel are consistent with Abbott's travel policy (including economy coach air travel, reasonable and customary lodging and meal rates based on the geographic region of travel). (b) In the event of premature termination of this Agreement by Abbott for any reason other than for Institution's breach, Abbott shall pay Institution for work performed in accordance with the budgeted amounts set forth in the Budget. (c) All payments shall be made within thirty (30) days of Abbott's approval of an invoice detailing Institution's work performed under this Agreement or incurrence of pass-through expenses, and only after full execution of this Agreement. (d) The final payment to be made under this Agreement will be accompanied by a financial reconciliation, taking into account the payment to be made in accordance with this **Section 8**. If, at the time of such financial

得款项，则雅培应在此时向研究机构支付该等款项。在作最终账项调整时确定的、根据本协议属于雅培超额支付的任何款项，研究机构应在收到雅培通知退回该超付款之日起四十五（45）天内退回雅培：财务负责人，陈颖，应收账款，上海市南京西路 388 号仙乐斯广场 33 楼。退回雅培的款项应当附随汇款说明以及相关汇款证明文件并抄送本协议**第 2 条**中的雅培联络人。	reconciliation, the total amount Abbott has paid is less than the amount to which Institution is entitled hereunder, Abbott shall pay the amount due Institution at such time. Any overpayment due Abbott pursuant to this Agreement, as determined at the time of final reconciliation, shall be made payable to Abbott within forty five (45) days of Abbott's notice to Institution of such overpayment and sent to: the Controller, Cherry Chen, Accounts Receivable, 33F Ciros Plaza, 388 West Nanjing Rd., along with an explanation for such payment and accompanying support documentation for the remittance with a copy to the Abbott contact set forth in **Section 2** of this Agreement.
9. 保密。 a) 在本协议期限内，包括展期及之后的十（10）年内，研究机构、他们的雇员，包括研究者、代理人、分包商或关联机构（统称"接收方"），未经雅培事先书面同意，不得披露机密信息。尽管有前述规定，对于任何雅培视为商业秘密的机密信息，只要该信息在适用法律下可继续作为商业秘密，则关于该信息的保密及不使用义务即应持续有效。"机密信息"是雅培或其他代表雅培的主体提供给接收方的信息，包括但不限于研究药物以及其他与雅培和研究相关的、或者因进行研究而开发出来的所有材料和信息，但不包括以下部分的信息： i. 如该信息在本协议项下收到之前已为接收方获知，但应有其书面记录加以证明； ii. 如该信息由有权以非保密方式进行披露的第三方披露给接收方;或 iii. 如该信息并未因接收方之过错是或成为公众所知领域的一部分 b) 在本协议期间及以后，接收方未经雅培事先	9. Confidentiality. (a) During the Term of this Agreement, including any extensions thereof, and for a period of ten (10) years after the expiration or termination of this Agreement, Institution, its employees, including Investigator, agents, subcontractors and affiliates (collectively, "Receiving Party") shall not disclose Confidential Information (other than to Abbott or Abbott-designated parties) without Abbott's prior written consent. Notwithstanding the foregoing, obligations of confidentiality and non-use with respect to any Confidential Information identified as a trade secret by Abbott shall remain in place for so long as the applicable Confidential Information retains its status as a trade secret under applicable law. "Confidential Information" shall include any information provided to Receiving Party by or on behalf of Abbott, including but not limited to Study Product(s), and all materials and information concerning Abbott or the Study or developed as a result of conducting the Study, except any portion thereof which: (i) is known to the Receiving Party prior to receipt thereof under this Agreement, as evidenced by its written records; (ii) is disclosed to the Receiving Party after acceptance of this Agreement by a third party who has a right to make such disclosure in a nonconfidential manner; or (iii) is or becomes part of the public domain through no fault of the Receiving Party.

书面批准，不得在本协议规定的目的以外使用机密信息。	(b) During the Term and thereafter, the Receiving Party shall not use Confidential Information for any purpose other than as indicated in this Agreement without Abbott's prior written approval.
c) 本协议中的任何规定不限制接收方依据法律或法院命令或其他政府命令或要求对机密信息进行的披露，但是接收方应及时书面通知雅培（在任何情况下，至少五（5）个工作日内通知）以便雅培采取所有其认为必要的措施以保护其机密信息。如果未能获得保护令或其他补救措施，或雅培放弃实施本**第 9 条**赋予的权利，接收方应依据法律顾问的意见仅提交法律要求的机密信息的部分。此外，接收方应允许雅培采用适当的法律手段限制该等披露。	(c) Nothing in this Agreement will be construed to restrict Receiving Party from disclosing Confidential Information as required by law or court order or other governmental order or request, provided in each case Receiving Party shall give Abbott prompt written notice (and in any case at least five (5) business days notice) in order to allow Abbott to take whatever action it deems necessary to protect its Confidential Information. In the event that no protective order or other remedy is obtained, or Abbott waives compliance with the terms of this **Section 9**, Receiving Party shall furnish only that portion of the Confidential Information which it is advised by counsel as being legally required. In addition, Receiving Party will permit Abbott to attempt to limit such disclosure by appropriate legal means.
d) 研究机构、及其雇员、代理人、分包商或关联机构不得向雅培披露第三方视为保密或专属第三方的任何信息，除非研究机构事先取得该第三方及雅培的书面批准。	(d) None of Institution, Institution's employees, agents, subcontractors or affiliates will disclose to Abbott any information which is confidential or proprietary to a third party unless Institution has first obtained the prior written approval of both such third party and Abbott.
e) 在本协议终止之日起三十（30）日内，研究机构应按雅培指令保证接收方归还或销毁所有包含雅培机密信息的有形资料。	(e) Within thirty (30) days after the effective date of any termination of this Agreement and at Abbott's direction, Institution will ensure Receiving Party returns or destroys all tangible materials that contain Abbott's Confidential Information.
10. 受试者保密和数据保护。 a) 双方同意遵守与受试者保密和数据保护有关的一切法律、法规。研究者应在每一受试者参加研究之前，代表研究机构从每一受试者处取得受试者签署的知情同意书，该知情同意书应由 IEC 书面批准。研究者也应取得许可雅培、及其参与或评估研究的代表能够接触、获得研究数据副本的知情同意书或单独的授权文件。	10. Subject Confidentiality, Data Protection. (a) The parties will comply with all laws and regulations regarding Study subject confidentiality and data protection. Investigator will be responsible on behalf of the Institution for obtaining from each Study subject, prior to the Study subject's participation in the Study, a signed informed consent in a form approved in writing by the IEC. Investigator shall also obtain in the

	informed consent or separate authorization document, permission for Abbott and Abbott's representatives involved with or evaluating the Study to access and obtain copies of the Study data.
b) 研究机构及/或研究者在履行本协议项下义务，收集、保留、处理或披露可能透露（或结合其他信息后可能透露）某个人（包括研究受试者及其他参与或与研究相关的个人）身份的信息（"个人数据"）时，研究机构及/或研究者应仅根据本协议或适用的法律进行操作。 研究机构及研究者应采取适当的安保措施以保证个人数据的保密和安全。如果出现非经授权的接触及披露情况（"安全漏洞"），研究机构及研究者应立即通知雅培，告知雅培安全漏洞的次数和性质，并采取所有合理措施以补救该安全漏洞。如果有适用的数据保护法要求双方另外签署协议或作出承诺，包括国际数据转让协议，研究机构承诺确保所有必要的协议就绪并被实施。	(b) Where Institution and/or Investigator collects, retains, processes or discloses information identifying or, in combination with other information, identifiable to a living individual, including Study subjects and others, participating in or associated with the Study ("Personal Data"), in performing its obligations under this Agreement, it shall only do so in accordance with this Agreement and with all applicable laws. Institution and Investigator shall adopt appropriate safeguards to ensure the confidentiality and security of the Personal Data. Institution and Investigator shall promptly inform Abbott about any unauthorized access to or disclosure of Personal Data ("Security Breach"), including the timing and nature of the Security Breach, and take all reasonable measures to remedy the Security Breach. Where applicable data protection laws require that the parties enter into additional agreements or undertakings, including international data transfer agreements, Institution will undertake to ensure that all necessary agreements are implemented and in place.
c) 研究者承认并同意并应让所有参与研究的协同研究者承认并同意雅培可以收集、使用、处理和披露研究者和协同研究者的个人数据包括他们的具体的姓名、地址、资质和临床试验的经验。附加的可以使用和披露的信息还包括财务信息（包括报酬和报销的费用）和雅培为未来研究以及遵守适用法律的目的对研究者参与研究的适合性的评估。研究者理解并明确同意，并应让所有参与研究的协同研究者明确同意，该等信息如果为了上述目的的需要，可提供给道德委员会、政府机构、雅培集团下在本研究实施地或实施地以外的国家的关联公司，包括美国或其他适用法律要求的，或出于药品临床实验管理规范或数据保护审计或检查的目的需要的其他地方的关联公司。	(c) Investigator acknowledges and consents to, and shall cause all subinvestigators for the Study to acknowledge and consent to, Abbott's collection, use, processing, and disclosure of Investigator's and sub-investigator's Personal Data including details of his/her name, address, qualifications and clinical trials experience. Additional uses or disclosures may include financial information (including compensation and reimbursement payments), assessments by Abbott of Investigator's suitability for future studies, and for purposes of complying with applicable laws. Investigator understands and expressly agrees and shall cause all subinvestigators for the Study to expressly agree that this information may, if necessary for these purposes, be made available to ethics committees, government authorities

	and other companies within the Abbott group of companies located both in the country in which the Study is carried out and in other countries, including in the United States or elsewhere as required by applicable law or as necessary for the purposes of Good Clinical Practice or data protection audits or inspections.
11. 公开。除本协议**第 13（c）条**中规定外，研究机构不得并应确保接收方不得未经雅培事先书面批准，在任何宣传、广告或向第三方或公众传播的信息中披露本协议的存在或其条款，或使用雅培的称谓、商标、服务标志、或雅培的标识。研究机构理解本协议条款和条件包括支付的金额可以由雅培依据法律、法规的要求或雅培认为合适的情况予以披露和公开。	11. Publicity. Except for the requirements set forth in **Section 13(c)** of this Agreement, the Institution shall not and shall ensure Receiving Party shall not disclose the existence or terms of this Agreement or use the name, trademark, servicemark or logo of Abbott in any publicity, advertising or information, which is disseminated to any third person or to the general public without Abbott's prior written approval. Institution understands that the terms and conditions of this Agreement, including the amount of any payment made hereunder, may be disclosed and made public by Abbott as required by law or regulation or where Abbott deems appropriate.
12. 发明。对于接收方因开展研究或使用研究药物而构思、落实、制作、生成或开发的任何信息、发明、数据或发现（不论是否可取得专利权或著作权）、创新技术、通信及报告，接收方应及时向雅培披露、转让，且该等发明应归雅培所有。研究机构和研究者同意，经雅培要求并由雅培承担相应费用，其应签署相关文件或使相关文件得以生效，并采取雅培认为必要的行动，以便雅培能以其名义获取对前述发明创造的专利权和其他专属权利。	12. Inventions. Any information, invention, data or discovery (whether patentable or copyrightable or not), innovation, communication or report, conceived, reduced to practice, made, generated or developed by the Receiving Party that either results from use of any of the Study Product(s) or results from conduct of the Study will be promptly disclosed to Abbott, assigned to Abbott and will be the sole property of Abbott. Institution and Investigator each agree, upon Abbott's request and at Abbott's expense, to execute or cause to have executed such documents and to take such other actions as Abbott deems necessary or appropriate to obtain patent or other proprietary protection in Abbott's name covering any of the foregoing.
13. 发表和演示。 a) 发表要求：为实现科技发表方面的最高行为准则，包括原稿、摘要及海报/口头演示	13. Publications and Presentations. (a) Publication Requirements. To foster the highest standards of conduct related to

（统称为"发表"），雅培致力于透明、道德的发表实践。如果研究者作为任何因研究而产生的发表的作者，雅培建议其遵循本协议的**附录 C**（科技发表要求）。	scientific publications, including manuscripts, abstracts, and poster/oral presentations (collectively, "Publication(s)"), Abbott is committed to transparency and ethical publication practices. If Investigator serves as an author on any Publication(s) emanating from the Study, Abbott advises compliance with the Recommendations for Scientific Publications attached hereto as ***Exhibit C***.
b) 程序。如果研究者或研究机构准备发表或以其他方式公开披露研究成果（统称为"研究结果披露"），则研究机构（或要求研究者）应至少在提交拟议的研究结果披露前六十（60）日向雅培提交该研究结果披露的草案供雅培审核和提出意见，以确定在该研究结果披露中是否披露了任何可获得专利的事项或雅培的机密信息（不包括在本协议项下产生的研究结果）。雅培应在收到该研究结果披露的草案后的六十（60）日内（"审查期"）向研究机构或研究者反馈评议。此外，如雅培要求，研究机构或研究者应在该审查期以外再将拟议的发表/演示延后六十（60）日（"延后期"），以便雅培能够落实专利或其他专有权利的保护。研究机构同意（并应要求研究者同意）对拟议的发表保密，直到审查期或（如雅培选择延后）延后期届满。研究机构同意（并应要求研究者同意）将考虑雅培的建议，并从任何研究结果披露中删除雅培的机密信息（不包括在本协议项下产生的研究结果）。如研究机构或研究者以及雅培对研究结果披露中的数据的意见或解释发生分歧，则双方应基于真实诚信通过适当的科学辩论来解决此等分歧。	(b) Procedures. If Institution or Investigator prepares a Publication(s) or any other public disclosure of Study results (collectively a "Study Results Disclosure"), Institution shall provide or shall require Investigator to provide Abbott, at least sixty (60) days prior to any submission of Study Results Disclosure, with a draft of the same for Abbott's review and comment to ascertain whether any patentable subject matter or Abbott Confidential Information (other than the results of the Study generated hereunder) are disclosed therein. Abbott shall return comments to Institution or Investigator within sixty (60) days after receipt of the draft Study Results Disclosure ("Review Period"). Furthermore, Institution or Investigator shall delay any proposed Study Results Disclosure an additional sixty (60) days in addition to the Review Period in the event Abbott so requests to enable Abbott to secure patent or other proprietary protection ("Delay Period"). Institution agrees and shall require Investigator to agree to keep the proposed Study Results Disclosure confidential until the Review Period and, if elected by Abbott, the Delay Period has expired. Institution agrees and shall require Investigator to agree to delete Abbott Confidential Information (other than the results of the Study generated hereunder) from any Study Results Disclosure. In the event that Institution or Investigator and Abbott differ in their opinion or interpretation of data in the Study Results Disclosure, the parties shall resolve such differences in good faith through appropriate scientific debate.
c) 研究机构和研究者同意不论杂志或研讨会如何要求，都会在适用法律法规和行业准则	(c) Institution and Investigator agree to fully disclose Abbott's support of the Study to

规定的限度内，向杂志或研讨会充分地披露雅培对于本研究的支持。研究机构同意在研讨会或其他会议上，或在医疗或其他杂志上发表该研究成果时会包括以下文字："本研究得到了雅培的大力支持。"本文字会显示在所有海报上、所有演讲和原稿的摘要和致谢中，以及任何财务披露信息中。	the extent required by applicable laws, regulations, and industry guidelines and to journals, congresses, or other entities, regardless of the journal's or congress' requirements. Institution agrees to include the following acknowledgement language when submitting the Study research results to congress' or other meetings and for publication in medical or other journals: "This research was supported by a grant fromAbbott Inc." This language shall appear on all posters, as a sentence within abstracts and as an acknowledgment in all manuscripts and presentations, as well as in any financial disclosure information.
14. 研究注册。研究机构同意充分地遵守与本研究的注册以及本研究成果的公告有关的所有适用的法律、规则和法规。为促进但不受上述情况限制，研究机构应在www.clinicaltrials.gov上注册本研究，或依照国际医学期刊编辑委员会的政策（De Angelis C, et al., 临床试验注册: 国际医学期刊编辑委员会的声明, Ann Intern Med 2004; 141:477-8, 及其不时的修订, "ICMJE政策"）要求按照研究机构关于ICMJE政策的指导方针规定的方式进行注册。	14. Registration of Study. Institution agrees to be fully compliant with all applicable laws rules and regulations relating to the registration of the Study and posting results of the Study. In furtherance of and without limitation on the foregoing, Institution shall register the Study on www.clinicaltrials.gov, or any other registry with requirements consistent with the policy of the International Committee of Medical Journal Editors (De Angelis C, et al., Clinical trial registration: a statement from the International Committee of Medical Journal Editors, Ann Intern Med 2004; 141:477-8, as amended from time to time, the "ICMJE Policy"), in a manner consistent with Institution's guidelines regarding the ICMJE Policy.
15. 陈述和保证。 a) 研究机构陈述和保证： (i) 本协议之条款对研究机构有效且有约束力，并且与研究机构或研究者可能负有的任何其他合同和/或法定义务，以及与研究机构的政策和程序或者与研究机构或研究者相关的任何研究机构或公司的政策和流程相一致。 (ii) 研究机构履行服务及接受报偿，包括	15. Representations and Warranties. a) Institution represents and warrants that: (i) the terms of this Agreement are valid and binding obligations of Institution, and are not inconsistent with any other contractual or legal obligation it or Investigator may have or with Institution's policies and procedures or the policies and procedures of any institution or company with which each of Institution or Investigator are associated; (ii) Institution's performance of the work and acceptance of compensation,

接受可能在本协议项下因研究者会议或雅培要求的其他会议而提供给研究者的任何伙食和/或合理报销费用，均符合研究机构政策和流程及适用法律，并且研究者履行该等服务与其本职工作并无利益冲突。	(including acceptance of any meals and/or reimbursement of reasonable expenses for investigator meetings or other Abbott approved meetings, which may be provided to Investigator) hereunder, is in compliance with all policies and procedures of Institution, and that Investigator's performance of such work does not present a conflict of interest with Investigator's official duties;
(iii) 研究机构和研究者具备高效、快速、专业、称职地实施研究的经验、能力、足够的受试者群体和资源，包括但不限于充足的人员和设备，并且利用尽职调查和必要的人力和设备来实施本研究。	(iii) Institution and Investigator have the experience, capabilities, adequate subject population, and resources, including but not limited to, sufficient personnel and equipment, to efficiently and expeditiously perform the Study hereunder in a professional and competent manner and will utilize due diligence and devote the necessary personnel and equipment at all times to perform the Study hereunder in such a manner;
(iv) 研究机构选用的协同研究者应当符合以下条件：（A）接受过相关领域的培训，具备相关领域的专业知识；（B）适当的研究设施；（C）具有与相关受试者群体合作的经验，更有可能录用适当的研究参与者并坚持完成研究；（D）具有科学研究或临床经验；（E）有能力依照适用的法律和规范的要求实施研究。	(iv) any subinvestigators used by Institution for the Study will be selected based upon a consideration of the following: *(A)* training and expertise in relevant fields; *(B)* appropriate research facilities; *(C)* experience with the relevant subject population so that the subinvestigator has a reasonably high likelihood of recruiting the appropriate research participants and following through to the completion of the Study; *(D)* prior scientific research or clinical experience; and *(E)* ability to conduct the Study in accordance with applicable legal and regulatory requirements; and
(v) （i）研究者在研究履行地法域持有现行有效的行医执照；（ii）该行医执照从未被医务委员会或其他发照机构吊销、限制或暂停；（iii）该研究者的执业权限或资质从未被医疗机构或其他医疗服务提供者吊销、限制或暂停；（iv）据研究者所知，其目前不是任何调查的对象（若该等调查可能导致其行医执照或者在医疗机构或者其他医疗服务提供者处的执业权限或者资质被吊销、限制或暂停）。如果发生前述任何情况，研究者应当立即通知雅培，雅培有权立即终止本协议。	(v) (i) Investigator has a current and valid medical license in the jurisdiction in which the Study is being performed; (ii) such license has never been revoked, restricted, or suspended by a medical board or other licensing agency; (iii) his/her privileges or ability to practice have never been revoked, restricted, or suspended by a health care institution or other provider of health care services; and (iv) to the best of his/her knowledge, Investigator is not under an investigation that could lead to a revocation, restriction, or suspension of his/her medical license, or equivalent, or privileges or ability to practice at a health care institution or other provider of health care services. In the event that any of the foregoing occurs, Investigator

在本协议期限内，如果与本协议相关的任何情况发生任何重大变更（例如某一政策或程序发生变更，可能被合理视为影响到研究机构或研究者参与本协议之恰当性），则研究机构同意立即将此等变更通知雅培。	or Institution shall immediately notify Abbott, and Abbott shall have the right to immediately terminate this Agreement. During the term of this Agreement, if any significant changes occur with regard to the circumstances surrounding this Agreement (e.g., there is a change in a policy or procedure that could reasonably be interpreted to affect the propriety of Institution or Investigator's involvement in this Agreement), Institution agrees to immediately notify Abbott in writing of any such changes.
b) 各方陈述并保证，雅培支持本研究无意也不应被理解为意欲诱使购买、处方、使用、推荐任何雅培产品或由雅培促销或推广的产品或为该等产品提供有利处方地位。	b) Each party represents and warrants that Abbott's support of this Study is not intended to be, nor shall it be construed as, an inducement to purchase, prescribe, use, recommend, or provide a favorable formulary status for any Abbott product or product co-promoted or marketed by Abbott.
16. 期限和终止。 a) 本协议在生效日期生效，并应在以下日期中的较晚一个日期终止：(i)生效日期起一（1）年；（ii）双方在本协议项下的所有义务完成之日（"期限"），除非依据下文**第 16 条 b 款**规定提前终止。如果本研究因任何理由被终止，研究机构应立即书面告知雅培。	17. Term and Termination. a) This Agreement will be effective on the Effective Date and shall terminate on the later of: *(i)* one (1) year from the Effective Date; or *(ii)* the date of completion of all the obligations of the parties hereunder (the "Term"), unless terminated earlier as provided in **Section 17(b)** below. Institution shall immediately notify Abbott in writing in the event the Study is terminated for any reason.
b) 本协议在下述情形下可以终止： (i) 雅培或研究机构可在书面通知对方后终止本协议，如果：(A)另一方违反本协议实质性条款；或(B)本研究被任何政府部门或监管机关终止；	b) This Agreement may be terminated: (i) by either Abbott or Institution upon written notice to the other party if: *(A)* the other party has breached a material term of this Agreement; or *(B)* in the event of termination of the Study by any governmental or regulatory authority;
(ii) 雅培有权书面通知研究机构立即终止本协议，如果：(A) 依据**第 2 条**之规定，无法获得研究者本人的服务；(B) 依雅培单独判断，与研究药物相关的	(ii) by Abbott immediately upon written notice to Institution if: *(A)* the personal services of Investigator are not available, pursuant to **Section 2** of this Agreement, *(B)* in Abbott's sole judgment, an adverse safety concern with respect to

不良安全问题使得继续进行研究已不适当；(C) 研究机构或研究者成为受禁、除外或被判刑的实体或个人，或涉入任何程序而可能导致其变为受禁、除外或被判刑的实体或个人，或依照本协议**第 19 条**被列入美国食品药品管理局（"FDA"）不合格/受限临床研究者名单；(D) 依据**第 15 条 (a)(v)**之规定，研究者受到任何医疗委员会的调查或纪律处分，或研究者的医疗执照被医疗委员会以任何方式限制或暂停执业。	the Study Product makes continued testing unadvisable, or *(C)* Institution or Investigator becomes a Debarred, Excluded or Convicted Entity or Individual or becomes the subject of a proceeding which could lead to that party becoming a Debarred, Excluded or Convicted Entity or Individual or becomes added to the United States Food and Drug Administration's (the "FDA") Disqualified/Restricted List for clinical investigators pursuant to **Section 19** of this Agreement; *(D)* Investigator is under investigation or subject to any disciplinary action by any medical board, or has his medical license restricted or suspended by any medical board in any way, pursuant to **Section 15(a)(vi)**; or
(iii) 雅培亦有权无需任何理由终止本协议，但需提前至少三十（30）日书面通知研究机构。	(iii) by Abbott without cause upon at least thirty (30) days prior written notice to Institution.
c) 本协议的终止或到期不影响此前已履行的权利或义务。	c) Termination or expiration of this Agreement will not affect any rights or obligations which have accrued prior thereto.
17. 责任。研究机构应单独对本方案的设计以及本研究实施的其他所有方面承担责任，包括但不限于获取和维持所有适当的IEC和法律上的/监管上的批准。雅培不应承担由以下情况产生或导致的任何损失、成本、损害或其他费用：（a）本方案的设计、内容、实施或研究药物的使用以及研究受试者的选择；和（b）本研究涉及的所有人身伤害（不论是否与研究相关）或财产损害。	17. Liability. The design of the Protocol, as well as all other aspects of the Study conduct (including, but not limited to, securing and maintaining all appropriate IEC and legal/regulatory approvals) shall be solely Institution's responsibility. Abbott will not be responsible or liable for any losses, costs, damages, or other expenses arising out of or resulting from: *(a)* design, content, or implementation of the Protocol or use of the Study Product(s) and selection of Study subjects; and *(b)* any injury (whether or not Study related) to persons or damage to property involved in the Study.
18. 保险。研究机构同意维持充足的团体或个人保险单以在商业可保利益范围内覆盖其在本协议项下的义务和责任。研究机构进一步同意在收到雅培书面要求后的七（7）个工作日内向雅培提供该等保险的书面证明资料包括但不限于保险凭证或其他能提供合理担保的证明。	18. Insurance. Institution agrees to maintain a policy or policies of insurance or self-insurance sufficient to satisfy its duties and obligations under this Agreement to the extent such duties and obligations are commercially insurable. Institution further agrees to provide written evidence of such insurance (including certificates of insurance or other evidence providing reasonable assurances) to Abbott within

	seven (7) business days following receipt of written request by Abbott.
19. 受禁及除权 。研究机构陈述并保证，研究机构及其雇员，包括研究者、履行本协议服务的代理人、分包商、包括协同研究者过去未曾是、目前也不是受禁、除外或被判刑的实体或个人（视情况而定），也没有涉入可能导致其或该等雇员或代理人或分包商成为受禁、除外或被判刑的实体或个人（视情况而定）之程序或被列入 FDA 不合格/受限临床研究者名单。研究机构进一步承诺并保证，如果在本协议期限内，研究机构、代理人、分包商（包括履行本协议服务的协同研究者）成为或是受禁、除外或被判刑的实体或个人（视情况而定）的程序针对的对象，或被列入 FDA 不合格/受限临床研究者名单，研究机构应立即通知雅培，雅培有权立即终止本协议。本节关于本协议期间内发生行为的通知的规定在本协议终止或期满后仍继续有效。为本条之目的，有关词语适用下列定义：	19. Debarment and Exclusion. Institution represents and warrants that none of Institution, any Institution employees, including Investigator, agents and subcontractors performing services hereunder, including any subinvestigators, have ever been, are currently, or are the subject of a proceeding that could lead to Institution or such employees, agents or subcontractors becoming, as applicable, a Debarred, Excluded or Convicted Entity or Individual, nor are they listed on the FDA's Disqualified/Restricted List for clinical investigators. Institution further covenants, represents and warrants that if, during the Term, Institution, or any of Institution's employees, including Investigator, agents or subcontractors, including any subinvestigators, performing services hereunder, becomes or is the subject of a proceeding that could lead to that party becoming, as applicable, a Debarred, Excluded or Convicted Entity or Individual or added to FDA's Disqualified/Restricted List for clinical investigators, Institution will immediately notify Abbott, and Abbott will have the right to immediately terminate this Agreement. The provision of this paragraph regarding notice of acts occurring during the Term will survive termination or expiration of this Agreement. For purposes of this provision, the following definitions will apply:
a) "受禁个人"指被 FDA 依据《美国法典》（"美国法典"）第 21 篇第 335a 条(a)款或(b)款之规定，或其他有权机构包括但不限于任何当地有权机构禁止以任何身份向拥有已批准的或待批准的药品申请的人提供服务的个人。	(a) A "Debarred Individual" is an individual who has been debarred by the FDA pursuant to Title 21 of the United States Code ("USC") Section 335a (a) or (b) or by any other competent authority, including, without limitation, any local competent authority, from providing services in any capacity to a person that has an approved or pending drug product application.
(b) "受禁实体"指被 FDA 依据美国法典第 21 篇第 335a 条(a)款或(b)款之规定，或其他有	(b) A "Debarred Entity" is a corporation, partnership or association that has been debarred by the FDA pursuant to Title 21

权机构包括但不限于任何当地有权机构禁止递交或协助递交任何简化药物申请书的公司、合伙组织或协会，或受禁实体的分支机构或关联机构。	of USC Section 335a (a) or (b) or by any other competent authority, including, without limitation, any local competent authority, from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity.
(c) "除外个人"或"除外实体"是指(i)被美国卫生与公共服务部监察长办公室排除，受禁，中止或以其他方式取消参加如医疗保险或医疗补贴项目的联邦保健项目资格的个人或实体（视情况定）；(ii)被排除，受禁，中止或被以其他方式取消参加联邦集中采购或非集中采购项目资格（包括美国总务管理局的该等项目）的个人或实体（视情况定）	(c) An "Excluded Individual" or "Excluded Entity" is (i) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General of the U.S. Department of Health and Human Services; or (ii) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration.
(d) "被判刑的个人"或"被判刑的实体"是指依据《美国法典》第 21 篇 335a(a)条或第 42 篇 1320a – 7(a)条规定受到刑事处罚，但尚未被除外，受禁，中止或被以其他方式宣告无资格的个人或实体（视情况定）。	(d) A "Convicted Individual" or "Convicted Entity" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of Title 21 of USC Section 335a(a) or Title 42 of USC Section 1320a – 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.
(e) "FDA 不合格/受限研究者名单"是指被 FDA 认为多次、故意不遵守研究的规范性要求或给研究申办者或 FDA 提交错误信息而限制其获得研究药品、生物制剂或器械的临床研究者名单。	(e) "FDA's Disqualified/Restricted List" is the list of clinical investigators restricted from receiving investigational drugs, biologics, or devices if FDA has determined that the investigators have repeatedly or deliberately failed to comply with regulatory requirements for studies or have submitted false information to the study sponsor or the FDA.
20.独立签约人。在本协议项下，研究机构及研究者与雅培之间的关系属于独立签约人的关系，研究机构或研究者无权约束雅培或代表雅培行事。	20. Independent Contractor. Each of Institution and Investigator's relationship to Abbott under this Agreement is that of an independent contractor, and neither Institution nor Investigator has the authority to bind or act on behalf of Abbott.

21. 转让。 未经雅培事先书面同意，研究机构和研究者均不得将本协议或者本协议项下的任何工作转让或分包给任何第三方。未经雅培事先书面同意，任何试图进行的转让均无法律效力，并且构成对本协议的严重违约行为。任何经许可的受让人应承担研究机构在本协议项下的所有义务。转让不免除研究机构对于已履行的义务所负有的责任。	21. Assignment. Institution may not assign this Agreement to any other party, or subcontract any of its work hereunder, without Abbott's prior written consent. Any attempted assignment without Abbott's prior written consent will be null and void and will constitute a material breach of this Agreement. Any permitted assignee shall assume all obligations of Institution under this Agreement. Assignment shall not relieve Institution of responsibility for the performance of any accrued obligation.
22. 通知。本协议所要求的通知或依据本协议作出的任何通知应采用书面方式，由专人递送或以寄挂号信的方式寄送（需附收件回执），或通过被广泛认可的快递服务商（需妥善注明地址）发送，或者通过传真发送（附确认回执），通过上述方式发出的通知均按下述地址发送。通知的生效日为 (a) 以专人递送、挂号信或被广泛认可的快递服务商发送时以收到当日为准(b)当以传真方式传送时，则以收到传真回执的日期为准。 **如发给研究机构：** 姓名：[redacted] 地址：[redacted] 电话：[redacted] 传真：[redacted] **如发给研究者：** 姓名：张炜 地址：上海市方斜路 419 号 电话：86 13611691036 **如发给雅培：** 姓名：葛怡琳 职位：医学顾问 雅培医药贸易（上海）有限公司 地址： 上海市南京西路 388 号仙乐斯广场 32 楼 电话：86 21 23204040 传真：86 216334 6311 **抄送：** Divisional Vice President and Associate General Counsel Legal Regulatoyr and Compliance , Bldg. AP6A Abbott Laboratories 100 Abbott Park Road, Abbott Park, IL 60064 U.S.A. 传真: 847-938-1200	22. Notices. Any notice required or otherwise made pursuant to this Agreement shall be in writing, personally delivered or sent by certified mail, return receipt requested, or recognized courier service, properly addressed, or by facsimile with confirmed answer-back, to the other party at the address set forth below. Notices shall be deemed effective (a) on the date received if personally delivered or sent by certified mail or recognized courier, or (b) upon the date of confirmed answer-back if sent by facsimile: **If to Institution:** Insert Name Insert Address Phone: Insert # Fax: Insert # **If to Investigator:** Insert Name Zhang Wei Insert Address Number 419, Fangxie Road, Shanghai, China, 200011 Phone: 86 13611691036 **If to Abbott:** Ge Yilin Medical Advisor Abbott Pharmaceutical Trading (Shanghai) Co., Ltd. 32/F, 388 Nanjing West Road, Shanghai Phone: 86 21 23204040 Fax: 86 216334 6311 **with a copy to**: Divisional Vice President and Associate General Counsel Legal Regulatoyr and Compliance , Bldg. AP6A Abbott Laboratories 100 Abbott Park Road, Abbott Park, IL 60064 U.S.A. Fax: 847-938-1200

23. 完整协议。本协议包括所有附录包含了双方就本协议标的事宜达成的全部谅解，其取代与本协议标的事宜有关的所有先前协议和承诺。如果方案中的规定与本协议或其任何附录发生冲突，有关科技、医疗实践及研究受试者安全方面的事项应以方案为准，而有关其他方面的事项应以本协议为准。本协议或其条款包括所附附件附录的变更、重述或其他变动除非经双方签署书面协议才能生效。	23. Entire Agreement. This Agreement, including all exhibits hereto, contains the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. In the event of a conflict between provisions of the Protocol and this Agreement or any exhibits hereto, the Protocol shall control with respect to matters of science, medical practice, and Study subject safety. In all other matters, the provisions of this Agreement shall control. None of this Agreement or any of its terms, including any attachment or exhibit hereto may be amended, restated or otherwise altered except by written agreement signed by the parties.
24. 存续。本协议无论因何种原因终止，根据本协议条款规定在终止后仍然存续的权利和义务仍然具有完全效力。	24. Survival. Notwithstanding termination of this Agreement for any reason, rights and obligations which by the terms of this Agreement survive termination of the Agreement, will remain in full force and effect.
25. 可分割性。如果本协议中的任何规定，规定的权利或补救措施被具管辖权的法院判定不可强制执行或者不可行，其他条款的效力与可强制执行性不受影响。	25. Severability. If any provision, right or remedy provided for herein is held to be unenforceable or inoperative by a court of competent jurisdiction, the validity and enforceability of the remaining provisions will not be affected thereby.
26. 副本。本协议可以签订多份副本，每一份副本都应被视作原件，所有副本应组成同一个协议。任一方确认，为本协议之目的，原始签名、其传真件或其 PDF 版本应构成签名原件。	26. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same agreement. Each party acknowledges that an original signature or a copy thereof transmitted by facsimile or by PDF shall constitute an original signature for purposes of this Agreement.
27. 管辖法律。本协议应由中华人民共和国法律管辖并据之解释，但排除冲突法的适用。	27. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of People's Republic of China, excluding its conflicts of laws provisions.
28. 仲裁。对于因本协议引起的或与本协议相关的任	28. Arbitration. Any dispute, controversy or

何纠纷、争议或主张，如果各方在三十（30）日内未能就解决事宜达成一致，该纠纷、争议或主张应递交至中国国际经济贸易仲裁委员会（"贸仲委"）并依据生效日之时有效的贸仲委的仲裁规则进行最终裁决。仲裁应在上海进行。本协议终止或期满后，本条款仍继续有效。	claim arising out of or relating to this Agreement which cannot be resolved within thirty (30) days by mutual consent of the parties, shall be settled by arbitration before the China International Economic and Trade Arbitration Commission ("CIETAC") in accordance with the CIETAC Arbitration Rules in force on the Effective Date. The place of arbitration shall be Shanghai. This Section shall survive termination or expiration of this Agreement.
有鉴于此，双方已由其授权代表代为签署本协议。	**IN WITNESS WHEREOF**, the parties have caused this Investigator Initiated Study Agreement to be executed by their duly authorized representatives.

ABBOTT PHARMACEUTICAL TRADING (SHANGHAI) CO.,LTD./ 雅培医药贸易（上海）有限公司

By/签字: 谢抒

Name/姓名: 谢抒

Title/职位: 医学总监

Date/日期: 2013年12月20日

INSERT INSTITUTION NAME IN ALL CAPS/请以大写填入究机构名称

By/签字: 李大金

Name/姓名: 李大金

Title/职位: 副院长

Date/日期:

I agree to be bound by the provisions of this Agreement./
我同意受本协议条款之约束。

By/签字: 张炜

Name/姓名: 张炜

Title/职位: 教授

Date/日期: 2013-12-25

EXHIBIT A – PROTOCOL
EXHIBIT B – BUDGET SUMMARY AND PAYMENT SCHEDULE
EXHIBIT C – RECOMMENDATIONS FOR SCIENTIFIC PUBLICATIONS
附录 A 方案
附录 B 预算概况及付款计划
附录 C 科学发表要求

[Institution Name] Obstetrics and Gynecology Hospital of Fudan University, Shanghai
[Investigator Name] Professor Zhang Wei
[Dec 19, 2013]
[机构名称] 上海复旦大学附属红房子医院
[研究者姓名]张炜教授
[12月/19日/2013年]

EXHIBIT A

PROTOCOL

附录 A

方案

1.0 标题

方案

地屈孕酮调整异常子宫出血-排卵障碍患者的不规则月经周期：一项基于门诊病人的前瞻性、观察性研究

产品名称： 地屈孕酮

研究类型： 前瞻性观察研究（研究者发起的非干预性研究）

时间： 2013 年 10 月

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本研究遵循此方案实行

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3.0 介绍

正常女性月经周期一般持续 21 到 35 天。对于月经周期不规则患者最佳的治疗即使用孕酮[1]。孕酮能拮抗子宫内膜的增生，并支持和转化雌激素作用下的子宫内膜。当停用孕酮后，从内膜基底层开始的脱落可迅速止血。在规律的周期调整治疗过程中，周期性的应用孕酮可使内膜依次发生量可控的撤退出血，之后通过反复周期性的孕酮治疗可保证治疗效果[2]。

功能失调性子宫出血（dysfunctional uterine bleeding, DUB）经常作为那些未在全身系统或局部找到确定的结构改变的异常子宫出血（AUB）的同义词。由于DUB不属于PALM-COEIN系统，因此不再建议使用此名称[3]。2011 年国际妇产科学会(FIGO)提出,描述子宫异常出血的新的分类系统[子宫内膜息肉(Polyp)，子宫腺肌病（Adenomyosis），子宫肌瘤（Leiomyoma）,子宫内膜非典型性增生、子宫内膜癌、子宫平滑肌肉瘤（Malignancy and hyperplasia）,凝血障碍（Coagulopathy），排卵障碍（Ovulatory Disorders）,子宫内膜功能紊乱（Endometrium），医源性因素（Iatrogenic），未分类（Not Classified）]，即现在的PALM-COEIN分类系统,被广泛接受[4]。在本研究中我们主要关注的是异常子宫出血-排卵障碍（abnormal uterine bleeding - ovulatory dysfunction，AUB-O）患者。

作为有效的口服孕酮，地屈孕酮仅在分子结构上与天然的孕酮稍有不同 [5][6]。地屈孕酮在国际上被广泛用于各种妇产科疾病和适应症。对于雌激素作用下的子宫内膜，地屈孕酮可促进转化为分泌期，从而降低由单一雌激素作用的内膜增生和/或癌变的风险。地屈孕酮适用于所有内源性孕酮缺乏病例中，包括月经周期不规则患者，同时不具有雌激素、雄激素活性，不致热、无合成代谢和皮质激素的活性[7]。

本研究是前瞻性非干预的观察性研究。诊断为 AUB-O 的月经周期不规律的患者，医生基于临床常规予以地屈孕酮治疗，同时根据患者意愿将其纳入研究。

4.0 原理

地屈孕酮在周期治疗中是有效的。关于应用地屈孕酮对月经疾病的治疗的大部分文章是针对青春期患者[8][9][10][11]，其他则是针对育龄期妇女的[12、13、14、15、16]。而且这些文献都证明地屈孕酮在治疗月经周期规律的良好疗效。其中一篇研究表明，月经周期紊乱的妇女在月经周期第 11 至 25 天每天服用 10mg地屈孕酮，3 个周期治疗后 91.6%患者月经周期恢复正常。在这项研究中，服用地屈孕酮治疗期间的平均月经周期是 28.8 天，而未治疗前月经频发组是 17.9 天，月经稀发组是 50.6 天，并且还发现地屈孕酮缩短了月经出血时间[16]。在我们的研究中，研究者将主要记录与月经相关的信息，为避免信息偏倚，由患者自行判断描述的出血量，将不会作为收集的数据。

关于地屈孕酮的建议治疗方案，国内的一份文献观察到，相对于从月经第 16 天开始用药，从月经第 11 天用药突破性出血更频繁。作者建议调整月经周期，从月经第 16 至 25 天用药以减少非预期的突破性出血发生率[15]。

在推荐剂量下，地屈孕酮不干扰下丘脑-垂体-卵巢（hypothalamus pituitary ovary, HPO）轴，不抑制排卵和雌激素（Estradiol, E）、卵泡刺激素（Follicle-Stimulating Hormone, FSH）或黄体生成素（Luteinizing Hormone, LH）[17]，所以地屈孕酮对于有生育需求的妇女特别合适[18]。基础体温呈双相型常作为育龄期妇女排卵的标志，故可将其作为治疗期间自发排卵是否被抑制的指标。

不同与其他的孕激素，地屈孕酮可能在糖、脂代谢方面无不良作用。几个临床研究结果显示，每日 2mg雌二醇与 10mg的地屈孕酮序贯治疗，与血脂和空腹血糖长期改善有关[19][20][21][22]。然而，地屈孕酮单药对糖、脂代谢的影响是一个

有趣的问题，特别是对有代谢紊乱的患者，例如多囊卵巢综合症（polycystic ovarian syndrome, PCOS）和围绝经期女性。

本研究是前瞻性非干预的观察性研究。诊断为 AUB-O 的月经周期不规律的患者，医生基于临床常规予以地屈孕酮治疗，同时根据患者意愿将其纳入研究对象。

5.0 研究目标

主要目标：

在 AUB-O 的患者中，观察治疗 3 个周期末时，地屈孕酮调整月经周期的疗效。

次要目标：

1．观察地屈孕酮治疗第 1 个周期和第 2 个周期后，调整月经周期的疗效。

2．在月经周期天数<21 天和>35 天的两组患者中，分别观察地屈孕酮治疗 3 个周期后，调整月经周期的疗效。

3. 在经期>8 天的患者中，分别观察地屈孕酮治疗 3 个周期后，调整经期的疗效。

4．观察地屈孕酮治疗 3 个周期后，对性激素和排卵的影响。

5． 分为 PCOS 和非 PCOS 两组观察地屈孕酮治疗 3 个周期后，对血糖、血脂代谢的影响。

6.0 研究计划

本研究是前瞻性，单中心、观察性，非随机化，无对照研究。

6.1 研究人群选择

6.1.1 纳入标准

1. 16 岁及以上有月经的女性

2. 月经周期不规则（月经周期<21 天或>35 天至少 3 个月）的患者，且被诊断为异常子宫出血-排卵障碍。

3. 医生决定处方口服地屈孕酮 10mg 每天两次用于调整月经周期的患者，服用时间为月经周期第 16-25 天，连续治疗至少 3 个周期

4. 患者愿意签署知情同意书

6.1.2 排除标准

1. 高泌乳素血症、甲状腺功能异常者

2. 过去一个月口服避孕药、使用性激素或糖皮质激素调整月经周期的患者

3. 伴有雌激素缺乏症状的妇女

4. 其他具有中国地屈孕酮说明书中禁忌症的患者

5. 妊娠或哺乳期的患者

6. 医生认为不适合纳入该研究的患者

6.2 纳入患者数

计划总共纳入 100 名患者。

6.3 研究持续时间

作为一份观察性研究，我们收集所需要的研究人群的数据。这些患者不会进行临床常规不包括的额外实验室检查或操作。根据国内指南，地屈孕酮的治疗应该为 3 个周期[23]。本研究无筛查和随访。

治疗后未达到规律周期的病人在治疗后不再进一步随访，而是医生对其常规/标准治疗。这些病人治疗期结束即研究结束。

根据临床判断和国内指南推荐，医生可将病人召回。其他终止的原因如下：

- 如果医生认为该研究对患者不是最有益的。
- 患者希望收回其同意书。
- 患者在研究期间怀孕妊娠。
- 患者不按时随访。

6.4 研究实施

作为一项观察研究，给予患者地屈孕酮治疗并不根据欲将纳入研究的意图，而是根据每个医生的常规临床经验。因此地屈孕酮的治疗明确独立于欲将患者纳入研究的决定。

患者的随访将根据医生的常规检查安排。

建议每个患者 3 次随访：

第 1 次随访-第 1 个周期的第 16 天之前

第 2 次随访-第 1 周期撤退性出血停止到第 2 个周期第 16 天之间

第 3 次随访-第 3 周期在撤退性出血停止后的一周内

所有患者要求填写日志卡，记录有关其月经和基础体温的信息。记录研究相关的数据的日志卡内容包括：末次月经时间，月经周期持续时间（天），月经出血时间（天），用药时间，基础体温等等。所有数据将被记录成周期性的形式。对于随访时未出现患者如上的随访安排就无法进行，关于月经信息的数据就可通过日志卡来收集。

研究者根据本方案和病例报告表要求收集相关信息。包括但不限制于以下内容：

人口统计信息：出生日期

病史：高泌乳素血症、多囊卵巢综合症和甲状腺功能不全

产科病史：以前妊娠及结局，避孕方式

月经史：治疗前后的月经情况

其他：性激素水平，胰岛素，血糖，血脂水平，基础体温（如果有）

表 1 研究流程

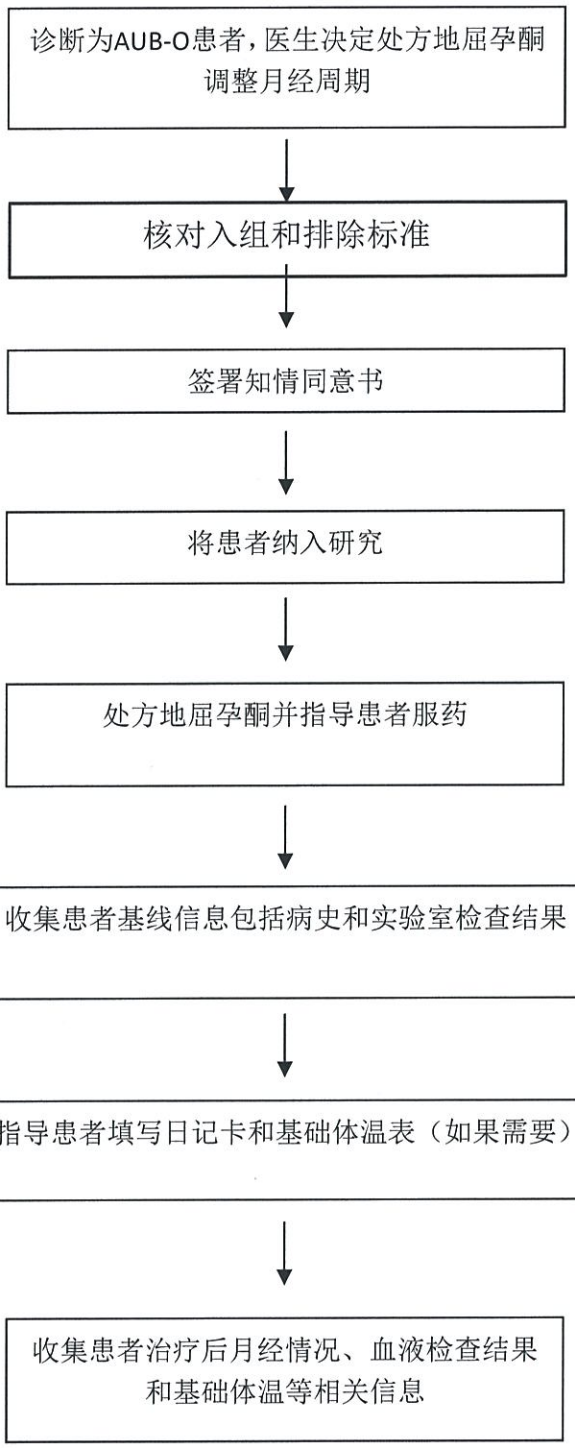

表 1　研究流程

	访视 1	访视 2	访视 3

访视窗	第 1 个周期的第 16 天之前	第 1 周期撤退性出血停止到第 2 个周期第 16 天之间	第 3 周期在撤退性出血停止后的一周内
知情同意	×		
采集病史		×	×
处方地屈孕酮，并指导服药	×	×	
指导/核对/收集日记卡，包括月经卡和基础体温表，如果需要	×	×	×
收集记录：E、FSH、LH、血脂、血糖、胰岛素结果（如果有）	×		×
开 Cycle 3 的化验单（如果需要）		×	
完成病例报告表	×	×	×
收集不良事件	连续观察并记录		

7.0 疗效评价

主要终点：

观察地屈孕酮治疗 3 个周期后，患者月经周期转为正常（定义为 21 天≤周期≤35 天）的百分比。

次要终点：

1．观察地屈孕酮治疗第 1 个周期和第 2 个周期后，患者月经周期转为正常的百分比。

2．在月经周期天数<21 天和>35 天的两组患者中，分别观察地屈孕酮治疗 3 个周期后，患者月经周期转为正常的百分比，和两组患者月经周期天数在 3 个治疗周期前后的差异。

3.在经期>8 天的患者中，分别观察治疗地屈孕酮 3 个周期后，患者经期转为≥4 天且≤8 天的百分比，和两组患者经期在 3 个治疗周期前后的差异。

4.对临床常规有相关检查或监测的患者，观察地屈孕酮治疗 3 个周期前后，雌激素、促卵泡生成素、黄体生成素水平的差异，和用药期间双向基础体温的出现次数。

5．对临床常规有相关检查结果的患者，分为 PCOS 和非 PCOS 两组（如果有），观察地屈孕酮治疗 3 个周期前后，胰岛素、血糖、血脂的差异。

8.0 不良事件

研究者/研究机构确保符合任何适用主管当局的报告要求。此外，如果研究者/机构 获悉一下药物安全相关信息，需要向雅培报告：

- 不良反应。（不良反应的定义是指：对医疗产品有害的和非预期的反应。上述这种反应是不良事件与医疗产品之间存在因果关系，这种因果关系至少具有合理的可能性。不良反应可能是由于职业暴露或者市场授权内或外的产品使用。市场授权外的使用包括超适应症使用，过量使用，错误使用，滥用和治疗差错）
- 怀孕期的药物暴露（包括母亲，父亲或者胎儿的药物暴露），有或没有不良反应
- 通过母乳的婴儿药物暴露（通过母乳喂养），有或没有不良反应
- 药物过量（即单次或者累计的医疗产品给药剂量超过了授权产品信息的最大推荐剂量（注：通常需要临床判断），有或没有不良反应
- 药物滥用或错误使用（即非临床原因使用），有或没有不良反应

- 超适应症使用，有或没有不良反应
- 疏忽或者意外药物暴露，有或没有不良反应
- 职业药物暴露，有或没有不良反应
- 治疗差错（即当在医疗工作者，病人或者消费者控制下使用药物，任何导致或引起不适当的药物使用或者病人伤害），有或没有不良反应
- 治疗效果缺乏（即“缺乏疗效”报告）
- 可疑的传染源传播，并将会被归为严重不良反应
- 产品使用导致的意外治疗效果或临床获益

上述信息，要求主要研究者/机构在获悉后 2 个日历日内报告给雅培。主要研究者/机构应当立即使雅培可以获得可能必须的记录并进行相关的事件调查。

进一步，主要研究者/机构需要立即向雅培通知或者提供：

- 任何危及研究的安全性问题
- 任何与雅培产品相关的安全信号
- 中期研究报告，如果适用
- 最终研究报告或至少相应的出版物
- 最终研究报告或至少相应的出版物，需要在研究数据关闭后 12 个月内提供

上述所有与雅培产品相关的药物安全信息应当报告给以下联系人：

姓名: 赵璐

地址: 中国上海市南京西路 388 号 32 楼

电话: 86 21 23204158

传真: 86 21 63345041

电子邮件: pv.china@abbott.com

9.0 伦理和质量

在招募每名患者进入本项目之前必须获得使用和/或披露其健康数据患者的书面授权书，如患者不愿提供书面授权书则不得将其纳入本项目中。方案及相关项目文件将递交监督每个中心的独立伦理委员会(IEC)审查和批准，且只有在获得 IEC 的书面批准之后才能开始入组患者。

方案及相关项目文件将递交监督每个中心的独立伦理委员会(IEC)审查和批准，且只有在获得 IEC 的书面批准之后才能开始入组患者。

此观察研究将遵循本地法律法规。若可以，研究者有责任在研究开始前取得当地伦理委员会的同意。如果需要知情同意书，患者认可的知情同意文件和个人健康资料的公开即是可接受的。研究者有义务了解当地伦理委员会要求的知情同意书中的内容。

所有数据均按照不透露每个患者身份的方式进行采集和处理，因此在任何时候病人信息的保密性都会得到保证。

研究者将负责确保适当的质量控制和质量保证体系，以保证项目的开展、数据生成、存档和报告均依照方案、药物临床试验质量管理规范公认标准、以及任何适用的当地法律法规进行。

10.0 病例报告表

病例报告表由调查者提供。每一个登记入此研究项目的患者都需填写该病例报告表。所有病例报告表都应清晰可辨。病例报告表的所有信息都要反映在研究对象的资料里。

研究者将对病例报告表的完整性和准确性进行审查，并在每份病例报告表的指定位置签字、注明日期。研究者将对这些表的完整性、易辨认性和可接受性进行审查。研究者将被允许查阅所有的原始数据以对病例报告表中的条目进行核实。

11.0 数据分析计划

由于本研究为观察性、非随机、无对照、单组、上市后的研究，100 个研究对象的样本量并非出于统计效力的考虑。

然而，文献报道地屈孕酮能有效调节 91.6%的月经周期紊乱的患者。若纳入 74 个研究对象，以此比例（治疗有效的病人占 91.6%）计算，可获得 7%的精确度（即 95%可信区间的半宽度）。考虑到在较长的研究期间内可能有约 30%的患者退出，故共纳入 100 例研究对象。

数据分析方法，分析时间结点及分析人群。

描述性统计用于说明研究结果：用计数和百分数描述分类数据，用平均数、标准差、中位数、最小值、最大值和 95%可信区间描述计量数据。

分类变量，例如规律月经患者的百分比，用卡方检验或确切概率法分析。连续变量，如月经周期时间的改变，月经出血时间的改变和性激素、胰岛素、血糖、血脂，则用 t 检验或当数据未正态分布时用 Mann-Whitney U 检验。

在分析月经周期改变时，对“月经周期<21 天”和“月经周期>35 天”的两组分别作亚组分析。在分析月经经期时，将对“出血>8 天”的那个亚组进行分析。当计算胰岛素、血糖、血脂的变化时，对是否曾患多囊卵巢综合症（PCOS）者可以进行事后的亚组间分析。每个亚组应有足够的患者数以作有效的数据分析。

P 值和可信区间根据双侧检验估计。P<0.05 认为差异有统计学意义。应用 SPSS 软件(SPSS 13.0; Chicago, Illinois, USA)对数据进行分析。

所有服用地屈孕酮的患者，均会被指导监测不良事件和妊娠。

12. 0 References 参考文献

[1] Chuong CJ, Brenner PE. Am J Obstet Gynecol 1996; 175: 787-92.

[2] Anklesaria B, Balamba P,Banerjee B,et al. Obstet & Gynaecol 1999; 4: 559-564.

[3] Committee on Practice Bulletines Gynecology. Obstet Gynecol. 2012 Jul;120(1):197-206.

[4] Malcolm G. Munro, International Journal of Gynecology and Obstetrics 113 (2011) 3–13

[5] JR Pasqualini. J Steroid Biochem Molec Biol. 1996; 59 (5): 357-363

[6] Martin AJ. Progestins. Mod Med 1986; 31; 1.

[7] China Dydrogesterone Package Insert. Approved on 29 April 2011. Abbott

[8] Dilip Kumar Dutta, ASIAN JOURNAL OF OBS. & GYNAE PRACTICE, 2001: 5(2), 3-5

[9] Chomczyk I, Sipowicz M, Sipowicz I .Ginekol Pol. 1999 May;70(5):343-7.

[10] I Sipowicz .Ginekol Pol. 1998 Oct;69(10):767-70

[11] Tabaste JL Rev Fr Gynecol Obstet. 1984 Jan;79(1):19-20, 23-5.

[12]Savas KARAKUS, Australian and New Zealand Journal of Obstetrics and Gynaecology 2009; 49: 685–688

[13] Anklesaria B,Balamba P,Banerjee B et al. Obstet & Gynaecol.1999; 4 (9):559-64.

[14] Naib J M, Journal of Postgraduate Medical Institute, 2003, 17(2).

[15] Zhang Yiwen, Chin J Clin Obstet Gynecol July 2007 , Vol 18 , No 14; 290.

[16] Saldanha EF, Tank DK, Chainani MS. Int J Gynaecol Obstet India 1997; 1:36-4.

[17] Adolf E. Schindler, Maturitas 46S1 (2003) S7–S16

[18] Karl-Werner Schweppe, Maturitas 65S (2009) S23–S27

[19] Crook D, Godsland IF, Hull J, Stevenson JC.Br J Obstet Gynaecol 1997;104:298–304.

[20] De Kraker AT, Kenemans P, Smolders RG, Kroeks MV, van der Mooren MJ. Maturitas 2004;49:253–263.

[21] Stevenson JC, Rioux JE, Komer L, Gelfand M. Climacteric 2005;8:352–359

[22] Cieraad D, Conradt C, Jesinger D, Bakowski M. Arch Gynecol Obstet 2006;274:74–80.

[23] Chinese Menopause & Endocrinology Society, Chinese Society of Obstetrics and Gynecology, Chinese Medical Association, Chin J Obstet Gynecol 2009: 44(3) 234-6

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[研究者姓名]张炜教授
[12月/19日/2013年]

EXHIBIT B
附录 B

BUDGET SUMMARY AND PAYMENT SCHEDULE
预算概况及付款计划

INSTITUTION: Obstetrics and Gynecology Hospital of Fudan University, Shanghai 研究机构:上海市复旦大学附属妇产科医院
PRINCIPAL INVESTIGATOR: Professor Zhang Wei 主要研究者:张炜教授
Protocol Title: Dydrogesterone in Cycle Regularization in Abnormal Uterine Bleeding – Ovulation Dysfunction (AUB-O) Patients: A Prospective, Observational Study 方案标题: 地屈孕酮调整异常子宫出血-排卵障碍患者的不规则月经周期：一项基于门诊病人的前瞻性，自身对照观察性研究
IIS #: IIS 编号
Total Number of subjects: 100 cases 受试者总数:100 例

BUDGET SUMMARY
预算概况

Items 项目		Study activity/procedure 研究活动/流程	Vendor 供应商	Budgeted amount (RMB) 费用（人民币）
1	Site 中心	Ethics 伦理		6,000
2		Hospital management fee 医院管理费用		120,000
3		Insurance fee 保险费		60,000
4		Coordinator fee 协调费		114,000
5	SMO 临床研究管理组织	CRF 研究问卷	√	300,000
6		ICF 知情同意书	√	
7		Printing 打印费	√	
8		CRC 临床研究协调员	√	
9		Data Management 数据管理	√	
10		Statistics & SAR 统计&统计分析报告	√	
11		Translation	√	

		翻译		
12		Result Publication 结果发表	√	
		Total Funding (not to exceed) 资助总额 (不超过此数)		**600,000**

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[Investigator Name] Professor Zhang Wei
[Dec 19, 2013]
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[研究者姓名]张炜教授
[12月/19日/2013年]

EXHIBIT B (Continued)
附录 B（续）
PAYMENT SCHEDULE
付款计划

作为研究机构履行本协议工作的对价，雅培应支付研究机构总金额不超过拾万美元（$100,000）的报酬。如果最后阶段工作未在研究结束后十二（12）个月内完成，雅培没有义务支付下列所示的最后阶段的付款。付款应在雅培收到和批准发票后作出，具体付款安排如下：	In consideration for Institution's work hereunder, Abbott shall pay Institution the total sum not to exceed one hundred thousand Dollars ($100,000). If the final milestone is not completed within twelve (12) months of the conclusion of the Study, Abbott will not be obligated to make the final milestone payment listed below. Payment shall be made upon Abbott's receipt and approval of an invoice as follows:
付款阶段： 1. 在协议完全签署后四十五（45）日内支付壹佰捌拾万元（180,000 RMB）；	Payment Milestones: 1. One hundred and eighty thousand yuan (180,000 RMB) shall be paid within forty-five (45) days of full execution of the Agreement;
2. 在通过伦理审批后四十五（45）日内支付叁万元（30,000 RMB）；	2. Thirty thousand yuan (30,000 RMB) shall be paid within forty-five (45) days of independent ethical committee approval
3. 在完成第一例受试者招募后四十五（45）日内支付柒万贰仟元（72,000 RMB）；	3. Seventy two thousand yuan (72,000 RMB) shall be paid within forty-five (45) days of completion of the 1st subject enrollment;
4. 在完成 50%受试者招募后四十五（45）日内支付拾贰万元（120,000 RMB）；	4. One hundred and twenty thousand yuan (120,000 RMB) shall be paid within forty-five (45) days of completion of 50% subject enrollment;
5. 在完成 100%受试者招募后四十五（45）日内支付拾万捌仟元（108,000 RMB）；	5. One hundred and eight thousand (108,000 RMB) shall be paid within forty-five (45) days of completion of 100% subject enrollment;
6. 完成受试者招募后（除非雅培另行批准），应在雅培收到并接受最终的总结报告、原稿、摘要或海报后四十五（45）日内支付叁万元（30,000 RMB）；	6. Contingent upon complete subject enrollment (unless otherwise approved by Abbott), thirty thousand yuan (30,000 RMB) shall be paid within forty-five (45) days of Abbott's receipt and acceptance of a final summary report, manuscript, abstract or poster;
7. 完成发表投稿后四十五（45）日内支付陆万元（60,000 RMB）。	7. Sixty thousand (60,000 RMB) shall be paid within forty-five (45) days of publication submission.

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[研究者姓名]张炜教授
[12月/19日/2013年]

Checks shall be made payable to: **支票受付人为：** Name of Payee: Obstetrics and Gynecology Hospital of Fudan University, Shanghai, China 收款单位：复旦大学附属妇产科医院 开户银行：工商银行中华路支行 开户账号：1001219709026408425	**Invoices shall be sent to:** **发票需送交：** Meng Tina 孟丽洁 Abbott Pharmaceutical Trading (Shanghai) Co., Ltd. 雅培医药贸易（上海）有限公司 32/F, 388 Nanjing West Road, Shanghai, 上海南京西路 388 号仙乐斯广场 32 楼

附录 C 科学发表建议	EXHIBIT C RECOMMENDATIONS FOR SCIENTIFIC PUBLICATIONS
1. 著作权标准。根据国际医学期刊编辑委员会（"ICMJE"）于 2007 年 10 月发布的指南，著作权的取得应基于下列条件: a) 对于概念和设计、数据获取、数据分析和阐释做出实质性贡献；及 b) 起草或修订了有关重要知识内容的文章；及 c) 对拟发表的版本作最终批准。 同时满足上述三项标准之个人方可获得著作权。	1. Criteria for Authorship. Based on the October 2007 guidelines of the International Committee of Medical Journal Editors (ICMJE), authorship credit should be based on: a) Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; and b) Drafting or revising the article for important intellectual content; and c) Final approval of the version to be published. A person should meet all three of the above criteria to warrant authorship.
2. 对医学撰写员及其他贡献者的致谢。那些对研究或发表作出了巨大贡献、但未能达到上述作者标准的个人，必须被列入致谢部分中，包括那些对贡献者提供财力支持的人员。对所有人的致谢应经过他们的书面同意。	2. Acknowledgement of Medical Writers and Other Contributors. Those individuals who have made a significant contribution to the Study or Publication, but do not meet the criteria for authorship noted above, should be listed in an acknowledgments section, including disclosure of the source of any financial support given to such contributors. All persons must give written permission to be acknowledged.
3. 利益冲突。为达到透明度及保证可能的最高行为标准，作者将遵守每一份期刊或大会关于在发表中披露利益冲突的要求。该等披露利益冲突要求可能包含但不限于，对作者取得研究资助情况的披露，作者因提供顾问或演讲服务而收取的款项及/或作者持有的股份的披露。	3. Conflict of Interest. In the interest of transparency and maintaining the highest possible standards of conduct, authors should comply with each journal's or congress's requirements for conflict of interest disclosure in the Publication. Such conflict of interest disclosure requirements may include, but are not limited to, disclosure of an author's receipt of research grants, author's receipt of payments for consultant or speaker services, and/or author's ownership of stock.
4. 数据准入。研究机构或研究者将向所有作者提供为拟议发表而准备的最终方案、统计分析计划、计划中生成的相关统计表、数据及报告。如果任何医学期刊就某递交的发表稿件提	4. Access to Data. Institution or Investigator should provide all authors with the final protocol, statistical analysis plan, relevant statistical tables generated from the plan, figures, and reports needed to prepare the planned Publication. Institution or Investigator provide a copy of the clinical trial protocol and plan for statistical analysis when requested by a

出要求，研究机构或研究者将向其提供临床试验方案及统计分析的计划的复印件。	medical journal considering a submitted manuscript for publication.
5. 重复发表。禁止将研究结果在同行评议期刊上进行二次或重复发表，但不禁止对重要及科技方面的附加数据分析和数据分类所作的二级发表。另外，在遵守相关期刊政策的前提下，允许对原稿外语翻译的发表。经科技会议政策许可，允许对数据的重复演示。	5. Redundant Publication. Duplicate or redundant publication of the Study results in peer-reviewed journals is not recommended. Secondary Publications that present significant and scientifically sound additional analyses or groupings of data are acceptable. Publication of foreign language translations of the original manuscript, in accordance with the policies of the journals involved is acceptable. Encore presentation of data, when permitted by scientific congress policy, is acceptable.