

INFORMED CONSENT FORM**知情同意书****VOLUNTARY BLOOD DONATION FOR RESEARCH USE****自愿献血供研究使用**

BeiGene (Beijing) Co., Ltd.
百济神州（北京）生物科技有限公司

Study Title: TESTING AND CHARECTERIZATION OF IMMUNE-REGULATORY AGENTS IN HUMAN IMMUNE CELLS AND CANCER IMMUNOLOGY RELATED ISSUES

实验题目：免疫调节药物分子对人体免疫细胞的作用机理和调控效应的研究及有关肿瘤免疫学问题的探索。

You are being asked to provide some blood for a research study. Your participation is completely voluntary.

本实验希望您能献血供研究使用。您的参与完全基于自愿。

Your decision whether or not to provide some blood or a decision to withdraw your blood for research use will not involve any penalty or loss of benefits to which you are entitled.

无论您是否同意献血，是否决定将血液供研究使用，都不会损害您的利益。

● ***What is the purpose of this research?***

本研究的目的是什么？

The purpose of this study is to investigate how human immune cells respond to immune-modulating agents in vitro, and how it affects on cancer cells, as well as other cancer immunology-related questions.

本实验的目的在于研究人体免疫细胞在体外实验中对免疫调节药物分子有何反应，对癌症细胞有何影响，以及其他有关肿瘤免疫的问题。

● ***What does participation in this research involve?***

参与本实验需要做什么？

Your participation in this research project is to provide blood samples during the period from _____ to _____ as scheduled below.

本实验需要您于____年____月____日至____年____月____日期间按照以下时间表提供血液样本。

[illegible]

血液收集将严格按照上述时间表进行，如您被要求在时间表以外的时间进行献血，您可以选择(i)拒绝该等要求，或(ii)重新签署变更后的知情同意书。

本次收集的血液仅供研究使用，不会用于：

1. Regular health check items such as white blood cell counts, lipid, vitamin and cholesterol level, etc.
常规体检项目，如白细胞计数、血脂、维生素和胆固醇水平等
2. Viral carrier, anti-viral antibody titer, etc.
病毒携带情况、抗病毒抗体浓度测定等
3. DNA or cDNA sequencing to determine any genetic information.
DNA 或 cDNA 测序以确定个人的遗传和基因信息
4. Employmnet and performance review filed with human resources
人事部门备案的雇佣和绩效考评管理信息

此外，为了保证献血者身体健康，本研究可能会使用您的健康信息，如近期患流感或其他急性传染病的情况。请您如实完整地填写随附献血者健康信息表。



- *How the blood sample will be stored, used or destroyed?*
血液样本将如何保存、使用或销毁？

Your blood sample will be kept in 4 degree C refrigerator, and used for cancer immunology and immune-regulatory agent testing and research until study activities are completed. If some cases, if there are PBMCs or T-cells isolated from the blood samples not used up, the unused blood will be stored at -80 degree C for later time to use in the same type of study and research. Any of the blood sample-derived immune cells will be regarded as expired after storage for one year, and discarded as bio-waste.

您的血液样本将保存在 4℃的冰箱中，用于癌症免疫和免疫调节药物分子的检测和研究，直到研究活动完成。如果血液样本中分离出来的外周血单核细胞或 T 细胞有剩余，未使用的剩余部分将保存在 -80℃环境中，供以后的同类试验和研究使用。任何血液样本中提取的免疫细胞在保存一年后将视为过期，会作为生物废弃物处理。

- *Are there any benefits participating in this research?*
参与这项实验有哪些福利？

There are no benefits to you should you decide to participate in this study. You will not receive any results from tests done on your blood, because they have no reliable meaning at this time. 参与本实验没有任何福利。您不会收到任何血液检测结果，因为这些没有实际参考意义。

- *Are there any risks from participating in this research?*
参与这项实验对身体有不良反应吗？

A risk of providing blood is mild to moderate pain at the site of the needle puncture into your vein. Other risks are redness, minor bleeding, swelling and a bruise at the site of the needle puncture or, rarely, an infection. Some people feel dizzy or faint when blood is taken; however, most people do not experience any problems.

献血的一个不良反应是，针刺进血管的部位会产生轻微至中度疼痛。其他反应有针刺部位红、肿、少量出血、淤青，极少情况下会出现感染。抽血时，有人会感到头晕，甚至昏厥，但是大部分人不会有任何问题。

- *Other important information you should know.*
您应该知晓的其他重要信息。

✓ Any identity information or health information you may provide will be kept confidential, unless its disclosure is permitted by law. Information created or collected in this research may be shared with other researchers, but none of it can be traced back to you. Your name will not be used in any publication or presentation that may result from this research.

除非法律规定，否则您可能提供的任何个人身份信息和健康信息都将保密。本实验产生或收集的信息可能会与其他实验员共享，但是不会追溯到您。基于本项研究的任何出版物或展示都不会使用您的名字。

✓ We will not notify you every time your sample and information are used. For any use of your samples in the same type of study and research in the future, there will be a new consent process



for such study and research. You can decide then if you would like to take part.

您不会在每次您的样本和信息被使用时收到通知。在未来同类试验和研究开展时，将会有新的同意流程。您可以届时选择是否参与。

- ✓ You will not receive any compensation if the results of this research are used towards the development of a commercially available product.
您不会收到任何补贴，即使本实验的结果用于开发有上市可能性的产品。
- ✓ You will not be paid to participate in this study because the donation is completely on your willingness and voluntary base. However, BeiGene will make a small amount of nutritional compensation the donor.
参加本研究是无偿的，因为献血是您的自愿行为。但是，百济神州将给献血者发放少量营养费。
- ✓ You may choose to withdraw your consent to provide blood at any time. You may withdraw your blood from use in this research at any time. If you wish to withdraw your consent or to remove your blood from use in the study, please contact the researcher in writing. If your blood has not already been used up by the researchers, any blood that remains will be destroyed.
您可以随时选择撤回您关于献血的同意。无论何时，您都可以将血液撤出本研究。如果您想撤回同意或将血液撤离本研究，请书面联系研究员。如果您的血液还没有用完，剩余的所有血液都将被销毁。
- ✓ Questions about this study or concerns about a research-related injury should be directed to the researcher in charge of this study.
如有任何关于本研究的问题或对实验相关的伤害有所疑虑，请直接联系本实验负责人。

Name of Kang Li/Lai Wang

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If you have questions, concerns, or suggestions about human research at BeiGene (Beijing)Co.,Ltd., you may call the Dr.Kang Li or Dr.Lai Wang at the phone number mentioned above.

如有任何关于百济神州（北京）生物科技有限公司人体实验的问题、疑虑或意见，请致电李康博士或汪来博士。

Consent: I have read the above information and have been given an opportunity to ask questions. I agree to provide blood for this study “**TESTING AND CHARECTERIZATION OF IMMUNE-REGULATORY AGENTS IN HUMAN IMMUNE CELLS AND CANCER IMMUNOLOGY RELATED ISSUES**”. I consent voluntarily to have my blood samples stored and used in the manner and for the purpose indicated above, and I have been given a copy of this signed consent form for my own records.

同意：我已阅读以上信息，并有权提出问题。我同意为本研究“**免疫调节药物分子对人体免疫细胞的作用机理和调控效应的研究及有关肿瘤免疫学问题的探索**”献血。我自愿同意按照以上所述目的及方式储存和使用本人血液样本。我已收到一份已签名的同意书供我参考。



BeiGene

百济神州（北京）生物科技有限公司

Participant's Printed name

参与人姓名

Signature

签名

Date

日期



Blood donor's health info sheet
献血者健康信息表

Your Name / 姓名:		
Gender / 性别:		
Department / 部门:		
Please check on the answer to following questions 请勾选以下问题的答案	Yes 是	No 否
1. Are you having flu, diarrhea and other infectious diseases? 目前您是否患有流感、腹泻或其他传染病?		
If yes, please stop here. You may come back after recovered. 如果是, 请停止作答。您可以在恢复健康后再参加本研究。		
2. Have you experienced hepatitis B, or hepatitis A viral infection in last one year? 在过去一年中您是否患过乙肝或甲肝?		
3. Have you received any treatment for HBV, HCV and HIV infections, or receive any medications for the infections in last one year? 您是否接受过任何针对HBV、HCV 或HIV 感染的治疗, 或最近一年中是否接受过任何针对上述感染的药物治疗?		