**Consent to Processing and use of Personal Information**

**个人信息处理与使用同意函**

|  |  |  |
| --- | --- | --- |
| **Name of Site Staff:**  **研究中心人员姓名：** | **Site #:**  **研究中心：** | **Protocol #:**  **方案编号：** |
| **Sponsor:**  **申办方： Chugai Pharmaceutical Co., Ltd. 中外制药株式会社** | | |
| **Site Address:**  **研究中心地址：** | | |

The CRO of *【fill the study name】* study (“Study”), IQVIA RDS (Shanghai) Co., Ltd. (“IQVIA”) is engaged by the sponsor (“Sponsor”) to conduct the Study at your site. Those working on the Study will be asked to provide personal information to the Sponsor, either directly or through IQVIA. Your personal information will be processed from you as follows.

艾昆纬医药科技（上海）有限公司（“艾昆纬”），是一项【*填入研究名称*】研究（“研究”）的CRO，受申办方（“申办方”）委托在贵研究中心开展该研究。参与该研究的相关人员将被要求直接或者通过艾昆纬向申办方提供个人信息。您的个人信息将根据以下所述予以处理。

Both prior to and during the course of the Study, the Investigator and his/her delegated study team members and Site staff may be called upon by IQVIA to provide certain personal information (“Personal Information”). The Consent to Processing and Use of Personal Information (“Consent”) tells you how IQVIA process and use your Personal Information.

艾昆纬可能会在该研究开始前和进行期间，要求研究者及其被授权的研究团队成员、研究中心人员（以下合称为“您”）提供特定的个人信息。本《个人信息处理与使用同意函》（“《同意函》”）旨在向您说明艾昆纬如何处理和使用您的个人信息。

IQVIA will process and use the Personal Information for the following purposes:

艾昆纬将出于以下目的处理和使用您的个人信息：

|  |  |  |
| --- | --- | --- |
| **Scenarios**  **处理场景** | **Purposes**  **处理目的** | **Types of Personal Information**  **个人信息类型** |
| Conduct of clinical trials/studies实施临床研究/试验 | * Conduct of the Study   该研究的实施   * Verification by local and foreign governmental or regulatory agencies, the Sponsor, IQVIA, their agents and affiliates   国内外政府或监管机构、申办方、艾昆纬及其代理和关联公司验证 | [Name, phone number (can be personal or hospital), email (can be personal or hospital), address (can be personal or hospital), date of birth, working institution, gender, professional and technical title, position, professional expertise, CV, professional qualification]  【姓名、联系电话（个人或医院）、电子邮箱（个人或医院）、联系地址（个人或医院）、生日、工作机构、性别、职称职级、职位、专业技能、简历、执业资格】 |
| Study approval/drug registration研究申报/药品注册 | * Compliance with relevant legal and regulatory requirements for the approval and drug/medical device registration of the Study   遵守该研究申报和药品/医疗器械注册相关法律法规要求   * Publication on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and websites and databases that serve a comparable purpose   发布于[www.clinicaltrials.gov](http://www.clinicaltrials.gov)及其他具有同等目的的网站和数据库 | [Name, phone number (can be personal or hospital), email (can be personal or hospital), address (can be personal or hospital), date of birth, working institution, gender, professional and technical title, position, professional expertise, CV, professional qualification, **ID number**]  【姓名、联系电话（个人或医院）、电子邮箱（个人或医院）、联系地址（个人或医院）、生日、工作机构、性别、职称职级、职位、专业技能、简历、执业资格、**身份证号**】 |
| Site and Investigator selection  选择研究中心和研究者 | * Selection of Sites and Investigators for future clinical trials/ studies   为将来的临床研究/试验考量研究中心、选择研究者   * Identification of and outreach to Investigators as Key Opinion Leaders to complement Sponsors’ efforts for scientific exchange of information in support of Sponsors’ product   为申办方就其产品进行科学性的信息交流，查找和联络可以作为关键意见领袖（KOL）的研究者 | [Name, phone number (can be personal or hospital), email (can be personal or hospital), address (can be personal or hospital), date of birth, working institution, gender, professional and technical title, position, professional expertise, CV, professional qualification]  【姓名、联系电话（个人或医院）、电子邮箱（个人或医院）、联系地址（个人或医院）、生日、工作机构、性别、职称职级、职位、专业技能、简历、执业资格】 |

IQVIA may process and use the Personal Information of Investigators and Site staff by any means (including electronic means) and may store such information in a server located outside of China. Your Personal Information may be transferred to or accessed by IQVIA’ affiliates or project partners in other countries for the purposes described above. Overseas recipients may vary based on different projects, please contact your IQVIA representative for details. IQVIA will strictly follow relevant procedures to transmit and process your Personal Information,, and sign contracts with overseas recipients to ensure that your Personal Information will be adequately protected.

艾昆纬可能使用各种方法（包括电子手段）处理和使用您的个人信息，并可能在中国境外的服务器上存储该等信息。此外，您的个人信息可能会因上述目的而被转移至位于中国以外的其他国家的艾昆纬的关联公司或项目合作方，或受到该等关联公司或项目合作方的访问。由于具体的境外接收方将随项目实际情况有所不同，请您向您的艾昆纬代表了解详情。艾昆纬会严格遵循相关程序对您的个人信息进行传输与处理，并与境外接收方签订合同，确保您的个人信息得到与在中国境内同等水平的保护。

Personal Information will not be stored and processed for longer than is necessary for the purposes described above or as required by law. IQVIA have technical and administrative measures that meet industry standards to store and protect your Personal Information.

艾昆纬仅在前述目的所必需期间和法律法规要求的时限内保留和处理您的个人信息，并会采取符合业界标准的措施和技术手段存储及保护您的个人信息。

By signing below, you consent to the processing and use of your Personal Information described in this form. If you choose not to consent, you may not be selected to participate in the conduct of the above-mentioned Study.

在下方签名即表示您同意依据本《同意函》描述之方式和目的处理和使用您的个人信息。如果您选择不同意，您可能无法入选或参加上述研究。

For the Personal Information collected for the purpose of selection of Sites and Investigators, you can revoke your consent. For those processed for fulfilment of IQVIA’s statutory obligations, e.g. conduct and approval of clinical trials/studies, drug/medical device registration, you have no right to revoke your consent or request for deletion. If you find that IQVIA does not process or use your Personal Information in accordance with the provisions of relevant laws and regulations or as described in this form, you have the right to request IQVIA to delete your Personal Information, unless IQVIA is required to retain such Personal Information by relevant laws and regulations. If you find that your Personal Information we process is wrong or has changed, or you wish to delete your Personal Information or revoke your consent, or have any questions regarding the handling of your Personal Information, please contact your IQVIA representative.

对于为选择研究中心和研究者之目的而收集的个人信息，您可以撤回您的同意。对于为实施临床研究/试验、药品/医疗器械注册等艾昆纬履行法定义务之目的所收集的个人信息，您无权撤回同意或要求我们删除您的个人信息。如您发现艾昆纬未按照有关法律、法规的规定或者未依据本《同意函》描述之方式和目的处理或使用您的个人信息，您有权要求艾昆纬删除您的个人信息，除非法律法规明确要求艾昆纬保留该等个人信息。如您提供的个人信息有误或发生变更，或您希望艾昆纬删除您的个人信息或撤销您的授权同意，或对处理您的个人信息有任何其他问题，请与您的艾昆纬代表联络。

Please do not fill Personal Information of others in this form, and please do not submit to IQVIA any Personal Information prior to providing consent by signing below. It is the responsibility of the Principal Investigator to ensure that additional site staff provides the consent with full understanding of this form.

请勿在本《同意函》中填入他人的个人信息，亦勿在签署本《同意函》前向艾昆纬提交任何您的个人信息。主要研究者应确保其研究团队成员和研究中心人员在充分理解本《同意函》的情况下进行签署。

方框打勾或打叉

**Please check below if you agree to the processing of your Personal Information (following personal information processing activities are required by law to obtain separate consent):**

**如您同意以下法律要求取得单独同意的个人信息处理行为，请您在下方每一项方框处进行标记确认：**

|  |  |
| --- | --- |
| **When my ID number is provided, I agree IQVIA to process and use my ID number for compliance with relevant legal and regulatory requirements for the approval and drug/medical device registration of the Study.**  **当我提供身份证号时，我同意艾昆纬为国内外政府或监管机构验证或遵守该研究申报和药品/医疗器械注册相关法律法规之要求处理和使用我的身份证号。** |  |
| **I agree IQVIA to publish my Personal Information to relevant websites and databases for the purpose described above on the premise of complying with relevant Chinese laws and regulations.**  **我同意艾昆纬为前述目的在符合中国相关法律法规的前提下将我的个人信息发布至相关网站和数据库。** |  |
| **I agree IQVIA to store my Personal Information in a server located abroad or transfer my Personal Information abroad for the purpose described above on the premise of complying with relevant Chinese laws and regulations.**  **我同意艾昆纬为前述目的在符合中国相关法律法规的前提下将我的个人信息存储于境外的服务器/传输出境。** |  |
| **I agree IQVIA to provide my Personal Information to IQVIA’s affiliates, the Sponsor and project's other partners for the purpose described above.**  授权人签名姓名，日期是授权当天  **我同意艾昆纬为前述目的将我的个人信息提供给艾昆纬的关联公司、申办方和项目的其他合作方。** |  |

**I, the undersigned, have read this Consent and consent to my personal information being processed and used as described above:**

**我已阅读本《同意函》，并同意艾昆纬以上述方式处理和使用我的个人信息：**

|  |  |  |
| --- | --- | --- |
| **Printed Name of Site Staff**  **研究中心人员姓名** | **Signature of Site Staff**  **研究中心人员签名** | **Date**  **日期** |
|  |  |  |