

# 中国新型冠状病毒灭活疫苗接种知情同意书

## Inactivated COVID-19 Vaccine (Vero Cell) Consent Form

新型冠状病毒肺炎是一种由新型冠状病毒感染引起, 经呼吸道飞沫和接触传播为主要传播途径, 人群普遍易感的新发传染病。常见的临床表现有发热、乏力、干咳等, 少数患者伴有鼻塞、流涕、咽痛、肌痛和腹泻等症状。多数患者预后良好, 少数患者病情危重。随着疫情的蔓延, 对全球公众健康构成严重威胁。根据当前新型冠状病毒肺炎防控需要, 依据《疫苗管理法》有关规定, 结合已有的临床研究数据, 按照国家相关要求, 开展新型冠状病毒疫苗接种, 预防新型冠状病毒感染引起的流行性疾病。

COVID-19 is a new infectious disease caused by a novel coronavirus (SARS-CoV-2), transmitted by droplets and direct contact. All people are susceptible to this disease. Symptoms often include fever, fatigue and dry cough, and a few patients may suffer from nasal congestion, running nose, sore throat, myalgia, and diarrhea. Prognosis for most patients is good, though a few patients may become critically ill. The spread of the disease has posed a severe threat to global public health. To prevent and control COVID-19, vaccination is now carried out in accordance with provisions of the Vaccine Management Law and relevant requirements of the government, and on the basis of acquired clinical research data.

【疫苗品种】新型冠状病毒疫苗灭活疫苗, 每1次人用剂量为0.5ml。疫苗具体信息详见疫苗说明书。

【Type】Inactivated COVID-19 vaccine (Vero Cell), 0.5 mL per dose. (Please refer to vaccine instructions for more information)

【疫苗作用】接种疫苗后可刺激机体产生抗新型冠状病毒的免疫力, 已有的疫苗临床试验数据显示, 全程免疫后28天受种者产生抗体的比例均超过90%, 提示该疫苗具有潜在的临床应用价值。疫苗针对新型冠状病毒肺炎的保护效果还要在疫苗上市后的实际应用中进一步观察。

【Functions】The body will develop immunity against COVID-19 after vaccination. According to data from clinical trials, over 90% of the recipients developed antibodies 28 days after completing the full course of vaccination, suggesting that the vaccine could be administered for clinical use. The protective efficacy of the vaccine in preventing COVID-19 will be further observed in its application.

【接种对象】18-59岁新型冠状病毒易感者。

【Target Group】Adults aged 18 through 59 years

【免疫程序】共接种2剂, 两剂间隔14-28天。

【Schedule】Two doses, 14-28 days apart

【接种途径、部位】推荐肌肉注射, 注射前须摇匀, 上臂外侧三角肌肌内注射。

【Administration】Intramuscular injection recommended. Shake well and inject in the deltoid muscle of the upper arm.

【不良反应】已完成的疫苗临床试验数据显示, 接种疫苗后发生局部不良反应以接种部位疼痛为主, 还包括局部瘙痒、肿胀、硬结和红晕等, 全身不良反应以疲劳乏力为主, 还包括发热、肌肉痛、头痛、咳嗽、腹泻、恶心、厌食和过敏等。

【Adverse Reactions】According to existing clinical trial data, pain at the injection site is the most frequently reported local reaction, with other local reactions such as itching, swelling, induration and redness. The most reported systemic reaction is fatigue, and others include fever, muscle pain, headache, cough, diarrhea, nausea, anorexia and allergy.

此外, 既往在其他冠状病毒疫苗的动物实验研究中发现, 接种灭活疫苗后再次感染同种冠状病毒时, 该病毒所致疾病出现加重现象。虽然本疫苗已完成的大动物实验及人体临床试验中尚未观察到以上现象, 但本疫苗是否存在上述安全性问题还要在疫苗上市后的实际应用中进一步观察。

In addition, previous animal tests for other coronavirus vaccines found that symptoms will aggravate when the vaccinated subject got infected again by the same coronavirus. Such cases have not occurred in the large animal test and human clinical trials for this vaccine, yet this safety issue will be further observed in its application.

【接种禁忌】因已开展的临床试验数据有限, 以下人群不在本次接种范围。请明确是否存在以下情况:

【Contraindications】Due to limited data of clinical trials, the following groups are currently not eligible for vaccination. Please confirm whether you have the following conditions:

|                                                                                                                                                                                                                                                  |        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|
| 1. 年龄<18岁或≥60岁                                                                                                                                                                                                                                   | 是□ 否□  |
| 1. Are you aged below 18, or 60 and above?                                                                                                                                                                                                       | Yes No |
| 2. 对疫苗或疫苗成分过敏者, 既往发生过疫苗接种严重过敏反应(如急性过敏反应、荨麻疹、皮肤湿疹、呼吸困难、血管神经性水肿、腹痛)                                                                                                                                                                                | 是□ 否□  |
| 2. Are you allergic to vaccines or their components? Have you ever had a severe allergic reaction after vaccination? (including but not limited to: acute allergic reaction, urticaria, eczema, dyspnea, angioneurotic edema and abdominal pain) | Yes No |
| 3. 患有血小板减少症或者出血性疾病者                                                                                                                                                                                                                              | 是□ 否□  |
| 3. Do you have thrombocytopenia or hemorrhagic diseases?                                                                                                                                                                                         | Yes No |
| 4. 惊厥、癫痫、脑病、其他进行性神经系统疾病和精神疾病史或家族史                                                                                                                                                                                                                | 是□ 否□  |
| 4. Have you or anyone in your family ever had convulsion, epilepsy, encephalopathy or other                                                                                                                                                      | Yes No |

|                                                                                                                                                                                                                                                                                     |                                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
| aggressive neurological or mental illnesses?                                                                                                                                                                                                                                        |                                                                 |
| 5. 严重的肝肾疾病、药物不可控制的高血压（收缩压 $\geq 140$ mmHg，舒张压 $\geq 90$ mmHg）、糖尿病并发症、恶性肿瘤<br>5. Do you have severe liver or kidney diseases, resistant hypertension (systolic blood pressure $\geq 140$ mmHg, diastolic blood pressure $\geq 90$ mmHg), diabetic complications, or malignant tumor? | 是 <input type="checkbox"/> 否 <input type="checkbox"/><br>Yes No |
| 6. 已被诊断为患有先天性或获得性免疫缺陷、HIV 感染、淋巴瘤、白血病或其他自身免疫疾病<br>6. Have you been diagnosed with congenital or acquired immunodeficiency, HIV infection, lymphoma, leukemia or other autoimmune diseases?                                                                                           | 是 <input type="checkbox"/> 否 <input type="checkbox"/><br>Yes No |
| 7. 已知或怀疑患有以下疾病：严重呼吸系统疾病、严重心血管疾病、恶性肿瘤<br>7. Do you have or are you suspected of having diseases including: severe respiratory diseases, severe cardiovascular diseases, and malignant tumor?                                                                                         | 是 <input type="checkbox"/> 否 <input type="checkbox"/><br>Yes No |

**【暂缓接种】**

**[Vaccination to be postponed if the following conditions are applicable to you]**

|                                                                                                                                                                                                                                           |                                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
| 1. 孕妇、哺乳期妇女<br>1. Are you pregnant or breastfeeding?                                                                                                                                                                                      | 是 <input type="checkbox"/> 否 <input type="checkbox"/><br>Yes No |
| 2. 发热、各种急性疾病、慢性疾病急性发作期，如感染性疾病（急性上呼吸道感染、感染性腹泻）<br>2. Are you currently having fever or acute diseases, or are you at the acute stage of chronic diseases, such as infectious diseases, e.g. respiratory infection and infectious diarrhea? | 是 <input type="checkbox"/> 否 <input type="checkbox"/><br>Yes No |

发热、各种急性疾病、慢性疾病急性发作期，如感染性疾病（急性上呼吸道感染、感染性腹泻）在完全康复后方可接种。

\*People with scenario 2 can only be vaccinated after full recovery.

**【安全性观察】**每剂接种后，现场观察 30 分钟，出现不适情况应及时咨询现场医生。离开现场后，如果出现怀疑与接种有关的不良反应，请及时就诊并联系中国驻当地使领馆。

**[Post-injection Observation]** After each shot, the recipients are required to stay on site for observation for 30 minutes. Should any discomfort occur, the recipient must immediately consult with on-site doctors. If adverse reactions occur after leaving the vaccination site, please seek immediate medical help and contact the nearest Chinese embassy or Consulate.

**【获益】**根据现有的临床研究数据显示，绝大多数人接种疫苗后能产生预防新冠病毒感染的抗体，但是任何疫苗的保护效果都不能达到 100%，因此部分人接种后可能仍会感染新冠病毒，或者发病，这种现象的产生与疫苗本身特性和受种者个人体质有关。

**[Benefits]** Clinical research shows that most recipients can develop antibodies after vaccination. But no vaccine is 100% effective, and as personal health conditions vary from people to people, some may still be infected or develop symptoms after vaccination.

**【其他】**个人的知情同意书、接种信息等资料将不向外界公布。监测数据可能刊登于科学杂志，但不会列明您个人的任何身份资料。

**[Others]** All personal information such as this letter of consent and vaccination information will not be made public. Monitoring data may be published in science journals but no personal information will be mentioned.

医学建议 (Medical advice): 您此次疫苗接种

☐ 建议接种 (recommend vaccination)

☐ 推迟接种 (defer vaccination)

☐ 不宜接种 (not suitable for vaccination)

请认真阅读以上内容，如已对告知内容理解并同意接种，请签字确认！

*I hereby declare and confirm that I have read through and understood the aforementioned information and give my consent for a vaccination.*

①受种者签字 Signature of recipient: \_\_\_\_\_

日期 Date: \_\_\_\_\_年\_\_\_\_月\_\_\_\_日

②医护人员签字 Signature of medical officer: \_\_\_\_\_

日期 Date: \_\_\_\_\_年\_\_\_\_月\_\_\_\_日

③接种组织单位联系电话 Contact number of the Organizer: \_\_\_\_\_

接种组织单位（盖章）Organizer (Seal):

④驻马达加斯加使领馆联系电话 Contact number of PRC Embassy in Madagascar: \_\_\_\_\_

驻马达加斯加使领馆（盖章）PRC Embassy in Madagascar (Seal):

本知情同意书一式三份（受种者 1 份、接种组织单位 1 份、驻马达加斯加使领馆 1 份），请妥善保存 5 年。

This Consent Form is in triplicate (one copy for the recipient, one copy for the vaccination organizer and one copy for the Embassy of the People's Republic of China in Madagascar). Please keep it properly for five years.

(非正式译文，如有问题，以中文为准)  
Unofficial translation, for reference only.  
In case of discrepancies, the Chinese version shall prevail.

## 接种新型冠状病毒灭活疫苗免责承诺书

### Letter of Commitment on Receiving Inactivated COVID-19 Vaccine (Vero Cell)

本人\_\_\_\_\_，性别\_\_\_\_，出生于\_\_\_\_年\_\_\_\_月\_\_\_\_日，中国居民身份证号（或中华人民共和国护照、旅行证号）\_\_\_\_\_。本人已认真阅读后附《新型冠状病毒灭活疫苗接种知情同意书》，认同文件内容，自愿、自费接种新型冠状病毒灭活疫苗，承诺将向现场工作人员如实告知本人的健康状况和接种禁忌等情况。本人已清楚了解疫苗的品种、作用、禁忌等以及接种疫苗可能导致的不良反应，对选择接种疫苗引起的一切风险和责任完全由本人自行承担。

Name: \_\_\_\_\_

Gender: ☐ Male ☐ Female

Date of Birth: \_\_\_\_ / \_\_\_\_ / \_\_\_\_ (yyyy/mm/dd)

Resident ID/Passport/Travel Document No.: \_\_\_\_\_

Employer: \_\_\_\_\_

Phone Number: \_\_\_\_\_

- ☐ I have read the attached *Inactivated Vaccine (Vero Cell) Consent Form* and agree to its content.
- ☐ I consent to voluntary vaccination and will pay for all relevant expenses.
- ☐ I will truthfully inform on-site health workers of my personal information such as health conditions and vaccine contraindications.
- ☐ I am fully aware of the type, usage of the vaccine and its contraindications, as well as the possible adverse reactions after vaccination.
- ☐ I shall bear all risks and responsibilities associated with vaccination.

本人签名 (Signature):

日期 (Date): \_\_\_\_ / \_\_\_\_ / \_\_\_\_ (yyyy/mm/dd)

**特别提醒：**本免责承诺书一式三份（受种者 1 份、接种组织单位 1 份、驻马达加斯加使馆 1 份），请妥善保管。

Reminder: This Letter of Commitment is in triplicate (one for the recipient, one for the organizer, and one for the Embassy of the People's Republic of China in Madagascar). Please keep it properly.