广东省卫生健康委关于自由贸易试验区医疗

机构人体器官移植执业资格认定工作的

实施方案（征求意见稿）

为规范我省自由贸易试验区医疗机构人体器官移植执业资格认定审批工作，依据《人体器官移植条例》《国家卫生健康委关于印发自由贸易试验区“证照分离”改革卫生健康事项实施方案的通知》（国卫法规发〔2019〕62号）等法律法规及文件要求，结合工作实际，制定本实施方案。

1. 总体要求

认真落实国务院行政审批制度改革要求，做好自由贸易试验区医疗机构人体器官移植执业资格认定行政审批事项下放至省级卫生健康行政部门后我省自由贸易试验区医疗机构人体器官移植执业资格认定工作。合理资源布局，优化专科设置，严把标准程序，规范能力审查，严格准入机制。持续改进和提高人体器官移植技术水平和医疗质量，规范医疗行为，保障医疗安全，建设健康广东，打造卫生强省，满足人民群众日益增长的多层次、多样化、高质量医疗卫生服务需求。

1. 主要内容

省卫生健康委组织开展自由贸易试验区医疗机构人体器官移植执业资格认定审批工作，我省自由贸易试验区内各类医疗机构可根据本实施方案向省卫生健康委申请人体器官移植资质。

（一）申请医疗机构条件。

医疗机构从事人体器官移植，除应符合《人体器官移植技术临床应用管理规范（2020年版）》（国卫办医函〔2020〕705号）外，依照《人体器官移植条例》第十一条、十二条，还应当具备下列条件：

1.有与从事人体器官移植相适应的执业医师和其他医务人员；

2.有满足人体器官移植所需要的设备、设施；

3.有由医学、法学、伦理学等方面专家组成的人体器官移植技术临床应用与伦理委员会，该委员会中从事人体器官移植的医学专家不超过委员人数的1/4；

4.有完善的人体器官移植质量监控等管理制度；

5.有合法的器官来源（连续两年公民逝世后器官捐献成功案例每年不少于5例）；

6.符合广东省器官移植规划；

7.医疗机构执业地点位于广东省自由贸易试验区内。

（二）申报材料。

1.器官移植相应专业诊疗科目登记申请表（附件），可在广东省卫生健康委网上办事大厅（https://www.gdzwfw.gov.cn/）下载；

2.《医疗机构执业许可证》复印件；

3.有合法器官来源的证明资料：连续两年公民逝世后器官捐献成功案例每年不少于5例；

4.拟开展人体器官移植的执业医师和拟开展人体器官移植的其他技术人员名单及其履历；

5.与拟开展的人体器官移植相适应的设备目录、性能、工作状况说明和相应辅助设施情况说明；

6.人体器官移植技术临床应用与伦理委员会组成及人员名单；

7.与拟开展的人体器官移植相关的技术管理规范和管理制度。

（三）申请流程。

1.医疗机构根据相关法律法规及管理规范开展自评，经自评合格后，经同级卫生健康行政部门同意，登录广东省卫生健康委网上办事大厅（https://www.gdzwfw.gov.cn），向我委提交申请材料。我委定期于4、8月最后一周集中受理自贸区医疗机构网上申报，其他时间段不接受申报。

2.省卫生健康委在收到医疗机构人体器官移植执业资格认定申请后，在5个工作日内对申请材料进行形式审查。医疗机构提交的申请材料齐全，符合法定形式的，予以受理；申请材料不齐全或者不符合法定形式的，告知医疗机构需要补正的材料。医疗机构应当在5个工作日内按照要求补正材料，逾期不补正的，省卫生健康委不予受理。

3.省卫生健康委自受理后30个工作日内作出是否审核通过的决定并告知申请单位。其中办理过程中所需要的专家审核、现场抽检复查等，不计入时限，省卫生健康委专家审核、现场抽检复查等时间不超过10个工作日。

4.通过审核的医疗机构，持医疗机构执业许可证和评审通过通知到所属卫生健康行政部门办理相关人体器官移植诊疗科目登记。

1. 监督管理

（一）省卫生健康委依法加强对各移植医院的监督管理，定期对移植医院开展人体器官移植临床应用质量和能力进行评估，对评估不合格的或存在严重违法违规行为、不具备移植条件和能力、连续2年以上未开展人体器官移植等情形的医疗机构，撤销人体器官移植诊疗科目登记。

（二）各级卫生健康行政部门要落实属地监管责任，提升辖区内医疗服务能力和医疗质量水平，完善制度设计，创新监管手段，加强对辖区内各级各类医疗机构的监督管理，对违法违规行为严肃处理。

（三）相关医疗机构和医务人员要加强相关法律、法规及技术管理规范的学习，必须按照核准的诊疗科目开展器官移植。不得擅自开展人体器官移植工作。严禁未取得资质或在取得资质以外的诊疗科目开展器官移植。

本方案自2022年 月 日起施行，有效期5年。

具体执行过程中如有疑问或意见建议，请及时反馈省卫生健康委医政医管处。联系人：姚瑞洁，联系电话：020-83836457。

附件：器官移植相应专业诊疗科目登记申请表

附件

医疗机构人体器官移植

执业资格认定申报表

地市：

自贸区：

申请医院名称：

申请项目：

二〇 年 月 日

申 报 概 要

**一、 医院概况**

**二、 医院综合技术能力**

**三、 医院现有条件已达到人体器官移植技术管**

**理规范相关要求**

**四、 医院人体器官捐献开展情况**

**五、 医院其他需要说明的情况**

1. 一般情况

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 医院名称 | | 第一冠名 | | | | | | | | | |
| 第二冠名 | | | | | | | | | |
| 医疗机构执业许可证 | | 登记号 | | | | | | 有效日期 | | | |
|  | | | | | |  | | | |
| 院 长 | | 姓名 | | | 最高学历 | | | | 现任职时间 | | |
|  | | |  | | | |  | | |
| 与高等院校所属关系 □附属医院 □教学医院 □无 | | | | | | | | | | | |
| 医院等级 | | | | | | | | | | | |
| 医院类型 □综合性 □专科 | | | | | | | | | | | |
| 移植指导医院 | | | | | | | | | | | |
| 核定床位数 开放床位数 | | | | | | | | | | | |
| 医院地址 | | | | | | | | | | | |
| 分部地址 | | | | | | | | | | | |
| 联系电话 | | | | | | | | | | | |
| 邮编 传真 | | | | | | | | | | | |
| 分管院长 | | | 职务 | | | 职称 | | | | 手机 | |
|  | | |  | | |  | | | |  | |
| 职能部门负责人 | 部门 | | | 职务 | | | 职称 | | | | 手机 |
|  |  | | |  | | |  | | | |  |

1. 相关学科基本情况

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| **（一）相关专业科室情况（请填写申报相关学科）** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 普通外科 | | | | 已开展工作时间 | | | | | | | | | | | | | | | | | |  | | | | | | | | 开设床位 | | | | | | | | | | |  | | | | | | | |
| 普通外科（肝胆专业） | | | | 已开展工作时间 | | | | | | | | | | | | | | | | | |  | | | | | | | | 开设床位 | | | | | | | | | | |  | | | | | | | |
| 泌尿外科 | | | | 已开展工作时间 | | | | | | | | | | | | | | | | | |  | | | | | | | | 开设床位 | | | | | | | | | | |  | | | | | | | |
| 胸外科 | | | | 已开展工作时间 | | | | | | | | | | | | | | | | | |  | | | | | | | | 开设床位 | | | | | | | | | | |  | | | | | | | |
| 心脏外科 | | | | 已开展工作时间 | | | | | | | | | | | | | | | | | |  | | | | | | | | 开设床位 | | | | | | | | | | |  | | | | | | | |
| 重症监护病房 | | | | 已开展工作时间 | | | | | | | | | | | | | | | | | |  | | | | | | | | 开设床位 | | | | | | | | | | |  | | | | | | | |
| 移植病房 | | | | 有无独立的 移植病房 | | | | | | | | | | | | | | | | | | | | | | | | | 有□ 无□ | | | | | | | | | | | | | | | | | | | |
| 开设床位 | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | |
| 氧气  通道 | | | | | | | | | | | | 有□ 无□ | | | | 监护  系统 | | | | | | | | | 有□ 无□ | | | | | | 负压吸引系统 | | | | | | | | | | | | | 有□ 无□ |
| 手术室 | | | | 有无肝脏移植专用手术室 | | | | | | | | | | | | | | | | | | | | | | | | | 有□ 无□ | | | | | | | | | | | | | | | | | | | |
| 肝脏移植专用手术室面积 | | | | | | | | | | | | | | | | | | | | | | | | | 40平米以上□  40平米以下□ | | | | | | | | | | | | | | | | | | | |
| 是否达到I级洁净标准 | | | | | | | | | | | | | | | | | | | | | | | | | 是□ 否□ | | | | | | | | | | | | | | | | | | | |
| 重症监护室 | | | | 设置符合规范要求，达到III级洁净辅助用房标准 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 是□ 否□ | | | | | | | | | | | | |
| 开设床位 | | | | | | | | 不少于10张□  少于10张□ | | | | | | | | | | | | | 每病床净使用面积 | | | | | | | | | | | 不少于15平米□  少于15平米□ | | | | | | | | | | | | |
| 符合相应申请项目危重病人救治要求 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 是□ 否□ | | | | | | | | |
| 空气层流设施 | | | | | | | | | 有□  无□ | | | | | | | | 呼吸机 | | | | | | | | 有□  无□ | | | | | | | 多功能监护仪 | | | | | | | | | | 有□  无□ | | |
| 能够开展有创监护项目和有创呼吸机治疗 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 有□ 无□ | | | | | | | | | | | | |
| 有无持续性床旁血液滤过设备 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 有□ 无□ | | | | | | | | | | | | |
| 有无床边生化检测仪 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 有□ 无□ | | | | | | | | | | | | |
| 血液净化室 | | | | 有无独立的血液净化室 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 有□ 无□ | | | | | | | | | | | | |
| 血液净化设备数量 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 20台以上□  20台以下□ | | | | | | | | | | | | |
| 有无人工肝支持系统和设备 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 有□ 无□ | | | | | | | | | | | | |
| 实验室 | | | | 能否开展免疫抑制剂血药浓度检测 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 能□ 否□ | | | | | | | | | | | | |
| 能否开展PRA和HLA检测 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 能□ 否□ | | | | | | | | | | | | |
| 病理科 | | | | 能否开展移植器官组织活检的病理诊断 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 能□ 否□ | | | | | | | | | | | | |
| 介入科 | | | | 能否独立进行介入诊治 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 能□ 否□ | | | | | | | | | | | | |
| 心/肺功能室 | | | | | 有无独立的心/肺功能室 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 有□  无 □ | | | | | | | | | | | | |
| 不同功能肺功能设备数量 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 5台以上□ 5台以下 □ | | | | | | | | | | | | |
| 心肺运动仪 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 有□  无 □ | | | | | | | | | | | | |
| 支气管镜室 | | | | | 能否开展TBLB、EBUS检查及术后气道管理 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 能□ 否 □ | | | | | | | | | | | | |
| **（二）移植项目负责人  移植** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 姓名 | | |  | | | | | | | | | | | 性别 | | | | | | | | |  | | | | | | | | | | 出生年月 | | | | | | | | | | |  | | | | |
| 所在科室 | | |  | | | | | | | | | | | | | | | | | | | | | | | 执业医师资格证书编号 | | | | | | | | | | | | |  | | | | | | | | | |
| 毕业院校 | | |  | | | | | | | | | | | | | | | | | | | | | | |
| 学历 | | |  | | | | | | | | | | | | | | | | 学位 | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | |
| 专业 | | |  | | | | | | | | | | | | | | | | 专长 | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | |
| 工作年限 | | |  | | | | | | | | | | | | | | | | 相应工作年限 | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | |
| 职称 | | |  | | | | | | | | | | | | | | | | 获得职称时间 | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | |
| 1.何时何地开始本项目的专业工作 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 时间 | | | | | | 地点 | | | | | | | | | | | | | | | | | | | | | 项目 | | | | | | | | | | | | | | | | | | | | | |
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| 2.本项目专业培训（进修）情况 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 时间 | | | 地点 | | | | | | | | | | | | 指导医师 | | | | | | | | 操作例数 | | | | | | | | | | 参与例数 | | | | | | | | | | | 其他需说明情况 | | | | |
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| 个人专业工作简述（含主要科技成就）： | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 其他 | | | 近三年内是否发生与同类技术有关的医疗事故：是□ 否□ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **（三）相关人员 移植** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 学历结构 | 总计人数 | | | | | | | | 博士 | | | | | | | | 硕士 | | | | | | | | | | | | | | | 本科 | | | | | | | | | | 专科及以下 | | | | | | |
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| 职称结构 | 总计人数 | | | | | | | | 主任医师 | | | | | | | | 副主任医师 | | | | | | | | | | | | | | | 主治医师 | | | | | | | | | | 住院医师 | | | | | | |
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| 人体器官移植医师情况 | 姓名 | | | | | | 性别 | | | | 年龄 | | | | | | 学历 | | | | | | | | | | | 职称 | | | | | | | | | 专业 | | | | | | | | | | 从事专业年限 | |
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| **（四）麻醉科相关人员** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 学历结构 | 总计人数 | | | | | | | | 博士 | | | | | | | | 硕士 | | | | | | | | | | | | | | | 本科 | | | | | | | | | | 专科及以下 | | | | | | |
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| 职称结构 | 总计人数 | | | | | | | | 主任医师 | | | | | | | | 副主任医师 | | | | | | | | | | | | | | | 主治医师 | | | | | | | | | | 住院医师 | | | | | | |
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| 主要人员情况 | 姓名 | | | | | | 性别 | | | | 年龄 | | | | | | 学历 | | | | | | | | | | | 职称 | | | | | | | | | 专业 | | | | | | | | | | 从事专业年限 | |
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| **（五）相关设备** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 设备名称 | | | | | | | | | | | 设备情况（型号、产地、数量等） | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 磁共振（MRI） | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 计算机X线断层摄影（CT） | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 彩色多普勒超声波诊断仪 | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 床边X光机 | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 纤维胃镜 | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 纤维胆道镜 | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 肺功能测定仪 | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 快速冰冻切片设备 | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 器官移植专用器械 | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 供体器官摘取与保存的药品与器械 | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 人工膜肺（ECMO） | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 心肺运动仪 | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **（六）项目所在科室的专用设备、设施及工作基础** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 场所情况 | |  | | | | | | 独立病区   个 | | | | | | | | | | | | | | | | | | | | | | | | | | 独立病床   张 | | | | | | | | | | | | | | |
| 其他场所情况︵包括专用实验室︶ | | | | | | 场所名称 | | | | | | | | | | | | | | | | | | | | | | | | | | 面积（平方米） | | | | | | | | | | | | | | |
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| 专用设备情况 | |  | | | | | | 设备名称 | | | | | | | | | | | | | | | | 型号及产地 | | | | | | | | | | | | | | | | | | | | | 台数 | | | |
| 必备设备 | | | | | | 体外循环呼吸支持设备 | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | |  | | | |
| 应有设备 | | | | | | 多功能监护仪 | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | |  | | | |
| 目前已开展同类技术应用情况 | | 已开展项目（具体名称） | | | | | | | | 开展时间（年） | | | | | | | | 已开展该项目总数 | | | | | | | | | | | | | 手术成功率（%） | | | | | | | | | | | | 3年/5年生存率（%） | | | | | |
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三、相关制度建设情况

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四、人体器官捐献案例统计

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| **申请医院所在区域器官获取组织（OPO）：** | | | | |
| 年度 | 捐献案例数 | | 捐献器官数量 | |
|  |  | |  | |
|  |  | |  | |
| 人体器官捐献案例详情 | 捐献者姓名 | 住院号 | 捐献日期 | 分配系统中捐献者编号 |
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五、需说明的其他情况

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六、各级单位意见

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| 医院意见：    盖 章  日 期 |
| 市生健康局（委）审核意见：  盖 章  日 期 |

（注：本申请表各表格均可续页）