

# 世界中医药学会联合会文件

世界中联发〔2017〕14号

## 关于印发《世界中联在各国设立中医临床研究国际合作中心 实施办法》的通知

各团体会员、分支机构及相关部门：

为进一步构建世界中联科技工作平台，推动国际中医药临床科研合作，现制定了《世界中联在各国设立中医临床研究国际合作中心实施办法》，经第三届第九次常务理事会讨论通过，印发给你们，请认真学习，遵照执行。





## 世界中联在各国设立中医临床研究国际合作中心实施办法

**第一条** 为推动中医药的国际传播，开展跨国中医临床研究国际合作研究，为中医药安全有效等临床优势提供更多的循证证据，世界中联拟选择条件较好的国家和城市示范区域，依托中医药学术组织和当地中医医疗机构，整合优势资源，设立“中医临床研究国际合作中心”（以下简称“合作中心”）。

**第二条** 合作中心的建设目标为：构建国际中医药临床研究、登记注册、伦理审查等技术平台，组建临床研究设计、质量控制、数据统计分析等专业化团队，开展中医药防治重大疾病、难治性疾病、潜在优势病种、慢病防控、养生、保健、康复等领域的研究，取得安全、有效、经济学评价等循证证据，阐明起作用规律和可能机制，为中医药进入各国医疗卫生保健体系提供科技支持。

**第三条** 在世界中联的总体规划下，每个示范区域内原则上只设立一个合作中心，最终形成包括世界中联—合作中心—当地医疗机构的中医临床研究国际合作网络。

**第四条** 世界中联秘书处对合作中心承担指导、支持和协调管理职能：

1. 负责建立和实施合作中心体系总体发展规划、统筹管理政策与区域协调机制；引导和支持合作中心中医药科研项目开展，国际科技合作能力提升；

2. 组织和协调中医药临床、科研方法学、研究伦理领域专家参与和支持各合作中心工作开展和项目实施；

3. 建立合作中心在《世界中医药》中英文版发表论文的绿色通道，支持合作中心研究论文成果的及时发布。

4. 建立和实施合作中心研究成果评估推广机制，推动合作中心优秀成



果的推广应用。

**第五条** 合作中心依托所在的法人单位(以下简称“依托单位”)建立, 依托单位主要职责是:

1. 作为责任主体负责合作中心的建设实施, 为合作中心建设提供人、财、物等相应的条件保障。
2. 建立健全合作中心管理规章制度, 建立有利于合作中心发展的管理和运行机制。
3. 做好合作中心开展临床研究的条件保障工作。

**第六条** 合作中心主要承担如下工作任务:

1. 科研组织: 结合本地有关临床研究、伦理审查和受试者保护的相关要求, 联合本地中医医疗机构, 组织和推动本地区中医药临床研究工作开展, 优先承担世界中联组织的国际合作科研项目;
2. 伦理建设: 根据世界中联《伦理审查体系评估标准》等相关文件要求, 推动本地区伦理委员会和“中医药研究伦理审查体系”建设;
3. 区域调研: 调研所在国家或地区中医药科研工作相关法规制度, 了解并掌握本地区中医药相关科研工作开展情况;
4. 人才培养: 在世界中联的支持下, 培养所在国家或地区中医临床研究人才, 提高国际中医药从业人员科研素养;

**第七条** 合作中心应具备的基本条件为:

1. 世界中联团体会员单位, 或在所在国家或地区依法注册、具备组织和开展中医药临床研究条件的, 规模较大的学会、企业、医疗或研究机构;
2. 重视中医临床研究和研究伦理工作, 具备符合要求的伦理审查委员会;
3. 通过世界中联有关中医临床研究相关的管理体系评估, 如伦理审查体系认证。

**第八条** 合作中心设立程序

1. 申报合作中心的机构应根据申报要求, 填报《世界中联中医临床研



究国际合作中心申报书》等相关材料，向世界中联秘书处提出申请；

2. 经形式审核合格后，世界中联秘书处受理申报材料，组织专家对申报材料进行评审；

3. 世界中联秘书处组织专家对申报机构中医临床研究能力和相关的管理体系进行评估；

4. 世界中联秘书处根据认定标准并参考专家意见和考核情况进行综合评价，对符合条件的机构设立为合作中心并正式授牌。

**第九条** 合作中心实行中心主任负责制，具体负责合作中心的建设和研究工作，中心主任对其法人单位负责。

**第十条** 世界中联鼓励各合作中心根据所在国家和地区法规环境和自身实际情况，在满足相关政策要求的基础上，建立差异化和特色化的运行管理模式。

**第十一条** 经批准认定的合作中心所在机构，可以对外标注并在相关场所悬挂世界中联授予的牌匾和证书，以世界中联合作中心的名义开展活动，但不得以合作中心名义从事任何违反所在国家和地区法律法规，以及有损世界中联声誉的活动。

**第十二条** 本办法由世界中联秘书处负责解释，自发布之日起实施。



## **Implementation Bylaw on Establishing International Collaborating Centers of Chinese Medicine Clinical Research of World Federation of Chinese Medicine Society (WFCMS) in Various Countries**

**Article 1:** To promote the international transmission of Chinese medicine(CM) and conduct international cooperation in clinical research, to provide more evidence of clinical research for CM such as safety, efficacy and etc., World Federation of Chinese Medicine Society (WFCMS), proposed to select some national and city demonstration areas with comparatively favorable conditions to set up "International Collaborating Center for Clinical Research of Chinese Medicine" (hereinafter referred to as "cooperating center"), which is based on integrating resources of CM academic organizations and local Chinese medical institutions.

**Article 2:** The aims of the cooperating center include: build technical platform for clinical research, registry study and ethics review of CM; build specialized teams of clinical research design, quality control and data statistical analysis and etc.; carry out CM researches on prevention and treatment of major diseases, refractory diseases, potential predominance diseases, prevention and control for chronic diseases, health care, rehabilitation and other areas; acquire evidence of clinical research from safety, efficacy, economic evaluation and other aspects; clarify the rules and possible mechanisms of CM; provide scientific and technological support for CM entering into the medical and health care system of respective countries.

**Article 3:** Under the overall planning of WFCMS, only one cooperating center would be set up in each demonstration area by principle, and finally an international cooperation network for CM clinical research will be formed, which includes WFCMS—Cooperating Center—local medical institutions.

**Article 4:** The secretariat of WFCMS plays the role of guidance, support and coordination for the collaborating centers:

1. Be responsible for establishing and implementing the overall development plan of the center, coordinating administrative policies and regional coordination mechanisms;



- guiding and supporting the development of CM research projects in cooperating centers and upgrading their international cooperative abilities in science and technology;
2. Organize and coordinate experts of CM clinical research, research methodology, and research ethics to participate in and support the work and project implementation of all cooperating centers;
  3. Establish "Green Channel" in the *World Chinese Medicine* to support the research papers from collaborative centers to be published in time.
  4. Establish and implement research achievement evaluation mechanism to promote the application of outstanding achievements of cooperating centers.

**Article 5:** The establishment of cooperating center relies on the support legal entities (hereinafter referred to "support unit"), and their main responsibilities are:

1. As the main body of responsibility, support unit should be responsible for the construction and implementation of the cooperating center, including providing staff, property and goods etc., to guarantee the construction of the cooperating center.
2. Establish the management rules and regulations of the cooperating center and establish management and operation mechanism conducive to the center development.
3. Guarantee the cooperation centers have eligible conditions to carry out clinical research work.

**Article 6:** Cooperating center mainly undertake the following responsibilities:

1. Scientific Research Organization: Based on relevant requirements of the local clinical research, ethics review and the protection of subjects, unite local medical institutions to promote CM clinical research work, have priority to undertake international cooperation research projects of WFCMS;
2. Ethics Review System Construction: According to the requirements of relevant documents of WFCMS such as *Assessment Standard for Ethics Review of Biomedical Research with Human Participants*, to promote the local construction of ethics committee and "Ethics Review System of CM Scientific Research";
3. Regional Investigation: Investigate the relevant laws and regulations of CM research in local countries or regions, and get knowledge about the development of CM related scientific research work in local region;
4. Talents Training: On the support of WFCMS, cooperating centers should cultivate CM clinical research talents in local countries and regions and improve the research capabilities of international CM practitioners;



**Article 7:** Cooperating center should meet some basic requirements as follows:

1. Be unit members of WFCMS, or academic society, enterprise, medical institute or research organization of large scale with legal position in host countries as well as meet the basic requirements of carrying out CM clinical research;
2. Attach great importance to CM clinical research and research ethics, and have eligible ethics review committee;
3. Obtain the clinical research related management system assessment of WFCMS, such as Chinese Accreditation Program of Ethics Review of CM Research (CAP accreditation).

**Article 8:** Establishing Procedure of Cooperating Center

1. Institutions applying for cooperating center shall fill in the relevant materials such as "Application Form for International Cooperating Center for Clinical Research of CM" according to the secretariat of WFCMS;
2. After formal examination, the secretariat of WFCMS accepts the application materials and organizes experts to review the application materials.
3. Secretariat of WFCMS organizes experts to assess the capabilities and related management system of CM clinical research for applicants;
4. Secretariat of WFCMS should conduct a comprehensive evaluation based on the expert opinions and examination results according to the accreditation criteria, and formally authorize the qualified institutions.

**Article 9:** Employed by the support unit, the director of cooperating center assumes overall responsibility for the work of cooperating center including center construction and research implementation.

**Article 10:** WFCMS encourages all cooperating centers to establish differentiated and characteristic operation and management system based on the regulatory environment in respective countries, regions and their own actual conditions.

**Article 11:** Institutions authorized as the cooperating center may use the logo and certificates issued by WFCMS and carry out activities in the name of WFCMS cooperating center, but which shall not engage in any activities that violate laws and regulations in host countries and regions, as well as activities that are detrimental to the reputation of WFCMS.



**Article 12:** The secretariat of WFCMS is responsible for the interpretation of this bylaw, which shall come into force from the day of issuance.