

## 奇美醫院通過 AAHRPP 評鑑

美國臨床研究受試者保護評鑑協會(AAHRPP)的評鑑委員會，於今年3月20日的會議中，決議授予奇美醫院通過AAHRPP評鑑最高榮譽“完全認證 Full Accreditation”。

為提升本院臨床研究的品質，並與臨床研究國際標準接軌，在本院高度重視及相關研究團隊的積極努力之下，利用2年的時間建立了人體研究保護方案 (Human Research Protection Program, HRPP)，由邱院長直接指揮運作。本院於2014年8月成立受試者保護中心 (HRPC)，王志中副院長擔任該中心主任，人體試驗委員會主委邢中熹醫師擔任執行秘書，按照AAHRPP的標準程序展開自我評估，準備認證資料。審查範圍有三大領域，62章節，500多項指標；涵蓋醫學研究部、人體試驗委員會、臨床研究管理委員會、臨床試驗中心、臨床試驗藥局、生物安全會、輻射防護委員會、生物資料庫、及利益衝突小組等部門。於2016年1月和2016年8月先後遞交了第一階段和第二階段的申請與審查資料。AAHRPP經過嚴格的書面審查後，在2017年1月11日至12日安排了兩位美國AAHRPP專家前來本院實地訪查。訪查期間專家們與本院同仁包括院長在內共位30位行政與研究人員直接面談，對於本院的AAHRPP準備工作給予了高度肯定，並提出了一些回饋意見。訪查結束後，我們按照訪查意見與AAHRPP的標準立刻進行相關改進工作，並於2017年2月至3月遞交了兩次實地訪查回覆報告。最終本院在AAHRPP總部3月份的委員會上獲得了“完全認證 Full Accreditation”的殊榮，效期三年。

獲得AAHRPP認證是本院臨床研究走向國際化的重要一步，為開展高水準的國際多中心臨床研究創造了強而有力的基礎，提升了本院在臨床研究領域的核心競爭力和影響力。此次本院獲得國際最高級別的AAHRPP完全認證，將會進一步推動本院臨床研究體系的發展，提升人體試驗委員會的審查水準，保證人體研究中受試者的健康和福祉，更促進臨床研究專業人才的培養，將持續不斷地提高本院臨床研究的品質和水準。

附註：

美國臨床研究受試者保護評鑑協會 (Association for the Accreditation of Human Research Protection Program, AAHRPP) 成立於2001年，旨在促進高品質和規範的臨床研究。AAHRPP認證代表了全球人體研究的最高標準，迄今全球已經有包括美國NIH在內的238家醫療研究機構獲得了AAHRPP認證。

對於新申請的機構，AAHRPP的認證結果分為以下4種：

Full Accreditation 完全認證 (符合所有標準)、Qualified Accreditation 基本認證 (修正後符合標準)、Accreditation-Pending 認證待定(延後認證)、Accreditation Withheld 不合格 (不通過認證)。



圖為邱仲慶院長(左二)、王志中副院長(右一)及邢中熹執行秘書(左一)帶領奇美醫院同仁進行 AAHRPP 實地評鑑合照。評鑑委員 Janet Squires, M.D. (左三)及 Monika Markowitz, Ph.D (右二)。



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## FOR IMMEDIATE RELEASE

March 22, 2017

### AAHRPP Accredits Nine More Research Organizations

*List includes organizations in U.S., Belgium, China and Taiwan*

WASHINGTON, D.C.—The Association for the Accreditation of Human Research Protection Programs today announced that it has accredited nine more research organizations—in the U.S., Belgium, China and Taiwan.

The newly accredited organizations include hospitals, academic institutions and integrated health care systems. They are:

- Beijing Tiantan Hospital, Capital Medical University, Beijing, China
- **Chi Mei Medical Center, Tainan Taiwan**
- Houston Methodist, Houston, Texas
- St. Joseph Health, Irvine, California
- State University of New York College of Optometry, New York, New York
- Taipei Veterans General Hospital, Taipei, Taiwan
- Universitair Ziekenhuis Brussel, in Brussels, Belgium
- The University of New Mexico, Albuquerque, New Mexico
- Xiyuan Hospital of China Academy of Chinese Medical Sciences, Beijing, China

“These accreditations are the latest indication that AAHRPP standards for research protections have become the international benchmark for high-quality, ethically sound human research—and that makes a difference for all of us,” AAHRPP President and CEO Elyse I. Summers said.

“Put another way, organizations that commit to AAHRPP accreditation are also committing to conduct top-tier ethical research, so we, in turn, can have confidence in the results and the advances they make possible.”

To date, 238 organizations have earned AAHRPP accreditation. Of these, 41 are located outside the United States. “More and more, organizations are recognizing that clinical research is a global enterprise, and protecting participants is a global responsibility,” Summers said.

To earn AAHRPP accreditation, organizations must demonstrate that they have built extensive safeguards into every level of their research operation and that they adhere to high standards for research. In today’s global, collaborative research enterprise, organizations increasingly rely on AAHRPP accreditation status to help identify trusted research partners.

AAHRPP has accredited organizations in 47 states, Belgium, Brazil, Canada, China, India, Mexico, Republic of Korea, Saudi Arabia, Singapore, South Africa, Taiwan and Thailand. All major U.S. independent institutional review boards have earned AAHRPP accreditation. In addition, more than 60 percent of U.S. research-intensive universities and over 65 percent of U.S. medical schools are either AAHRPP accredited or have begun the accreditation process. The National Institutes of Health, the world's largest public funder of research, has earned accreditation, as has Pfizer, Inc., the largest industry sponsor of clinical research.

**About AAHRPP:** A nonprofit organization, AAHRPP provides accreditation for organizations that conduct or review human research and can demonstrate that their protections exceed the safeguards required by the U.S. government. To learn more, visit [www.aahrpp.org](http://www.aahrpp.org).

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