

## Certificates of Accreditation

AAHRPP issues a Certificate of Accreditation to each Organization that receives Full Accreditation or Qualified Accreditation. If an Organization has its accreditation revoked, the Certificate of Accreditation must be returned to AAHRPP. Organizations that are placed in Accreditation-Pending are not entitled to receive Certificates of Accreditation.

Display or use of any outdated, revoked, defaced or fraudulent AAHRPP certificate or of facsimiles that might deceive or mislead prospective participants, sponsors, or other persons, is considered a serious offense with the potential for harming the public confidence in research and the research protection system. Appropriate legal action may be taken by AAHRPP based on the facts of any such deception.

## Confidentiality

Information about specific AAHRPP clients (and the third parties with whom they do business or from whom they receive information) is confidential (“AAHRPP Client Confidential Information”). This applies to an Organization that participates at any level, including potential clients that have only indicated their intent to apply for accreditation. The only information that may be released by an AAHRPP Representative about the accreditation status of a participating Organization is that the Organization is or is not accredited. AAHRPP Client Confidential Information includes (but is not limited to) all information regarding the client’s business, personnel, facilities, management, technical and scientific information, and deliberations or comments originating from the accreditation process, as well as all information regarding third parties with whom the Organization does business or from whom the Organization receives information.

All AAHRPP Client Confidential Information made available by an Organization to AAHRPP or its Representatives is kept confidential to the extent required by law. No Representative may remove or retain copies of any Organization's confidential documents without the permission of the Organization. No Representative may disclose any of his or her findings to any person or agency except AAHRPP, except to the extent required by applicable law. AAHRPP Representatives who fail to adhere to this policy may be discharged. In addition, AAHRPP may pursue legal action against them.

Organizations must comply with all legal and ethical requirements for disclosing any research records with participants’ personally identifiable information. The Organization and AAHRPP Representatives must follow appropriate procedures to protect the confidentiality of records. Without limiting the foregoing, an Organization should “de-identify” records provided to or made available to AAHRPP. AAHRPP will not hold, maintain, or disclose records with research participants’ personally identifiable information.

AAHRPP and its Representatives will hold all files and records in confidence, and no confidential data will be released by AAHRPP except pursuant to direction by the Board of Directors, under the order of a court of law, pursuant to the execution of a valid search warrant, or as otherwise required by applicable law.

In some states, statutes pertaining to the “peer review” privilege may be applied and protect institutional peer review materials from subpoena. An Organization should determine whether the AAHRPP accreditation process is considered to be a “peer review” process and AAHRPP

and its site visitors part of the institution's "peer review committee." AAHRPP recommends that the governing bodies of an Organization appoint AAHRPP and its site visitors as part of the Organization's peer review committee prior to the submission date of the application in order to maximize the likelihood that the accreditation process will be considered "peer review."

## Protected Health Information

An Organization is not asked to submit protected health information as part of its application or other correspondence to AAHRPP. If, however, outside of a site visit protected health information is disclosed to AAHRPP or its Representatives, AAHRPP will abide by its confidentiality policy. AAHRPP, however, cannot commit to comply with HIPAA regulations or an Organization's "Notice of Privacy Practices" for protected health information disclosed to it, or its Representatives, outside of a site visit.

During a site visit, an Organization should de-identify protected health information from records provided to site visitors whenever practical. AAHRPP understands that at times such de-identification may be impractical, and protected health information may be disclosed to AAHRPP Representatives during the conduct of a site visit. In such circumstances AAHRPP Representatives will not record or disclose protected health information.

Because of the potential for disclosure of protected health information to AAHRPP Representatives, AAHRPP may be considered a "business associate" of an Organization who is a "covered entity," as defined in the privacy rules adopted pursuant to the Health Insurance Portability and Accountability Act of 1996. For the Organization's convenience, AAHRPP has developed a "business associate agreement" that is available upon request. Should an Organization wish to enter into a business associate agreement with AAHRPP, the Organization should include a signed copy of a business associate agreement with its application for accreditation. AAHRPP will sign and return the business associate agreement as of, or prior to, its site visit.




## Release and Indemnification

By submitting an application, an Organization certifies that the information contained in the application is accurate. The Organization agrees to release AAHRPP, its members, directors, officers, employees and agents (the "AAHRPP Representative") from any and all claims, and to indemnify and hold harmless the AAHRPP Representatives from and against any and all liability and costs incurred by them, including attorneys' fees, resulting from the application or site visit of its Human Research Protection Program.

## Records Retention

Applications, reports, and other documents from site visits resulting in accreditation and all documents following and relating to that accreditation are kept for 10 years from the date of that accreditation. Applications, reports, and other documents from site visits not resulting in accreditation are kept for three years from the date of the decision to Withhold Accreditation unless the Organization has within the three-year period, reapplied for accreditation and the application results in Accreditation, in which case the records are kept for 10 years from the date of accreditation.

ホーム ニュース ニュースリリース その他 2015  
倫理審査委員会認定制度の開始について ～平成26年度倫理審査委員会認定の申請を受け付けます～

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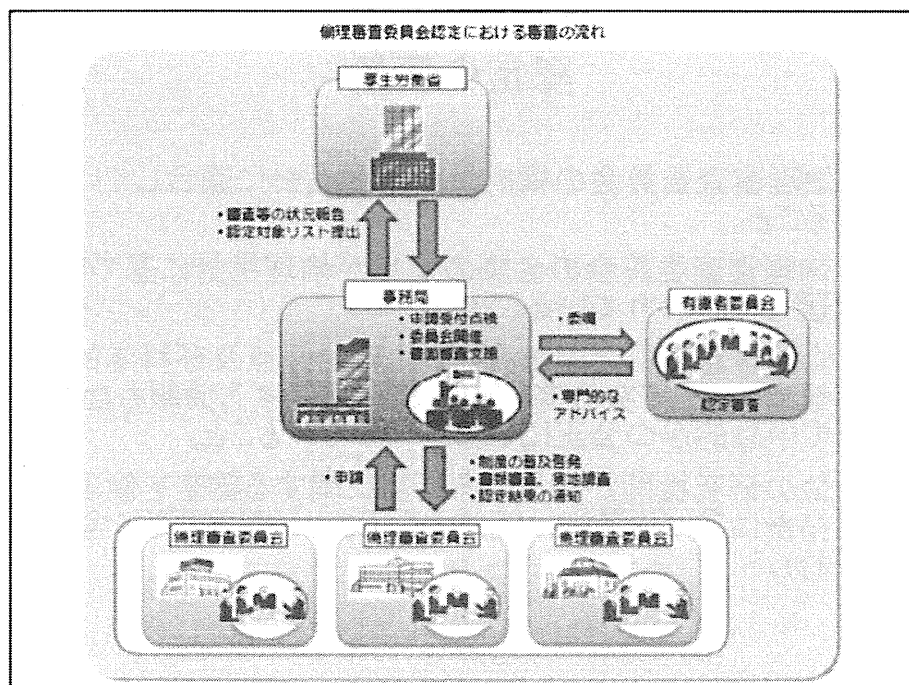
三貴総合研究所  
2015.02.02

### MRIニュース

この事業は、株式会社三貴総合研究所が厚生労働省からの委託を受け「平成26年度倫理審査委員会認定に係る補助業務」を実施するものです。

人を対象とする医学系研究においては、被験者保護や研究の質の確保のために、「臨床研究に関する倫理指針」に基づき研究の実施又は継続について倫理審査委員会での審査を求めています。平成26年3月現在、倫理審査委員会の設置は1,330件のみです（厚生労働省「倫理審査委員会報告システム」報告数）が、倫理審査委員会ごとに審査の質にばらつきが生じている状況との指摘があります。今後、国際水準の臨床研究、再生医療等分野の臨床研究等の高度化かつ複雑化する臨床研究について、倫理性・科学的妥当性を適切に判断できる倫理審査委員会が一層必要となっています。

本認定制度は、国が適切な審査を行える倫理審査委員会を認定することにより、倫理審査委員会における審査の質の向上を図ることを目的としています。



### 認定の要件

- ア 倫理審査委員会の設置者が、「人を対象とする医学系研究に関する倫理指針」(以下、倫理指針)に掲げる要件を満たしていること。
- イ 当該倫理審査委員会の組織及び運営に関する規定を定め、その規定が倫理指針に適合していること。
- ウ 倫理審査委員会の審査資料を適切に保管する体制が整っていること。
- エ 倫理審査委員会報告システムに、倫理指針に求められている事項が適切に公表していること。
- オ 倫理審査委員への教育・研修を適切に実施していること。

### 認定の要件

- カ 倫理審査委員会の構成員が倫理指針に適合していること。
- キ 倫理審査委員会の会議の運営が倫理指針に基づき適切に行われていること。
- ク 倫理審査委員会の審査が、倫理的観点及び科学的観点から、研究者等の利益相反に関する情報も含めて中立的かつ公正に審査を行っていること。
- ケ 他の研究機関が実施する研究に関する審査を倫理指針に基づき適切に実施できること(継続審査を含む)。

## 認定の要件

- コ 一定の頻度で継続的に倫理審査を行っている実績があること(研究の審査件数等(新規・継続、侵襲・介入を伴う研究に対する審査件数などの審査類型も含めた数も考慮))。
- サ 審査の効率性が保たれていること。
- シ 倫理審査委員会事務局の体制(人的体制や情報管理体制等)・機能が整っていること。

### 【申込受付期間】

平成27年2月2日～2月21日(事務局必着)

### 【審査スケジュール】

認定審査スケジュールは以下を予定しています。

2月2日～2月21日 申請書受付期間

3月上旬 書面審査

3月上旬～中旬 実地調査(書面審査合格者)

3月中旬～下旬 認定の通知

### 【認定申請について】

- 認定有効期間は3年です(更新審査の実施を予定しております)。
- 1機関で複数の倫理審査委員会がある場合において、運用規定等が共通である場合には、1つの倫理審査委員会として認定いたします。
- 認定に諸費用はかかりません。

研究成果の刊行に関する一覧表

書籍

著者氏名	論文タイトル名	書籍全体の 編集者名	書 籍 名	出版社名	出版地	出版年	ページ
	なし						

雑誌

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
	なし				



