

Confidentiality of Institutional Review Board Proceedings

Describes procedures to protect the privacy of human subjects and the confidentiality of proprietary information in the activities of the five MD Anderson Institutional Review Boards (IRBs).

1. Introduction

The purpose of these Guidelines is to maintain confidentiality to appropriately protect personal privacy of human subjects and proprietary information for protocols. The desirability of confidentiality with respect to the business of IRBs must be limited by considerations of privacy of human subjects, the confidentiality of proprietary data, the need to encourage free discussion at IRB meetings, and the desire to promote cooperation in carrying out the purposes of the IRBs.

It would be inappropriate to make any information available that would jeopardize the privacy of human subjects. Moreover, like a research proposal before it is funded, a protocol normally is considered proprietary to the principal investigator until the project is funded. Further, a protocol may contain data that are proprietary to the sponsor, which MD Anderson is contractually obligated to keep confidential. And, last, open and frank discussions of protocols should be encouraged. The incentives to do so can best be preserved by protecting the anonymity of the members of the Panels who raise questions or concerns about the risks or benefits involved in any particular protocol.

Therefore, the following policy guidelines have been established to aid the IRBs in carrying out their institutional obligations.

2. Attendance at Convened Board Meetings

Normally convened board meetings are closed to the public, although exceptions may be made by each IRB.

3. Minutes of IRB Meetings

In order to encourage open and frank discussion at IRB meetings, and to have detailed records of IRB business (including confidential issues and matters under investigation), minutes of IRB normally are not made available to others outside MD Anderson administration unless otherwise required by law or external regulations.

4. Implementation

Questions about interpretation or implementation of these Guidelines should be referred to the Director, Office of Human Subjects Protections, who is also responsible for adjudicating disputes related to any of the provisions of the Guidelines.