

## Rush University Medical Center Policies and Procedures

Policy Number: RA-IRB-101

Category Name: Research

Title: Appointment of IRB Members, Alternates, and Chairs

Type: Policy and Procedure

Revised: 4/2014 (replaces 10/2011)

Applies To: Rush IRB Members and IRB Administrative Staff

**Policy:** Rush IRB members are selected from Rush University Medical Center (RUMC) faculty and staff. Additionally, IRB members whose primary concerns are in non-scientific areas and represent the concerns and viewpoints of subjects and the community are solicited from the University and the community at large, with an emphasis on building a diverse committee. The IRB shall not consist entirely of one gender, religion, profession, and/or cultural background.

**Procedure:** Each Rush IRB committee has a minimum of five members, including at least one member whose primary concerns are in non-scientific areas and represent the concerns and viewpoints of subjects and the community and one member not otherwise affiliated with RUMC or an immediate family member of a person affiliated with RUMC. Each IRB committee also includes one or more individuals who are knowledgeable about and experienced in working with special populations such as children, pregnant women, fetuses, prisoners, subjects with impaired decision making abilities, and other vulnerable populations.

IRB Members are recruited and retained by the Director of Human Subjects Protection at the discretion of the Vice President for Research. Individuals who are responsible for business development (such as Philanthropy or Institutional Investments) or own equity in RUMC cannot serve as members, ex-officio members or IRB Administrative staff.

**Alternate IRB members** are appointed to share meeting duties with one or more other IRB members. Whenever possible, alternate members have comparable qualifications. Alternate members may attend any meeting, however alternate members may vote only if the appointed member of the committee is not present at a particular meeting.

Evaluation of IRB members will be conducted every three years (or earlier at the recommendation of the IRB Chairperson) by the Director of Human Subjects' Protection and IRB Chairperson(s), IRB members will be evaluated on timeliness and quality of review, attendance at meetings, and overall dedication to IRB service.

Recommendations for reappointment, reappointment with conditions, or discharge from service will be determined by the Vice President for Research and Director of Human Subjects' Protection. The Director of Human Subjects' Protection and appropriate IRB chairperson(s) will meet with all members to review their evaluation.

**The IRB chairpersons and vice-chairpersons** are chosen from among highly respected individuals within RUMC and appointed by the Vice President for Research. Their selection indicates that they are qualified and capable of managing the IRB and the matters brought before it with fairness and impartiality. The task of ensuring that the Rush IRB follows federal, state, local and institutional regulations falls on these individuals. These individuals must also ensure that the IRB demonstrates fairness and impartiality when conducting reviews of human subjects research and that the IRB remains immune from pressure either by the institution's administration, the investigators whose protocols are brought before it, or other professional and non-professional sources. The Chair and Vice-Chair(s) will serve for a minimum of three years, subject to reappointment by the Office of the Provost.

IRB chairpersons are evaluated in the same manner as IRB members by the Vice President for Research and Director of Human Subjects' Protection.

All non-Rush IRB members will be asked to sign confidentiality disclosure agreements to cover the sensitive nature of their service on the IRB.

The US Department of Health and Human Services, Office for Human Research Protections (OHRP) requires filing of IRB Membership rosters when created, changed or at renewal of the institution's Federal Wide Assurance Number. The IRB Administrative Staff are responsible for this ensuring this requirement is met.

Reference 45 CFR 46.103(b)(3), 45 CFR 46.107  
21 CFR 56.115(a)(5), 21 CFR 56.107

Related Forms IRB Member Evaluation Form

**Last reviewed: 5/2/2014**