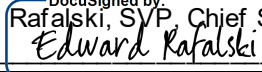


Title: QUALIFICATIONS AND EVALUATION OF IRB MEMBERS	Policy Number: BC-IRB-407 Page: 1 of 2
SPONSORED BY: Sponsored Programs & Research Committee	Issued for: All BayCare, including without limitation: Bartow Regional Medical Center BayCare Alliant Hospital BayCare Wesley Chapel Hospital Mease Countryside Hospital Mease Dunedin Hospital Morton Plant Hospital Morton Plant North Bay Hospital South Florida Baptist Hospital St. Anthony's Hospital St. Joseph's Hospital Winter Haven Hospital
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Approved by: Ed Rafalski, SVP, Chief Strategy & Marketing Officer Signatures: 	

This policy is developed as a guideline to address general circumstances. There may be certain instances in which the exercise of professional judgment and/or discretion by the health care provider warrants taking other actions.

This **QUALIFICATIONS AND EVALUATION OF IRB MEMBERS** Policy applies to BayCare Health System, Inc., and any of its affiliated entities, including those entities listed above (collectively, "**BayCare**").

SCOPE:

BayCare Human Research Protections Program

PURPOSE:

To delineate the qualification requirements of BayCare Institutional Review Board (IRB) members, and the expectations and evaluation program for BayCare IRB members.

PROCEDURE:

A. Qualifications of IRB Members

➤ **Chairperson**

The chair will hold a terminal degree (including but not limited to M.D., D.O., D.D.S., or Ph.D.) and be a member of the medical staff of a BayCare Health System Hospital, or team member within BayCare Health System, and must have previous service on the BayCare or other IRB as a committee member.

➤ **Scientific Committee Member**

The IRB Scientific Member will hold a scientific degree (e.g., M.D., D.O., D.D.S., Ph.D., Pharm.D. or Bachelor of Science in Nursing) with professional training and experience in an occupation that inclines them to view scientific activities from the standpoint of someone within a behavior or biomedical research discipline. Physicians, registered nurses, nurse practitioners, pharmacists, therapists, and other biomedical health professionals are regarded to have primary concerns in the scientific area.

➤ **Non-Scientific Committee Member**

The IRB Non-Scientific Member will have experience with complex information processing, interpersonal communication, and be comfortable with the electronic environment including email and the internet. Examples of non-scientific or non-medical occupations: lawyers, clergy, ethicists, teachers, engineers, accountants, musicians, or business majors.

➤ **Non-Affiliated (Community) Committee Member**

The Non-Affiliated Committee Member is experienced with complex information processing, interpersonal communication, and is sensitive to unique community populations and cultures. In addition, the non-affiliated member is comfortable with the electronic environment, including email, internet, and have access to highspeed internet. The Non-Affiliated Member is not a current or former employee of BayCare Health System and does not have an immediate family member who is a current or former employee BayCare Health System.

B. Attendance Expectations and Length of Service for All Members

- Expectation for minimum length of service for members is five years, membership can be renewed up to three times.
- The minimum attendance requirement is 75% of the meetings scheduled
- Notify the IRB Office of unavailability for a previously confirmed assignment, i.e. convened meeting attendance and for chairpersons, on-call and expedited review rotations.
 - When notification occurs the IRB Office queries designated alternates to identify an available substitute.
 - Upon confirmation with the alternate, the IRB Office updates related IRB schedules and notifies affected team members.
- Pursue current knowledge of human subjects' regulations
- When possible, record written review when attendance cannot be realized/resolved due to an emergency situation arising after the meeting agenda is distributed.

C. Recruitment of IRB Committee Members (except non-affiliated community members)

- Each calendar year, the Institutional Official (I/O, the Board Chair and the Manager of Office of Human Research Protection Program/IRB contacts selected chairpersons of clinical departments, physicians, and graduate medical education (GME) faculty throughout the institution to seek recommendations for convened IRB members to replace members whose term ends and he/she wishes not to continue an appointment at the new calendar year. There is an attempt to approach departments and divisions to achieve broad participation throughout the institution and to ensure representation from those specialties that have a high volume of human studies research. Unscheduled vacancies on the committees that occur during the course of the year are filled in a similar fashion.
- The IO and Board Chair make the final determination of whether nominated IRB members' primary concerns fall into scientific or non-scientific areas.

D. Evaluation of Convened IRB Members

- Self-assessment is used to provide members the opportunity to reflect on the IRB experience and identify potential learning needs.
- The IRB Member Self-Assessment survey and an IRB Chair Self-Assessment survey are used to facilitate the annual assessment process between the IRB members and Chairpersons and between the Chairpersons and the IO.
- Chairpersons annually evaluate each member's review of research and record of attendance for consideration of coaching or assessment regarding the ability of the member to meet the expectation for on-going committee membership. The Chairperson will discuss the evaluation with IRB members and provide documentation of the evaluation to the IO and the IRB Manager. Areas for improvement that are identified for an IRB member are forwarded to the Institutional Official and the IRB Manager for review.
- Annually, the IO will evaluate the IRB Chairperson's ability to lead meetings, review of research, and record of attendance for consideration of coaching and assessment regarding the ability of the Chairperson to meet the expectation for on-going Chairperson role and committee membership. The IO discusses the evaluation with the IRB Chairperson, including areas identified for improvement, and provide documentation of the evaluation to the IRB Manager for review. Evaluations are stored electronically with the IRB Office.
- A survey will be periodically distributed to IRB members. The results are to be used by the IRB Office to improve processes surrounding orientation, training, and education.

E. Recruitment and Recognition of Non-Affiliated (Community) Members

- Individuals not affiliated with BayCare are recruited to serve as members on the BayCare IRB.
- Non-Affiliated members participate in the IRB orientation, education, and training program.
- A minimum of 1 and a maximum of 50% of the total IRB Membership will be permitted to serve on the BayCare IRB at a given time as non-affiliated members.

F. Alternate Members

- IRB members may serve as an alternate for others within the same IRB member role (scientific, non-scientific, or non-affiliated) to ensure appropriate representation at each meeting. Qualifications, responsibilities, and recruitment processes do not differ from the member's primary role, but the member must meet the qualifications for the role they are serving as an alternate for.
- Alternate members are appointed to **serve as a substitute for a regular IRB member** and/or to ensure that the IRB has the appropriate expertise to review research (e.g., prisoner representative, pharmacy representative, etc.).
- The IRB roster designates the member role for which each member may substitute.