for a resolution of the matter. The IO may organize a meeting to help facilitate discussion between the IRB and the PI. While the IO may provide input and make recommendations to the IRB for expeditious resolution of the matter, final recommendations for approval remain under the purview of the IRB.

4. DOCUMENTATION AND RECORDS

4.1 IRB RECORDS

The IRB must prepare and maintain adequate documentation of the IRB's activities including copies of all items reviewed, including, but not limited to:

- research applications
- recruitment materials
- scientific evaluations (if any) that accompany the proposals
- approved consent documents
- records of continuing review activities, including progress reports submitted by investigators
- any proposed amendments and the IRB action on each amendment
- reports of injuries to participants and serious and unexpected adverse events
- documentation of protocol violations
- documentation of noncompliance with applicable regulations
- statements of significant new findings provided to participants
- IRB membership roster(s)
- IRB meeting minutes
- Copies of all correspondence between the IRB and the investigator

IRB records must also document any determinations required by the regulations and protocol-specific findings supporting those determinations, including:

- waiver or alteration of the consent process
- research involving pregnant women, fetuses, and neonates
- research involving prisoners
- research involving children

4.2 IRB MEMBERSHIP ROSTER

A membership list of IRB members must be maintained. It must identify members sufficiently to describe each member's chief anticipated contributions to IRB deliberations. The list must contain the following information about members:

1. Name
2. Earned degrees
3. Affiliated or non-affiliated status (neither the member nor an immediate family member of the member may be affiliated with the university)
4. Status as scientist (physician-scientist, other scientist, non-scientist or social behavioral scientist). For purposes of this roster, IRB members with research experience are designated as scientists (including student and HRCO staff members). Research experience includes training in research (e.g., doctoral degrees with a research-based thesis) and previous or current conduct of research. Students being trained in research fields will be designated as scientists.
5. Indications of experience, such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations.
6. Representative capacities of each IRB member; which IRB member is a prisoner representative (as required by Subpart C), and which IRB members are knowledgeable about or experienced in working with children, pregnant women, individuals with impaired decision-making, and other vulnerable populations locally involved in research.
7. Role on the IRB (Chair, Vice Chair, etc.)
8. Voting status (Any *ex officio* members are non-voting members)
9. Alternate status, including the member they alternate with
10. Relationship (e.g., employment) between the individual IRB member and the organization

The HRPP must keep the IRB membership list current.

4.3 IRB MINUTES

Proceedings should be written and available for review by the next regularly scheduled IRB meeting date. Once approved by the IRB at a subsequent IRB meeting, the minutes must not be altered by anyone.

Minutes of IRB meetings must contain sufficient detail to show:

- Attendance:
  1. names of members present
  2. names of members or alternate members who are participating through videoconference or teleconference and documentation that those attending through videoconferencing or teleconferencing received all pertinent material prior to the meeting and were able to actively and equally participate in all discussions
  3. names of absent members
  4. names of alternates attending in lieu of specified (named) absent members. (Alternates may substitute for specific absent members only as designated on the official IRB membership roster)
  5. names of consultants present
  6. names of investigators present
  7. names of guests present

The initial attendance list shall include those members present at any point during the meeting. The minutes will indicate, by name, those members who enter or leave the meeting. The vote on each action will reflect the number of members present for the vote on that item.

- The presence of a quorum throughout the meeting, including the presence of one member whose primary concern is in a non-scientific area
- Business Items discussed, including review and approval of previous meeting's minutes
- Continuing Education, if any
- Actions taken, including separate deliberations, actions, and votes for each protocol undergoing initial review, continuing review, or review of modifications by the convened IRB
- Votes on these actions (total number voting; number voting for; number voting against; number abstaining; number of those recused)
- Basis or justification for these actions including required changes in research
- Summary of controverted issues and their resolution
- Approval period for initial and continuing approved protocols, assumed to be 12 months unless otherwise indicated
- Risk level of initial and continuing approved protocols

- Review of interim reports, e.g. adverse event or safety reports, amendments, report of violation, etc.
- Review of Data and Safety Monitoring Board (DSMB) summary, if applicable
- Applications that have met or not met requested stipulations
- Protocol-specific documentation that the research meets the required criteria [45 CFR 46.116(d)] when approving a consent procedure that does not include or that alters some or all of the required elements of informed consent, or when waiving the requirement to obtain an informed consent
- Study-specific documentation that the research meets the required criteria [45 CFR 46.117(c)] when the requirements for documentation of consent are waived
- When approving research that involves populations covered by Subparts B, C, or D of 45 CFR 46, the minutes will document the IRB's justifications and findings regarding the determinations stated in the Subparts or the IRB's agreement with the findings and justifications as presented by the investigator on IRB forms.
- Review of COI Committee determinations of conflict of interest and COI management plans.
- Identification of any research for which there is need for verification from sources other than the investigator that no material changes are made in the research (e.g., Cooperative Studies, or other collaborative research).
- Special protections warranted in specific research projects for groups of participants who are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, regardless of source of support for the research.
- A list of research approved since the last meeting utilizing expedited review procedures
- Documentation of approval by the Chair or designee, or documentation of review and approval by a subcommittee of board members as designated by the convened board contingent on specific minor conditions in the minutes of the first IRB meeting that takes place after the date of the approval.
- An indication that, when an IRB member has a conflicting interest with the research under review, the IRB member was not present during the deliberations or voting on the proposal, and that the quorum was maintained.
- Key information provided by consultants will be documented in the minutes or in a report provided by the consultant.

A copy of the IRB-approved minutes for each IRB meeting will be made available to the Institutional Official or the IO's designee.

4.4 DOCUMENTATION OF EXEMPTIONS

Documentation of verified exemptions consists of the reviewer's citation of a specific exemption category and written concurrence that the activity described in the investigator's request for exemption satisfies the conditions of the cited exemption category.

4.5 DOCUMENTATION OF EXPEDITED REVIEWS

IRB records for initial and continuing review by the expedited procedure must include: the specific permissible category, a description of action taken, if any, by the reviewer, and any determinations required by the regulations and study-specific findings supporting those determinations.

4.6 RECORD RETENTION

The above detailed records must be stored securely by the HRCO and must be retained for at least three years after final close-out of the research. IRB records not associated with research or for studies closed without participant enrollment will be retained at the facility for at least three years after closure.

After that time, those records may be securely destroyed. All records must be accessible for inspection and copying by authorized representatives of the OHRP, sponsors, and other authorized entities at reasonable times and in a reasonable manner.

Records are primarily maintained electronically on secure servers and are available only to IRB members, HRCO staff, and senior leadership, as necessary. Some historical documents are maintained in paper format.

5. OBTAINING AND DOCUMENTING INFORMED CONSENT FROM RESEARCH PARTICIPANTS

5.1 PURPOSE

The following procedures describe the requirements for obtaining and documenting consent from participants in research conducted under the auspices of New York University.

5.2 DEFINITIONS

Legally Authorized Representative (LAR):