VSC Research Ethics Committee (REC) Constitution and Operational Guidelines

1. Terms of Reference

The VSC Research Ethics Committee (REC) is delegated authority by the Research Integrity Committee (RIC) to:

- **Develop and Review Guidelines**: Create and periodically review institutional guidelines on research ethics in consultation with RIC and faculties to ensure best practices.
- **High-Risk Proposals**: Review and approve or withhold approval from high-risk research proposals and amendments to approved protocols.
- **Independent Review Panel**: Act as an independent ethics review panel for external applications, delivering either a favorable or unfavorable review.
- **Appeals and Complaints**: Review appeals, complaints, and adverse events related to ethically approved research.
- **Annual Reporting**: Report annually to RIC, summarizing reviewed projects and the effectiveness of current practices.

2. Membership

- **Chair**: An academic member appointed by the Head of RIC, responsible for leading the committee and ensuring adherence to guidelines.
- **Deputy Chair**: At least one, appointed from within the committee, to assist the Chair and act in their absence.
- **Members**: 8-12 members, including the Chair, with at least one lay member and one with no connection to VSC, ensuring diverse perspectives.

3. Operational Guidelines

- **Chair's Review**: Minimum risk applications (light touch) to be reviewed by the Chair, Departmental Ethics Officer, or relevant subcommittee. Borderline cases should be referred to the full board as a matter of course.
- **Term of Office**: Three years, with an option for renewal for an additional year. Members should be rotated to maintain fresh perspectives.
- **Specialist Advice**: The Chair may invite specialists to meetings for advice, but they cannot participate in decision-making.
- **Declaration of Interest**: Members must declare any vested interests, which may disqualify them from discussions. A Register of Members' Interests will be maintained and updated annually.
- **Indemnity**: VSC provides insurance and indemnity for REC members acting in good faith.

4. Review Process

- **Submission**: Researchers submit applications three weeks prior to review dates. Late submissions are not accepted.

- **Initial Screening**: The Chair conducts an initial screening to categorize applications as minimum or high risk.
- **Review Assignment**: Applications are assigned to committee members based on expertise.
- **Review Criteria**: Applications are reviewed based on ethical principles, risk assessment, and compliance with guidelines.
- **Consensus Requirement**: Decisions must be made by consensus between reviewers. If the majority of the board is in agreement, the minority must be consulted to see if they will agree. If consensus cannot be reached, the Chair will have the final decision.
- **Specialist Consultation**: Where appropriate, the Chair may consult specialist advisors on the proposal's inherent risks to facilitate the decision.
- **Feedback**: Detailed feedback is provided to applicants, including reasons for approval, required modifications, or rejection.

5. Annual Reporting

The annual report to RIC includes:

- **Membership List**: Current members and any changes during the year.
- **Procedural Changes**: Details of any changes to procedures or guidelines.
- **Decisions Summary**: A summary of decisions made during the year.
- **Appeals and Complaints**: Reports on any appeals, complaints, and adverse incidents.
- **Committee Function**: An overview of the committee's function, including emerging ethical issues and challenges.

6. Powers of the REC

The REC can:

- **Approve Research**: Without requiring amendments.
- **Approval in Principle**: Grant approval requiring minor amendments.
- **Defer Approval**: Seek further advice before making a decision.
- **Reject Research**: Due to serious ethical flaws.
- **Comprehensive Feedback**: Provide detailed reasons for modifications, rejections, or deferrals.

7. Independent Researchers

The REC can only approve ethical applications for which it is the legal sponsor. Independent researchers can submit applications for a favorable/unfavorable review.

8. Training and Support

- **Training Programs**: Regular training for REC members on ethical guidelines, new regulations, and best practices.

- **Support Resources**: Provide resources such as FAQs, case studies, and decision-making frameworks.

9. Monitoring and Compliance

- **Ongoing Monitoring**: Develop a system for monitoring ongoing research projects to ensure compliance with ethical standards.
- **Incident Reporting**: Establish clear procedures for reporting and addressing ethical breaches or adverse events.

10. Technology Utilization

- **Data Security**: Ensure compliance with data security and privacy regulations.

11. Communication Protocols

- **Internal Communication**: Establish clear protocols for internal communication among REC members.
- **External Communication**: Define procedures for communicating decisions and feedback to researchers.

12. Inclusivity and Diversity

- **Diverse Membership**: Encourage a diverse membership to bring different perspectives and expertise to the committee.
- **Inclusive Practices**: Implement practices that ensure all members have an equal opportunity to contribute to discussions and decisions.

13. Ethical Oversight

- **Ethical Standards**: Maintain high ethical standards in all REC activities.
- **Compliance**: Ensure all research projects comply with ethical guidelines and regulations.