IBC Document Development, Review, and Control Policy

Document Number: **IBC-POL-001-V1-Document Development**

Effective Date: 2/10/2026 Last Updated: 2/10/2026 Next Review: February 2029

1. Purpose

This policy establishes the framework and standardized procedures for the development, review, approval, and maintenance of the Institutional Biosafety Committee (IBC) for the Ithaca, Agritech, and Tech campuses documents. It ensures consistency, quality, and appropriate oversight in the creation and management of IBC policies, guidance documents, and forms.

1.1 The objectives of this policy are to:

- Establish a systematic approach to document development and control
- Define clear roles and responsibilities in the document management process
- Ensure compliance with institutional and regulatory requirements
- Maintain document integrity through version control
- Provide transparency in the document approval process
- Facilitate efficient document retrieval and access

- Ensure regular review and updates of IBC documents

1.2 This policy applies to all documents that:

- Govern IBC operations and procedures
- Provide guidance for IBC-related activities
- Support the implementation of IBC policies
- Document IBC decisions and processes

2. Scope

This policy applies to the following types of IBC documents:

2.1 Document Types

A. Policies

- Formal documents that establish IBC requirements, responsibilities, and standards
- Documents requiring full IBC committee review and approval
- Documents that govern institutional biosafety practices and procedures

B. Guidance Documents

- Supporting documents that provide detailed instructions or clarification of policies
- Technical guidance materials
- Educational and training materials

C. Forms

- Standardized documents used to collect information
- Checklists and assessment tools
- Documentation templates

2.2 Document Coverage

This policy encompasses the entire document lifecycle, including:

- Initial development and drafting
- Review and revision processes

- Approval procedures
- Implementation
- Periodic review
- Document retirement or archival

2.3 Exclusions:

This policy does not apply to:

- Individual MUA submissions
- Meeting minutes and administrative records
    - Meeting minutes refer to Policy IBC-POL-003
- Correspondence and communications
- External documents not created by the IBC
- EHS Policies and Procedures
- Weill Cornell Medicine IBC and employees

3. Definitions

3.1 Policy

A formal, written document that communicates standards, requirements, and responsibilities related to institutional biosafety. Policies require full IBC committee review and approval through a formal voting process.

3.2 Guidance Document

A document that provides detailed information, instructions, or clarification to support the implementation of IBC policies. These documents are typically procedural in nature and may be modified as needed to ensure effective policy implementation.

3.3 Form

A standardized document designed to collect specific information in a consistent format for IBC purposes. Forms support policy implementation and administrative procedures.

3.4 Version Control

The management system used to track and maintain document versions, including revision history, modification dates, and approval status.

3.5 Document Owner
The individual or group responsible for the creation, maintenance, and regular review of a document. For IBC documents, this is typically IBC staff unless otherwise noted.

3.6 Approval Authority
The person(s) or body with the authority to approve different types of documents:

- For Policies: Full IBC Committee
- For Guidance Documents: IBC Staff, with input from relevant experts as needed
- For Forms: IBC Staff, with input from relevant experts as needed

3.7 Controlled Document
An official document that is maintained and updated according to this policy and requires version control.

3.8 Document Review Cycle
The established timeframe for systematic review and assessment of documents to ensure continued relevance and accuracy.

3.9 Effective Date
The date when a new or revised document becomes active and enforceable.

4. Roles and Responsibilities

4.1 IBC Staff

- Initiate and draft new documents or revisions to existing documents
- Maintain document control system and archives
- Coordinate document review process
- Track document versions and maintain revision history
- Ensure proper document formatting and consistency
- Implement and distribute approved documents
- Monitor review cycles and initiate periodic reviews
- Maintain document repository and ensure accessibility
- Distribute draft documents to committee members ahead of meeting

4.2 IBC Chair

- Review draft policies prior to committee presentation

- Provide subject matter expertise and guidance when applicable
- Facilitate committee discussion of proposed policies
- Ensure policies align with institutional mission and regulatory requirements
- Participate in periodic review of policies

4.3 Director of Research Assurance

- Review draft policies for alignment with institutional practices
- Ensure consistency with other institutional policies and procedures
- Provide guidance on policy content and implementation
- Review potential impacts on research community
- Participate in policy development and review process

4.4 EHS Biosafety

- Review documents for biosafety compliance
- Provide technical expertise and guidance
- Ensure alignment with biosafety regulations and best practices
- Contribute to development of safety-related procedures
- Participate in document review process as needed

4.5 Subject Matter Experts

- Provide specialized knowledge and expertise as needed
- Review documents within their area of expertise
- Recommend technical or procedural modifications
- Assist in developing guidance documents and forms

4.6 IBC Committee Members

- Review proposed policies
- Participate in policy discussions
- Vote on policy approval
- Provide feedback and suggestions for improvements

- Participate in periodic review of policies

4.7 Document Users

- Follow procedures outlined in approved documents
- Provide feedback on document usability and effectiveness
- Submit suggestions for improvements or modifications
- Use current version of each document

5. Document Development and Approval Process

5.1 Policies

see Appendix 1 for summary of process

A. Initial Development

- Need for new policy or revision is identified
- IBC Staff develops initial draft
- Draft follows standardized template and formatting requirements
- References and regulatory requirements are documented

B. Review Process

1. Internal Review

- Draft review by IBC Staff for completeness and clarity
- Technical review by relevant subject matter experts
- Review by IBC Chair
- Review by Director of Research Assurance
- Review by EHS Biosafety
- Incorporation of feedback and revisions

2. Committee Review and Approval

- Policy distributed to IBC committee members prior to convened meeting
- Policy presented at convened IBC meeting
- Discussion by committee members

- Formal vote with one of four outcomes:
    - Approved as written
    - Approved with minor revisions
    - Returned for major revisions and re-review
    - Rejected
- Documentation of vote in meeting minutes

C. Implementation

- Final formatting and assignment of version number
- Master copy saved to IBC Staff Teams Documents folder
- Posting of approved version to IBC website
- Distribution of access to affected parties
- Training or education as needed
- Archival of superseded versions

5.2 Guidance Documents

A. Development

- Created to support approved policies
- Drafted by IBC Staff
- Review by relevant subject matter experts
- Approval by IBC Staff

B. Implementation

- Version control applied
- Added to document control system
- Notify users of new document
- Updates as needed to maintain alignment with policies

5.3 Forms

A. Development

- Created to support policies and procedures
- Drafted by IBC Staff
- Review for usability and completeness
- Testing with end users as appropriate

B. Implementation

- Version control applied
- Added to document control system
- Distribution to users
- Updates as needed based on user feedback

5.4 Document Modifications

Policies and guidance documents must include this section; forms are exempt.

A. Administrative Updates

- Minor corrections (typographical errors, formatting, grammar, and similar)
- Contact information updates
- URL updates
- Can be implemented by IBC Staff
- Version number increased by a decimal point (ex. V1.1 to V1.2)
- Changes documented in “Changes from previous version” section of policy

B. Substantive Changes

- Changes affecting requirements, procedures, or content
- Must follow full review and approval process
- Requires new version number (V1 to V2)
- Changes documented in revision history

5.5 Website Management

A. Document Posting

- IBC Staff responsible for maintaining current documents on website
- New or revised documents posted to website following approval
- Website to maintain clear organization of policies, guidance documents, and forms

B. Website Maintenance

- IBC Staff ensures posted documents are current
- Outdated documents and links to them removed from website when replaced by new versions
    - Archived documents are watermarked with “Retired”
- Previous versions available upon request from IBC Staff

C. Implementation

- Documents become effective upon website posting unless otherwise specified
- IBC Staff to communicate significant document updates to affected parties as needed
- Training or transition periods communicated if required

5.6 Implementation and Effective Dates

A. Standard Implementation

- Documents become effective upon posting to IBC website unless otherwise specified
- Implementation date may be delayed if training or system updates needed
- Delayed implementation dates will be clearly noted on document

B. Grace Periods

- May be established when significant procedural changes are required
- Duration determined based on complexity of changes
- Communicated clearly to affected parties

C. Transition Process

- Current processes remain in effect until new version implemented
- IBC Staff to address questions during transition

- Additional guidance provided as needed during implementation phase

6. Version Control

6.1 Document Identification

Each controlled document shall include:

- Unique document identifier
- Title
- Version number
- Effective date
- Page numbers, and
- Document type.

6.2 Document Coding System

Documents shall follow this format: IBC-[TYPE]-[Number]-[Version]-[Short descriptive title]

Document Type Codes:

- POL = Policy
- PRO = Procedures/Training Materials/Guides
- FORM = Forms and Templates

Numbering: Three-digit sequential number (001, 002, etc.), assigned chronologically within each type.

Version Designation:

- Major versions: Whole numbers (V1.0, V2.0) for significant changes requiring committee approval
- Minor versions: Decimal increments (V1.1, V1.2) for editorial changes
- Draft versions: Add 'DRAFT' suffix (e.g., V1.0_DRAFT)

6.3 Changes from Previous Version

Each controlled document must include a “Changes from Previous Version” section. This section will summarize all modifications since the prior approved version, including:

- **Administrative updates** (e.g., formatting, typographical corrections, grammar, clarity, contact information changes), and the like.
- **Substantive changes** (e.g., new requirements, procedural updates). For major revisions, include a brief rationale for the change and reference the previous version number.

This will always be the final section of the policy.

Example template:

Version	Effective Date	Summary of Changes	Previous Version

6.4 Document Status Indicators

- DRAFT = Under development
- UNDER REVIEW = Submitted for review/approval
- APPROVED = Current active document
- RETIRED = Retained for historical purposes and no longer in effect

6.5 Document Access and Distribution

- Master copies maintained in IBC Staff Teams Documents folder
- Current versions posted on IBC website for public access
- Retired versions stored in Teams archive folder with no public access
- Email notification to relevant parties when significant updates occur
- IBC Staff to maintain current versions on website and retired versions in archives

6.6 Electronic File Storage

Files shall be stored using the official document code as the file name: Example: IBC-POL-001-V1-PI Eligibility-DRAFT

6.7 Version Control Documentation

Maintain a master list of all controlled documents including:

- Current version number
- Last review date
- Next review date
- Document owner
- Approval status

7. Document Retention and Archival

7.1 Document Storage, Access, and management

A. Active Documents

- Current approved versions will be posted on the IBC website for public access
- Master copies maintained in IBC Staff Teams Documents folder
- Edit access restricted to IBC Staff

B. Retired Documents

- Retired versions moved to "Archived" subfolder within Teams
- Retired documents maintained for reference and continuity
- Accessible only by IBC Staff

7.2 Retention Periods

- Active documents maintained until superseded
- Retired versions retained for minimum of 3 years
- Longer retention periods may be implemented as needed

8. Review Frequency

8.1 Regular Review Schedule

A. Policies

- Full review required every three (3) years from effective date
- Review date tracked by IBC Staff
- Earlier review may be initiated if needed

B. Guidance Documents

- Administrative review every three (3) years from effective date
- Review when related policy is updated
- Review if operational changes require updates
- Earlier review may be initiated if needed

C. Forms

- Administrative review annually for functionality and accuracy
- Update as needed based on user feedback
- Review when related policy or guidance is updated
- Earlier review may be initiated if needed

8.2 Triggered Reviews

Reviews may be initiated before scheduled review date due to:

- Changes in regulations or institutional requirements
- Identification of process improvements
- User feedback
- Operational changes
- Safety concerns
- Internal and external feedback

8.3 Review Process

- IBC Staff to maintain review schedule
- Review process follows Section 5 procedures for respective document types
- Documentation of review completion required even if no changes made

8.4 Review Documentation Minimum documentation of review to include:

- Date of review
- Reviewer(s)
- Outcome (no changes, minor updates, major revision)
- Next scheduled review date

9. Document Format Standards

9.1 General Format Requirements

All IBC documents shall include:

- Header with document code and title
- Version number and effective date
- Page numbers
- Review/revision date
- Clear section headings and numbering

9.2 Document Templates

A. Policies

- Standard IBC policy template
- Required sections:
    - Purpose
    - Scope
    - Definitions (if applicable)
    - Policy Statement/Requirements
    - Roles and Responsibilities
    - Procedures (if applicable)
    - References (if applicable)
    - Changes from previous version (forms do not require this section)
    - Appendices (if applicable)

B. Guidance Documents

- Consistent format for ease of use
- Clear step-by-step instructions
- Visual aids or diagrams as needed
- References to related policies

- Changes from previous versions

C. Forms

- Clear instructions
- Logical flow of information
- Consistent formatting
- Required fields clearly marked

9.3 Writing Style

- Clear, concise language
- Active voice
- Consistent terminology
- Defined acronyms
- Numbered or bulleted lists for clarity

9.4 Accessibility

- Documents formatted for easy online viewing
- PDF format for posted documents
- Compliant with institutional accessibility requirements

10. References

10.1 Related Institutional Policies and Requirements

- Institutional Records Retention Policy
- University Accessibility Standards

10.2 Regulatory Requirements

- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- Biosafety in Microbiological and Biomedical Laboratories (BMBL)

10.3 IBC Documents

- IBC Charge

11. Changes from previous version

This section will be used to document changes made to this policy after approval. Refer to **Section 6.3** for detailed formatting requirements.

Version	Effective Date	Summary of Changes	Previous Version

Appendix 1

IBC Document Review Process and Responsibilities

Step	Responsible Party	Key Responsibilities
Initial Drafting	IBC Staff	Identify need, draft document using template, include references and regulatory requirements
Internal Review	IBC Staff	Check completeness and clarity; coordinate review process
	Subject Matter Experts	Provide technical and procedural feedback
	EHS Biosafety	Ensure biosafety compliance and alignment with regulations
	Director of Research Assurance	Validate institutional compliance and consistency
	IBC Chair	Review draft for alignment with mission and regulatory standards
Committee Review	IBC Committee Members	Draft distributed to members ahead of meeting by IBC staff. Discuss draft, vote (approve, approve with revisions, return, reject), document outcome
Final Approval	IBC Staff	Assign version number, save master copy, post on website, notify stakeholders, archive old versions
Implementation	IBC Staff	Track review schedule, initiate reviews, document outcomes
Periodic Review	IBC Chair & Committee	Participate in policy review and updates