WCM Administrative Policy and Procedure	
Policy Title	Policy Management
Policy Number	CPO-C-400.07
Department/Office	Office of Compliance
Effective Date	July 30, 2024
Last Reviewed	N/A
Approved By	Clinical Compliance Oversight Committee (CCOC)
Approval Date	July 30, 2024

Purpose

The purpose of this policy is to establish a comprehensive framework for Weill Cornell Medicine's (WCM) policy management system which include centralization, standardization, policy development, review and approval processes, communication, and education.

Policy

In accordance with the rules established by the U.S. Department for Health and Human Services (HHS), WCM is committed to establishing and maintaining an effective policy management system. Under WCM's Compliance and Privacy Office, the Policy Office will establish a systematic process to manage its policies and procedures and ensure the standardization of administrative, clinical, research, and academic policies and procedures as well as Supplemental Documents.

WCM's policies and procedures (herein referred to as "Policies") serve as an essential tool for decision-making, defining workflows, delineating individual and organizational roles and responsibilities, mitigating risks, ensuring compliance with applicable laws, rules and regulations, as well as standardized practices. Through clear, consistent, and compliant Policies, WCM's objective is to foster a culture of compliance in line with its mission, vision, and values.

All WCM administrative, clinical, research and academic policies, as well as applicable Supplemental Documents, are subject to the policy management processes outlined in this policy. The *Policy Management Guidelines* should be used as instructional guidance on drafting new policies and revising existing policies.

WCM's policy management system will facilitate routine and non-routine review of WCM Policies. All WCM Policies shall be routinely reviewed at least biannually (every two years), or as otherwise required by regulation, regardless of whether Substantial Changes are necessary. Non-routine review may occur when new Policies are developed, or existing Policies require necessary updates outside of the time frame for the routine review process. The Expedited Policy review and approval process is a type of non-routine review which allows new or revised Policies to receive fast-tracked provisional approval status due to the time-sensitive institutional need for the new or revised Policy.

Scope

This policy applies to all WCM Workforce Members as defined in this policy.

Definitions

Affected Individuals – Individuals whose roles, responsibilities or activities are within the scope of the policy. Affected Individuals include but are not limited to: Workforce Members, board members, patients, customers, contractors, sub-contractors, agents, or other individuals impacted by the policy as determined by WCM.

Guideline – A narrowly tailored informational document associated with a particular policy, or set of policies, that provide instructions, recommendations, interpretations, best practice guidance, or framework to support policy implementation.

Interim Policy – A new or revised policy that is published with a limited and fast-tracked policy approval process due to the time sensitive institutional need for the policy.

Policy – A clear and concise statement designed to establish governing institutional principles, requirements, expectations, and rules.

Policy Owner – The department or Office responsible for creating, maintaining, communicating and enforcing compliance with a Policy or a set of Policies.

Procedure – Detailed steps, processes and/or actions to be followed by the individuals within the scope of the policy that guide implementation or demonstrate compliance with the policy.

Published Policy – A new or revised policy is published when the final and approved policy is made available to all affected individuals within the scope of the policy.

Stakeholder – Designated institution leadership, departments, Offices and/or Committees that have an interest, concern or are a subject matter expert of a particular policy.

Substantial Changes – Revisions made to a policy that directly impacts operations, procedures, requirements, and expectations of the Affected Individuals. All new policies developed will be considered a Substantial Change.

Supplemental Documents – Documents that are directly associated with a particular Policy such as appendices, regulatory forms, consent forms, regulatory notices and/or informational documents. Supplemental Documents shall be published along with its corresponding Policy and subject to the review and approval processes outlined in this Policy.

Supporting Documents – Documents that support the implementation or compliance with a Policy. Supporting Documents include Guidelines, toolkits, internal standard operating procedures (SOP), handbooks and other resources. Supporting Documents designed for instructional use by the Policy Owner may be maintained internally only if the information is not relevant to all Affected Individuals within the scope of the Policy (i.e., internal SOP). Other Supporting Documents intended to serve as guidance for Policy compliance and implementation to the Affected Individuals shall also be Published along with the corresponding Policy (i.e., handbook, manual, Guidelines, toolkits, charts, etc.). Supporting Documents may also serve as an educational tool, be updated as necessary and are not subject to the review and approval processes outlined in this Policy.

Tripartite Policies – Policies developed and owned by NewYork-Presbyterian Hospital (NYPH) and Columbia Doctors and Weill Cornell Medicine.

Workforce Members – includes full-time or part-time employees, faculty, physicians, students, interns and volunteers. Non-employees, including agency or contracted staff and vendors (such as BAs) are also included.

Procedure

A. General

The development of new WCM Policies, Policies due for routine review or Policies with non-routine updates, whether Substantial or non-substantial, are subject to the policy review and approval processes outlined in this Policy.

a. Roles and Responsibilities

<u>Policy Owners</u>

WCM Departments and Offices that develop and maintain Policies, or a set of Policies, are considered Policy Owners. For each policy, there shall be one Policy Owner. Policies in which more than one Department or Office collaborated to develop the policy, the primary Department or Office responsible to implementation and enforcement of the policy, shall be the designated Policy Owner. Policy Owners are responsible for creating and owning the content of their Policies and Supplemental Documents. Policy Owners may designate an individual within the Department or Office to manage their Policies and ensure active engagement in the established policy management processes set forth in this policy. Policy Owners are also responsible for reviewing their set of Policies to ensure the content of Policies are current and compliant with applicable laws and regulations. When drafting or revising Policies, Policy Owners shall engage relevant Affected Individuals, including Stakeholders and subject matter experts, for input. Policy Owners shall internally maintain retired Policies, archived Policies, active Policies as well as all draft and finalized versions. When new or revised Policies are approved, Policy Owners are responsible for ensuring that new Policies and Substantial Changes to existing Policies are appropriately communicated to Affected Individuals and understood by Affected Individuals. New and/or revised Policies with Substantial Changes may require the need to implement a training and education plan, which is to be developed by the respective Policy Owner. To facilitate Policy implementation and compliance, Supporting Documents may be developed and used as part of the Policy training and education materials..

<u>Policy Office</u>

The Policy Office will provide guidance and advice to Policy Owners on the application of this Policy as well as the implementation of the policy management processes for new and revised Policies as well as Supplemental Documents. The Policy Office will facilitate standardization, centralization, routine (and non-routine) review and approval processes for all WCM Policies. The Policy Office may review Policies under development to ensure proper formatting, clarity of language, use of standardized policy language, consistency with other WCM, Cornell University and NYP Tripartite policies and offer suggestions for improvement.

The Policy Office is the custodian of all active WCM Policies. The Policy Office will maintain and publish active WCM Policies on WCM's Compliance and Privacy Office website.

B. Policy Standardization

a. Policy Template

In effort to communicate clear expectations and guidance to Workforce Members, WCM Policy Office instituted a standardized policy template in which all WCM Policies shall be formatted. All WCM Policies shall be drafted on the approved WCM policy template and include each of the following sections:

- Policy Title
- Policy Number
- Department
- Effective Date
- Last Reviewed Date
- Approved By
- Approval Date
- Policy
- Purpose

- Scope,
- Definitions
- Procedure
- Compliance with this Policy
- Contact Information
- References
- Policy Approval
- Version History

b. Standardized Policy Language

To improve consistency in Policies, WCM's Policy Office may standardize language used universally in various policy sections such as the "Scope," "Definitions," and "Compliance with this Policy" sections. Common WCM acronyms, regulatory and legal terminology, industry-specific terms, and other common institutional terms may be approved as standardized definitions.

WCM Policy Office will maintain a list of standardized definitions. Each Policy will be reviewed for the appropriate a standardized language prior to its Publication. Changes made to a standardized definition will be considered a Substantial Change.

c. Naming and Numbering Convention

The Policy Office has established a naming and numbering convention to facilitate standardization, clarity and accessibility of all WCM Policies. WCM Policies will be assigned a name in accordance with the overarching policy group, general Policy subject matter and alignment with applicable Cornell University Policies.

WCM Policies will be assigned a policy number in accordance with the Policy Numbering Convention. Policy numbers contain three parts: (i) letters identifying the WCM Department or Office that owns the Policy, with additional letters identifying policy sub-groups, if applicable; (ii) a three digit numeric identifier unique to the respective WCM policy group and policy sub-group, followed by a period; and (iii) a second numeric identifier, after the period, unique to the specific Policy that also denotes the sequential order of the Policy in its overarching policy group or sub-group.

C. Policy Development

The WCM Policy management process accommodates the dynamic need for policy development. Policy Owners should consider the development of new Policies when there are significant changes to expectations or requirements that impact Workforce Members and/or other Affected Individuals institution wide. Significant changes include, but are not limited to:

- New or updated legal and regulatory requirements;
- Address operational needs and/or identified risks;
- Fill identified policy gaps with applicable University or NYP Tripartite Policies;
- Response to corrective actions; and
- Replace retired Policies and/or consolidate similar Policies.

WCM Departments and Offices planning to develop a new policy must first notify the Policy Office and subsequently other Stakeholders as outlined in the *Policy Management Guidelines*. The Department or Office that drafts the new Policy and is responsible for enforcing the Policy will be considered the Policy Owner. After approval, the Department or Office seeking the new policy shall follow the procedures for policy development set forth below. The policy should be developed by the Policy Owner, and in collaboration with other Stakeholders, if applicable.

D. New or Revised Policy Drafts and Formatting

When developing new Policies or revising existing Policies, Policy Owners must ensure the appropriate standardized policy template is used. WCM's Policy Office will assign new or revised policy drafts with an appropriate policy number consistent with the Department or Office's naming and numbering convention.

Policy language shall be carefully written to clearly communicate requirements and expectations to the Affected Individuals within the scope of the Policy. Policies that are driven by legal or regulatory requirements should not be drafted to restate the law but drafted to simplify the requirements in a comprehensible manner. If use of jargon, regulatory/legal terms or complex topics are necessary, such terminology must be clearly defined or explained. Policy owners drafting new policies should consult with the Policy Office on use of standardized definitions to avoid variances in definitions.

When drafting new or revised Policies, Policy Owners should review related WCM Policies, Cornell University Policies and NYP Tripartite Policies to ensure consistency and alignment. Substantively, WCM policies must not contradict any related WCM, Cornell University or NYP Tripartite policy. In the event there is a potential contradiction with a drafted WCM Policy, the Policy Owner shall collaborate with WCM's Policy Office and respective Policy Owners to address accordingly.

E. Policy Review and Approval

WCM's Policy Office established a systematic policy review and approval process detailed in the *Policy Management System Guidelines*. The policy review and approval process provides for a review period in which the Policy Office and relevant Stakeholders in each WCM Department and Office will be notified of the new or revised Policy and have an opportunity to review and comment on the Policy prior to its approval.

A Policy will be considered "reviewed and approved" when:

(i)   all relevant Stakeholders had an opportunity to make comments and suggestions for revisions,
(ii)   the Policy Owner revised the Policy draft to incorporate agreed upon suggested revisions, and
(iii)   the relevant Stakeholders have no further suggestions for material revisions to the final Policy draft.

When the final draft of a Policy is deemed "reviewed and approved," the Policy Owner is responsible for formatting the draft to its finalized version, updating the necessary review dates on the Policy, archiving the former version of the Policy and ensuring the new or revised Policy is appropriately Published. A WCM Committee with approval authority, or desginated group of WCM leadership, to be determined by the Policy Office shall be appointed to provide final approval of the Policy.

a. Routine Review

All WCM Policies shall be reviewed and approved at least biannually, or as otherwise required by regulation. The review date shall be calculated from the "last review date" as documented on each Policy. Each Policy shall undergo a routine review process even if there are no substantive changes to the Policy. During each routine review cycle, Policies should be checked to ensure the current standardized template and policy language is used.

b. Non-Routine Review

At any time, Policy Owners may seek review and approval of an existing Policy with Substantial Changes outside of the scheduled time frame for the Policy's routine review. Non-routine review should only be requested when time sensitivity for the Policy update is not at issue. Policies may also be submitted for non-routine review when a Policy is updated to align with the Policy Office's standardized format (template, language, definitions, alignment with other Policies), regardless of Substantial Changes.

c. Expedited Review – Interim Policies

In limited circumstances when the policy review and approval process may impede the implementation of a necessary policy update or development, the Policy Office may grant fast-tracked approval for an Interim Policy. As determined on a case-by-case basis, fast-tracked approval for a new or revised Policy may be permitted when there is a time-sensitive institutional need for the following reasons:

  i.   Changes to applicable regulatory/legal statutes or requirements
  ii. Results from an internal or external audit
  iii. Identified risks
  iv. Part of a corrective action plan
  v.   Emergency management needs (including Public Health emergencies); or
  vi. Other time-sensitive departmental needs

As a general rule, a matter will be considered "time-sensitive" for purposes of an expedited Policy review and approval when the Policy must be Published and made available to the Affected Individuals in less than three (3) months.

Interim Policies shall be reviewed and approved by the relevant Stakeholders prior to publication. After publication of the Interim Policy, the Policy Owner shall submit the Interim Policy for final review and approval by all other Stakeholders who were not initially involved in the Policy draft or revisions. If no changes are made to the Interim Policy, final approval will be granted, and the Interim Policy will no longer be considered "provisional." All Interim Policies should be accompanied by a Policy Communication Tool, and education plan, when necessary, as described in Section E of this Policy.

F. Communication and Education

WCM Workforce Members shall be notified, as applicable, when new Policies or revised Policies with Substantial Changes are Published. Communication of such Policy updates may be issued in an appropriate form to reach all Affected Individuals such as: an institution-wide distribution email; publication on the WCM Intranet and Internet (for applicable Policies); presentation to relevant Committee and leadership meetings; and internal departmental team meetings.

Policy Owners must complete and submit the Policy Communication Tool with the final Policy draft for approval. The Policy Communication Tool will summarize the purpose for the new, or revised sections, of the Policy. It should also include the scope of the Affected Individuals, key points, procedural changes and other significant information relevant to the Affected Individuals. Stakeholders and Department/Office leadership may disseminate The Policy Communication Tool, along with the Policy, as a means of Policy awareness. The Policy Office will communicate all Policy updates to Cornell University and relevant entities.

Communications should include:

- A copy of the new or revised Policy
- Supplemental Documents (if applicable)
- Policy Communication Tool
- Required training and time frame for completion (if applicable)
- Educational materials
- Contact information for additional Policy guidance

New or revised Policies with Substantial Changes may require the need to implement an education plan to ensure Workforce Member awareness and understanding of new requirements, expectations or procedures. Policy Owners are responsible for developing the education plan which includes the content, materials, format, assessment (if necessary) and implementation of the plan. Departmental leadership may be required to conduct further education on specific departmental procedures related to the Policy. Additionally,

new Policies or revised Policies with Substantial Changes may require the need to update existing training and education materials such as the new hire orientation, annual Compliance training and other routine trainings.

G. Policy Retention and Version Management

WCM's Policy Office will maintain a centralized repository of all policies for easy access by workforce members and relevant individuals. The Policy Office will separately maintain a centralized archive of retired and expired policies. Policy Owners are responsible for version management of their set of owned Policies and Supplemental Documents which include drafts, final and approved versions, expired and retired versions, as well as associated policy management documents (i.e., policy communication tools, education plans, etc.).

Compliance with this Policy

All WCM Workforce Members are responsible for adhering to this policy. Failure to comply will be evaluated on a case-by-case basis and could lead to corrective action, up to and including termination, consistent with other relevant WCM and University Policies. Instances of non-compliance that potentially involve a lapse of professionalism may lead to engagement of the Office of Professionalism for evaluation and intervention.

Contact Information

For inquiries or assistance regarding WCM policy management, please contact the WCM Policy Office at PolicyOffice@med.cornell.edu.

To report a known or suspected Compliance concern anonymously, you may contact the Cornell Hotline at the following:
- Website: www.hotline.cornell.edu
- Phone Number: 866-293-3077

References

University Policy 4.1 – *Development and Issuance of University Policies*

Policy Approval

This policy was reviewed and approved by the Clinical Compliance Oversight Committee (CCOC).

Version History

Date	Author	Revisions
07/30/2024	Office of Compliance	Original date of issue.