

## BYLAWS

### Clinical Research Standard Operating Procedure (SOP) Collaboration Group University of Utah

Adopted October 7, 2022

<b>ARTICLE I</b>	<b>NAME OF ENTITY</b>
<b>Section 1.</b>	The name of this entity shall be the <i>University of Utah Clinical Research SOP Collaboration Group</i> ("CRCG").
<b>ARTICLE II</b>	<b>PURPOSE</b>
<b>Section 1.</b>	The purpose of this entity is to create and maintain standard operating procedures (SOPs) for all clinical research conducted at the University of Utah. These SOP(s) are developed to ensure consistency in the conduct of critical research activities, adherence with Good Clinical Practice (GCP) guidelines, and compliance with federal, state, and local regulations common to all types of clinical research.
<b>ARTICLE III</b>	<b>AUTHORITY</b>
<b>Section 1.</b>	This entity operates under the authority of the Office of the Associate Vice President for Research Integrity & Compliance and the direction of the Office of Quality Compliance (OQC).
<b>Section 2.</b>	This entity will comply with all University of Utah policies and regulations.
<b>Section 3.</b>	This entity may establish Standing Rules to govern administrative and procedural matters (such as time and location of meetings, etc.). Standing Rules shall not conflict with these bylaws. Standing Rules may be adopted, amended, or temporarily suspended by a majority vote of the membership.
<b>ARTICLE IV</b>	<b>APPLICABILITY AND ADHERENCE</b>
<b>Section 1.</b>	The Clinical Research SOPs are applicable to all individuals that are conducting or contributing to the performance of clinical research at the University of Utah.
<b>Section 2.</b>	Campus-wide adherence to all CRCG SOPs is expected and every effort should be made to adhere to the principles and processes outlined in these SOPs.
<b>Section 3.</b>	Department/division SOPs that are of the same topic and similar processes should be retired, and the CRCG SOPs should be implemented.
<b>Section 4.</b>	Department/division SOPs that are of a different topic can be utilized as long as they do not contain contradicting principles and processes to those established by the CRCG SOPs.
<b>Section 5.</b>	If additional details or processes specific to an individual department/division are needed, Working Guidelines should be developed to supplement the CRCG SOPs. However, department/divisional Working Guidelines should not conflict


	with the SOPs in the CRCG library and should follow the same basic principles and standards.
<b>Section 6.</b>	<p>If an exception to an SOP is needed, a department/group may have SOPs that contain contradictory processes. In such rare instances, the department should document, in writing, what part of the SOP cannot be adhered to, the alternative process that will be followed, and why the alternative process is necessary for their department/group.</p> <p>Before implementing any SOPs containing contradictory processes, the department/group should consult the CRCG regarding the alternate SOP.</p>
<b>ARTICLE V</b>	<b>MEMBERSHIP</b>
<b>Section 1.</b>	Membership will be comprised of qualified and experienced clinical research professionals working in compliance-related roles at the University of Utah—across both Health Sciences and Main campuses.
<b>Section 2.</b>	Membership appointments are made by the Director of the Office of Quality Compliance.
<b>Section 3.</b>	<p>Members are responsible for actively contributing to the development of clinical research SOPs, including identifying SOP gaps/needs, drafting new content, updating and revising existing SOPs, and marketing/advertising SOP development to increase awareness and adherence to clinical research SOPs.</p> <p>The decision to develop and/or revise an SOP requires a majority vote (i.e., greater than 50%) of the voting membership in attendance at a regularly-scheduled or ad hoc meeting.</p>
<b>Section 4.</b>	Non-members with special experience and/or knowledge may be invited to attend meetings in order to advise and/or contribute to the development of clinical research SOPs. This will occur on an as needed basis, as proposed by one or more of the appointed members and upon approval by the President of the CRCG.
<b>Section 5.</b>	There shall be no dues or fees for membership in this entity.
<b>Section 6.</b>	The CRCG and its members will comply with <a href="#">Interim Policy 1-012: University Non-discrimination Policy</a> .
<b>ARTICLE VI</b>	<b>OFFICERS</b>
<b>Section 1.</b>	The officers of the entity shall be the President, Chair, Administrator, Marketing/Communication Lead, and Finance Lead.
<b>Section 2.</b>	<p>Positions and Duties of Officers</p> <ol style="list-style-type: none"> <li>a. The CRCG President shall: <ol style="list-style-type: none"> <li>i. serve as chief executive officer</li> <li>ii. preside at meetings (when in attendance)</li> </ol> </li> </ol>

	<ul style="list-style-type: none"> <li>iii. define official vision for the organization, representing the policies, views, opinions, and activities of the entity</li> <li>iv. appoint members</li> <li>v. have further powers and duties as prescribed by the entity</li> </ul> <p>b. The Chair shall:</p> <ul style="list-style-type: none"> <li>i. prepare meeting agenda</li> <li>ii. track searches performed on Google, Pulse, and other search platforms to identify University SOP needs for development</li> <li>iii. preside at meetings when the President is not in attendance</li> <li>iv. act as an official spokesperson, articulating vision, policies, views, opinions, and activities, as defined by the President</li> </ul> <p>c. The Administrator shall:</p> <ul style="list-style-type: none"> <li>i. take minutes at all meetings, and maintain minutes on file</li> <li>ii. be responsible for filing/documenting internal and external correspondence</li> <li>iii. maintain membership records</li> <li>iv. monitor CRCG group email (<a href="mailto:crcg@utah.edu">crcg@utah.edu</a>) and route/reply to emails, as appropriate and able</li> </ul> <p>d. The Marketing &amp; Communication Lead shall:</p> <ul style="list-style-type: none"> <li>i. complete a quarterly update on the “Updates to Clinical Research SOPs” webpage</li> <li>ii. notify University newsletter and blog partners of all new posts to the “Updates to Clinical Research SOPs” webpage</li> <li>iii. update the listserv(s) quarterly</li> </ul> <p>e. The Finance Lead shall:</p> <ul style="list-style-type: none"> <li>i. lead development of CRCG SOP content relating to clinical research fees, budget creation, and analysis (“finance”)</li> <li>ii. ensure that all CRCG SOP finance content is compliant with all applicable regulations and policies</li> <li>iii. perform annual review of all CRCG finance SOPs</li> <li>iv. oversee all University communications relating to finance standards and procedures established by CRCG SOPs</li> </ul>
<b>ARTICLE VII</b>	<b>SELECTION OF OFFICERS</b>
<b>Section 1.</b>	The office of the CRCG President is a non-elected position occupied by the Director of the Office of Quality Compliance (OQC).
<b>Section 2.</b>	Remaining officers will be nominated from the roster of current members. Members may nominate themselves or another member for an office.
<b>Section 3.</b>	The officers shall be elected in this order: Chair, Secretary, Marketing/Communication Lead, and Finance Lead.
<b>Section 4.</b>	Officers will be elected at the first regularly-scheduled meeting at the beginning each calendar year.

<b>Section 5.</b>	Nominations for officers shall be made at the last regular meeting immediately preceding the election (i.e., at end of preceding calendar year) and/or from the floor at the time of election.
<b>Section 6.</b>	Officers shall be elected by majority vote (i.e., greater than 50%) of the voting membership in attendance at the 'election meeting', as defined in Section 4 of this article.
<b>Section 7.</b>	Votes shall be cast by secret ballot; however, when there is only one candidate for an office, a motion may be made to elect the candidate by acclamation.
<b>Section 8.</b>	Officers shall assume the elected office following the election meeting, and shall serve a term of three (3) years. Officers can renew service for up to two (2) consecutive terms. No member may serve more than two (2) consecutive terms in the same office, for a maximum of six (6) consecutive years.
<b>Section 9.</b>	No member may hold more than one office.
<b>Section 10.</b>	If any officer position becomes vacant, the position shall be filled by election at the next regularly-scheduled meeting after the vacancy was announced. Nominations may be made at the meeting where the vacancy is announced and/or from the floor at the time of the election. The President may appoint an interim officer to fill the vacancy until the election is held.
<b>ARTICLE VIII</b>	<b>MEETINGS</b>
<b>Section 1.</b>	Regular meetings shall be scheduled bi-monthly (i.e., once every two months).
<b>Section 2.</b>	Business cannot be conducted unless a quorum of the membership is present/represented. A quorum is defined as one-third of the voting membership.
<b>Section 3.</b>	Members must be present to vote. Absentee or proxy voting is not permitted.
<b>ARTICLE IX</b>	<b>AD HOC BUSINESS</b>
<b>Section 1.</b>	SOP development between regular meetings may necessitate decisions be made by electronic correspondence (i.e., email).
<b>Section 2.</b>	Email correspondence must include all voting members.
<b>Section 3.</b>	Decisions about SOP development will require a majority vote, as defined in Article 3, Section 3.
<b>ARTICLE X</b>	<b>AMENDMENTS TO BYLAWS</b>
<b>Section 1.</b>	Proposed amendments to these bylaws shall be presented, in writing, to the administrator. The administrator shall share the proposed revisions with the CRCG officers. The CRCG officers will review and make recommendations on all bylaw revisions prior to consideration by the membership body.

<b>Section 2.</b>	Bylaw amendments require majority approval (i.e., greater than 50%) of the voting members present at a regular meeting. The amendment shall be effective immediately unless otherwise stipulated in the amendment.
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## Document Approval



Trent Foxley

Director, Office of Quality Compliance, University of Utah

President, University of Utah Clinical Research SOP Collaboration Group

11/09/2022

DATE