Japan Clinical Oncology Group

Policy No. 01
Title: Constitution/Bylaws
Scope of Application:
All JCOG members (researchers, committee members, JCOG Data Center, and JCOG Operations Office)

Constitution/Bylaws

1. Definition of JCOG

JCOG (Japan Clinical Oncology Group) is a multicenter cooperative group supported by public research grants, such as the National Cancer Center Research and Development Fund and research programs from the Japan Agency for Medical Research and Development (AMED) grants. The group conducts multi-center clinical researched according to JCOG's policies, including its constitution/bylaws. The studies conducted by JCOG are principally supported by the Clinical Research Support Office of the National Cancer Center Hospital

JCOG is a noncorporate association composed of disease-oriented or modality-oriented subgroups (study group) with the researchers belonging mainly to Designated Cancer Care Hospitals, various committees and headquarters including JCOG Data Center and JCOG Operations Office governed by the National Cancer Center Hospital.

2. JCOG's Mission Statement

JCOG conducts clinical researches in order to establish the best standard treatment and diagnostic methods which are to be recommended as a first choice for each cancer patient based on the reliable scientific evidences, through the development of new treatment methods and the conduct of confirmatory trials.

Through these research activities, JCOG aims to increase cure rates of each cancer and improve the quality of cancer treatment.

3. Principles of research activities

All research activities at JCOG are dedicated to realize global ethical and scientific standards through complying with the basic principles of medical research defined in the Declaration of Helsinki by the World Medical Association, other applicable regulations, ethical guidelines, and guidelines. Without exceptions, any scientific misconduct, such as false reporting, falsification and fabrication of data, is not allowed.

4. JCOG's Funding Source and Performance Evaluation

Operational and labor costs for JCOG headquarters and fundamental research grants for JCOG are mainly funded by the National Cancer Center. For this reason, activities at JCOG are monitored and directed by the JCOG Management Board and JCOG External Review Panel at the National Cancer Center. Furthermore, as for the individual JCOG studies and projects that are funded by AMED, each is evaluated by AMED.

Although research with financial support from pharmaceutical or medical device manufacturers is permitted, JCOG, as the responsible party for the research, must act independently in decision-making with respect to study design, conduct, data analysis,

and interpretation of the results.

The JCOG Management Board was established at the National Cancer Center to improve the fairness, transparency, and efficiency of JCOG operations. The function and membership structure of the JCOG Management Board are in accordance with the rules and regulations of the National Cancer Center. The JCOG Management Board is responsible for supervising JCOG's overall research activities and preselection of study concepts and protocols to be reviewed by the JCOG Protocol Review Committee (PRC).

5. JCOG Organizational Structure

5.1. JCOG Organizational Chart

JCOG's organizational structure is shown in the figure below (as of June 2022).

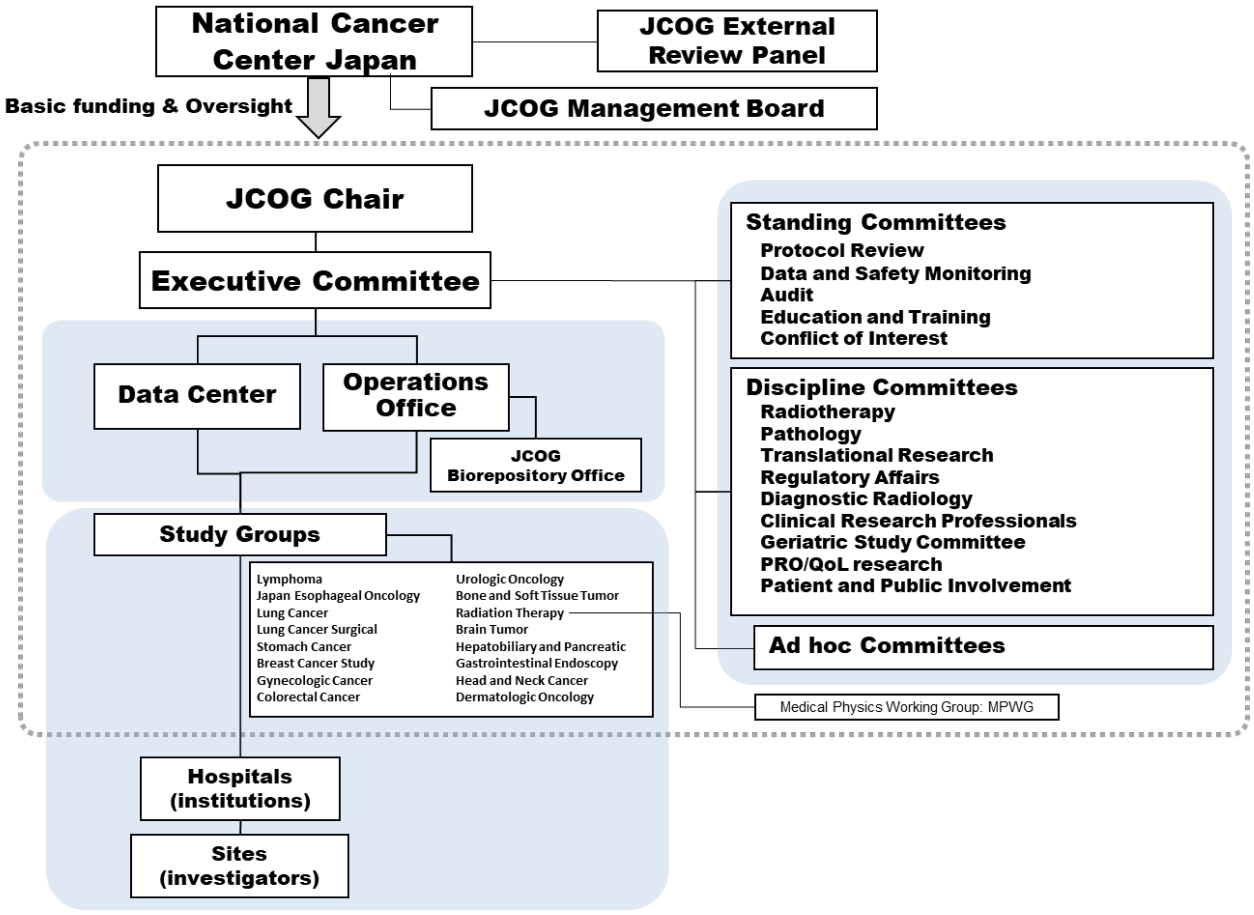

Figure: Organizational Structure of JCOG

5.2. JCOG Chair

5.2.1. JCOG Chair

A principal investigator of a research grant from National Cancer Center Research and Development Fund is appointed as the JCOG Chair.

The appointment term of JCOG Chair is 3 years with reappointment permitted. In cases where an assignment begins mid-term, the appointment term is the remainder of the standard 3-year term. The retirement age is 65 years with the retirement date established as the first March 31st following one's 65th birthday.

5.2.2. Responsibilities of the JCOG Chair

- To oversee JCOG's research activities and overall organizational operations

- To set up the JCOG Executive Committee, a decision-making body for JCOG's organizational operations and serve as its chairperson.
- To set up various committees necessary for JCOG's research activities and assign respective chairpersons.
- To appoint a study group chair for each study group for each specialty.

5.3. JCOG Executive Committee: EC

5.3.1. Responsibilities of the Executive Committee

The responsibilities of the Executive Committee are as follows:

- To make policy decisions regarding JCOG's research activities.
- To promote the development of the infrastructure for clinical research.

5.3.2. Chairperson of the Executive Committee

The JCOG Chair serves as the chairperson of the Executive Committee.

5.3.3. Vice Chair of the Executive Committee

The chairperson of the Executive Committee appoints the Vice Chair.

5.3.4. Committee Members of the Executive Committee

The Committee Members of the Executive Committee consists of members with the following roles. Each member may make statements that represent their respective roles and participate in the voting activities of the Executive Committee.

- Chairperson of the Executive Committee
- Vice Chair of the Executive Committee
- Study Group Chair of each specialty study group.
- Chairperson of Standing Committees
- Committee Member Statistician

5.3.5. Attenders of the Executive Committee

Attenders of the Executive Committee have the following roles. Each attender participates in the Executive Committee and makes statements that represent their respective roles. They should not be involved in voting.

- Principal investigator of a public research fund
- Committee members of Standing Committees (including vice-chairperson)
- Committee members of the Discipline Committee (including the chairperson and vice- chairperson)
- Study Group Coordinator (Group secretary) of each specialty study group.
- Attenders who is appointed by the chairperson of the Executive Committee

5.3.6. Executive Committee Office

The Executive Committee Office's responsibilities are administrative functions, such as operations related to meeting and reviews of the Executive Committee. The Director of JCOG Operations Office serves as the executive officer of Executive Committee Office.

5.3.7. Appointment terms of the Executive Committee Members

The appointment term is for 3 years with reappointment permitted. In cases where an assignment begins mid-term, the length of that term will be the remainder of the standard 3-year term. The retirement age is 65 years with the retirement date established as the first March 31st following one's 65th birthday.

5.4. Other Committees

The JCOG Chair establishes the Standing Committees and Discipline Committees and appoints a chairperson for each committee.

The JCOG Chair is able to set up Ad hoc Committees temporarily to address matters that the Standing Committees and Discipline Committees cannot handle.

5.4.1. Standing Committee: SC

The Standing Committees monitor and manage JCOG's studies and organizational operations. The chairperson of each committee appoints a vice-chairperson, committee members, and an executive officer for the committee. Responsibilities of each Standing Committee are as follows:

1）Protocol Review Committee: PRC

The Protocol Review Committee (PRC) conducts a review of the protocol concept and reports its findings to the Executive Committee.

They also review the study protocols of a JCOG study and approve the conduct of the study.

2）Data and Safety Monitoring Committee: DSMC

The Data and Safety Monitoring Committee (DSMC) reviews the progress, safety, and efficacy in JCOG studies according to the following reports submitted by the study groups or the Data Center during the study (from the activation of the trial to the end of follow-up). When needed, DSMC recommends termination of the study or revision of the protocol.

Adverse events report
Monitoring report
Interim analysis report

The committee reviews and approves protocol revision submitted by study groups.

They receive clinical summary reports that summarize the final results of a JCOG study and approve completion of the study.

They also determine whether data can be shared with a party outside of the JCOG.

3）Audit Committee: AC

The Audit Committee (AC) conducts site visit audits to ensure reliability of JCOG study results with the aim of improving research quality.

4）Education and Training Committee: ETC

The Education and Training Committee (ETC) plans and implements educational programs for researchers (e.g., physicians, CRC) and staffs at the JCOG Data Center/Operations Office to improve the quality of JCOG studies.

5）Conflict of Interest Committee: COIC

Conflict of Interest Committee (COIC) manages conflicts of interest (COI) in JCOG studies.

5.4.2. Discipline Committee: DC

The Discipline Committees engage in activities to improve the quality of JCOG studies from the viewpoint of each specialty. The chairperson of each committee appoints committee members and, if necessary, a vice- chairperson and executive

officer of the committee. Responsibilities of each Discipline Committees are as follows:

1）Radiotherapy Committee: RC

The Radiotherapy Committee (RC) manages the quality control and quality assurance activities of JCOG studies that include radiotherapy.

2）Pathology Committee: PC

The Pathology Committee (PC) manages the quality control and quality assurance activities of pathological diagnosis in JCOG studies.

3）Translational Research Committee: TRC

The Translational Research Committee (TRC) supports establishment and maintenance of the operational system for translational researches at JCOG as well as supporting researchers.

They also discuss about the operations of the JCOG BioBank Japan Biorepository and present suggestions as necessary.

4）Regulatory Affairs Committee: RAC

The Regulatory Affairs Committee (RAC) collects information related to the pharmaceutical/insurance administration and regulations infrastructure of the clinical research implementation system. They also make proposals on regulatory matters that JCOG should address.

5）Clinical Research Professionals Committee: CRPC

The Clinical Research Professionals Committee (CRPC) discusses about quality control or human research protection in JCOG studies, and present suggestions as necessary. These activities are done in cooperation with clinical research professionals (CRP) at active sites (local) and the JCOG Data Center/Operations Office (central).

6）Diagnostic Radiology Committee: DRC

The Diagnostic Radiology Committee (DRC) acts as an advisory board on matters regarding central imaging review in JCOG studies. The aim is to improve the quality of JCOG studies by means of diagnostic imaging.

7）Geriatric Research Committee: GRC

The Geriatric Research Committee (GRC) shares information regarding geriatric researches, optimizes JCOG geriatric studies, consultation regarding geriatric researches, development of geriatric assessment tools and improvement of operations.

8）PRO/QOL Research Committee: PQRC

The PRO/QOL Research Committee provides consultation on PRO/QOL evaluation methods and advice on questionnaires, frequency of evaluation, design, etc. The committee is actively involved in international standardization projects including the creation of a Japanese version of the PRO/QOL questionnaire and statistical analysis methods, through close collaboration with the European Organisation for Research and Treatment of Cancer (EORTC), which promotes overseas PRO/QOL research.

9）Patient and Public Involvement Committee：PPIC

The Patient and Public Involvement Committee (PPIC) promotes opinion exchanges among patients, public and JCOG researchers, and supports information sharing among JCOG study groups. The committee also plans and conducts JCOG Patient and Public Seminars, and supports the release of the results of JCOG studies to the public and notifications/explanations of them to the study participants.

5.4.3. Ad hoc Committee

Ad hoc Committees are temporarily developed when there is a matter out of the scope of the Standing Committees and Discipline Committees. The chairperson of the Ad hoc Committee appoints committee members and, if necessary, a vice-chairperson and executive officer of the committee.

5.4.4. Appointment terms of the committee members and executive officers

The appointment term is for 3 years with reappointment permitted. In cases where an assignment begins mid-term, the length of that term is the remainder of the standard 3-year term. The appointment term is not defined for commissioners of Ad hoc Committees.

Retirement age is 65 years with the retirement date established as the first March 31st following one's 65th birthday.

5.5. Study Group

5.5.1. Designation of each Study Group

The following study groups have been established in JCOG: Each study group should have an abbreviated name in English, e.g., JCOG-LSG.

1. Lymphoma Study Group (LSG)
2. Japan Esophageal Oncology Group (JEOG)
3. Lung Cancer Study Group (LCSG)
4. Lung Cancer Surgical Study Group (LCSSG)
5. Stomach Cancer Study Group (SCSG)
6. Breast Cancer Study Group (BCSG)
7. Gynecologic Cancer Study Group (GCSG)
8. Colorectal Cancer Study Group (CCSG)
9. Urologic Oncology Study Group (UOSG)
10. Bone and Soft Tissue Tumor Study Group (BSTTSG)
11. Radiation Therapy Study Group (RTSG)
12. Brain Tumor Study Group (BTSG)
13. Hepatobiliary and Pancreatic Oncology Group (HBPOG)
14. Gastrointestinal Endoscopy Study Group (GIESG)
15. Head and Neck Cancer Study Group (HNCSG)
16. Dermatologic Oncology Group (DOG)

(As of June 2022)

The Medical Physics Working Group (MPWG) is established within the Radiation Therapy Study Group to support clinical trials conducted by all 16 groups, to assure the quality of radiation therapy, and to propose research, from a medical physics

perspective.

5.5.2. Study Group Chair (Group Chair)

A study group chair should be appointed for each study group. A study group chair should be selected from among those who apply directly or are recommended by others in the group. The JCOG Chair makes an appointment after obtaining the approval by the JCOG Executive Committee. The appointment term of the study group chair is not established. The retirement age is 65 years with the retirement date established as the first March 31st following one's 65th birthday.

5.5.3. Study Group Coordinator (Group Secretary)

More than one member of each study group may be appointed as a study group coordinator. A study group coordinator should be recommended by the study group chair and then approved by the Executive Committee.

5.5.4. Establishment, Consolidation, and Abolition of Study Groups

(1) Establishment

When establishing a study group, someone who wishes to represent the study group should apply to the Executive Committee for approval.

(2) Consolidation and Abolition

When consolidating or abolishing a study group, a study group chair should apply to the Executive Committee for approval.

5.6. JCOG Active Sites and Medical Institutions

5.6.1. JCOG Active Sites

JCOG active sites (or participating sites) are defined as medical departments or medical care teams at medical institutions approved by the Executive Committee to join a JCOG studies through the recommendation by a study group chair.

5.6.2. JCOG Active Medical Institutions

The healthcare facilities that JCOG active sites belong to are referred to as JCOG active medical institutions (or participating medical institutions).

5.7. JCOG Headquarters

JCOG Data Center and JCOG Operations Office provide centralized support for JCOG studies, as well as for the committee offices of the Executive Committee and each of the Standing Committees. The Clinical Research Support Office of the National Cancer Center Hospital is responsible for operations of the JCOG Data Center and JCOG Operations Office. The functions of the headquarters may be outsourced to Academic Research Organization (ARO) or Contract Research Organization (CRO) when it involves a collaborative study with other cooperative groups or there is a shortage of resources at the Clinical Research Support Office of the National Cancer Center Hospital.

The directors of the JCOG Data Center and the director of the JCOG Operations Office are appointed by the JCOG Chair. Retirement age is 65 years with the retirement date established as the first March 31st following one's 65th birthday.

5.7.1. JCOG Data Center

JCOG Data Center oversees quality control for a wide variety of operations in JCOG studies, including patient registration, data management, central monitoring, and

statistical analysis, and provides support for study design, development of protocols, presentations at academic conferences and journal manuscripts for study chairpersons and study coordinators.

A vice director of the JCOG Data Center may be appointed. The director of the JCOG Data Center may appoint the vice director.

5.7.2. JCOG Operations Office

The JCOG Operations Office provides study chairpersons and study coordinators with support for study design, development of protocols, presentations at academic conferences and journal manuscripts, study project management, regulatory compliance, and safety information management, without delay while maintaining high quality. They also coordinate operations of site visit audit and the JCOG BioBank Japan Biorepository.

More than one person may be appointed as an assistant director of the JCOG Operations Office. An assistant director of the JCOG Operations Office should be appointed by the director of the JCOG Operations Office.

6. JCOG Study

"JCOG study" collectively means studies conducted by JCOG. JCOG studies are divided into "JCOG clinical trials (main study)" and "JCOG ancillary study."

6.1. JCOG Clinical Trial (Main Study)

Intervention studies approved by the Executive Committee, with a protocol approved by the Protocol Review Committee (PRC), are called "JCOG Clinical Trials." If there is an ancillary study, the original study is referred to as "the main study". Although the supporting mechanism and procedures should be determined by each study protocol, central support operations should be implemented in accordance with Policy No. 12 "JCOG Headquarters" and the SOP of the JCOG Data Center and JCOG Operations Office. Central support operations for physician-led registration trials ("Ishi-syudo-chiken") should be conducted as per the SOP of the Clinical Research Support Office at the National Cancer Center Hospital or the SOP of the JCOG Data Center / Operations Office. Implementation of a collaborative study with study groups outside JCOG is determined by JCOG Policy No. 38 "Intergroup Study."

6.2. JCOG Ancillary Study and Secondary Use of Data

When part or all of the existing data of a JCOG clinical trial is reused in another study outside the scope of the main study (secondary use of data), existing data is used along with new data collection, or collateral study is conducted along with a JCOG clinical trial, the study is defined as a "JCOG ancillary study." JCOG ancillary study also includes prospective observational studies. To implement a JCOG ancillary study, the study protocol should be approved by the Protocol Review Committee (PRC). Secondary use of data for purposes other than a JCOG ancillary study will require approval from the Data and Safety Monitoring Committee (DSMC).

Details regarding secondary use of data, including ancillary study, are described in "Secondary Use of Data and the Ancillary Study."

6.3. Study Period at JCOG

6.3.1. JCOG Clinical Trial (Main Study)

The “study period” will be the period from the approval date of the protocol concept by the Executive Committee until the submission date of the final report. The “study management period” at JCOG is defined as the period until the date the clinical summary report is published on jRCT for studies conducted under the "Clinical Research Act" and until the date the clinical summary report is accepted by the JCOG Operations Office for studies conducted under the "Ethical Guidelines for Medical and Biological Research Involving Human Subjects" (or previous ethical guidelines). The study coordinator’s and study chairperson’s authorities will end when the clinical summary report is published on jRCT for studies conducted under the "Clinical Research Act" and the clinical summary report is accepted by the JCOG Operations Office for studies conducted under the "Ethical Guidelines for Medical and Biological Research Involving Human Subjects" (or previous ethical guidelines).

6.3.2. JCOG Ancillary Study

The period from the approval date of the protocol of an ancillary study by the Protocol Review Committee (PRC) until the submission date of the primary analysis report is defined as the “study period.” The study management period of an ancillary study is defined as the period until a research paper on the main results of the ancillary study is accepted by a journal. The date on which a research paper of an ancillary study is accepted by a journal will be the end of the authority of the study coordinator and study chairpersons.

7. Revision of Constitution/Bylaws

These Constitution/Bylaws may be revised upon approval of the Executive Committee. Approval should, in principle, be based on consensus decision-making at a meeting with all members of the Executive Committee voting. If unanimous approval cannot be obtained, based on the judgment of the JCOG Chair (Chairperson of the Executive Committee), support from over 2/3 of the Executive Committee commissioners may be used as the criteria for approval.

First approval by the Executive Committee: 9/25/2000	7th Revision: 6/25/2016
1st Revision: 6/14/2008	8th Revision: 3/18/2017
2nd Revision: 3/11/2011	9th Revision: 6/24/2017
Effective Date: 4/1/2011	10th Revision: 3/17/2018
3rd Revision: 6/29/2013	11th Revision: 6/23/2018
4th Revision: 3/15/2014	12th Revision: 6/29/2019
5th Revision: 6/21/2014	13th Revision: 6/26/2021
6th Revision: 6/13/2015	14th Revision: 3/16/2022