J-SUPPORT Policy No. 2 Detailed Regulations for Research

ver. 2.1 November 15, 2022

1. Authorship of J-SUPPORT Research

All persons named as authors in accordance with the Recommended Authorship Guidelines established by the International Committee of Medical Journal Editors must satisfy all four criteria for authorship.

1) Have made substantive contributions to the research concept or design, or to the acquisition, analysis, or interpretation of the research data, AND
2) Drafted the article or made critical improvements to important intellectual content, AND
3) Approved the final manuscript submitted for publication, AND
4) Properly reviewed any questions related to the accuracy or impartiality of all aspects of the research, verified that the questions were investigated and resolved, and consented to accept accountability for all aspects of the research.

   Furthermore, the principal investigator will finalize the list of authors for the protocol paper and the article before registration of the first case after approval by the institutional review board of the associated institution, and then notify the office.

   Example A: ① Author X, ② Author Y…

   Example B: ① Principal investigator, ② Persons nominated by the representative of the institution with the highest number of accumulated cases… etc.

2. Implementation Procedures for J-SUPPORT Research

2.1 Confirmation Items

1) When applying for research funding, submit an application for J-SUPPORT clinical research consultation at least four weeks in advance of the application date..
2) Submit a protocol concept within 90 days of acceptance of the application for research funding.
3) Before implementation, interventional studies require registration of the clinical study.
   Clinical Trial Registration Systems: University Hospital Medical Information Network - Clinical Trials Registry (UMIN-CTR), Japanese Registry for Clinical Trials (jRCT), ClinicalTrials.gov
4) Obtain advance approval from the J-SUPPORT Office regarding the submission destination for the main paper, academic society publishing the results of the primary endpoint, and authorship of these items.
   *Refer to the protocols of approved studies, such as TOPICS (J-SUPPORT1602), J-FORCE (J-SUPPORT1604), and ACCESS (J-SUPPORT 1901).
5) The authorship of presentations at academic conferences is the same as that for the main paper.
   Before registering at an academic conference, obtain approval for presentations at a specific academic society stated in advance in the protocol. For the abstract of a presentation at an academic conference publishing the results of the main endpoint for the first time, submit this information to the J-SUPPORT Office. Presentations during the study period (e.g., study introduction, registration status, background factors) are to be conducted based on the protocol paper and the content registered in UMIN-CTR, jRCT, or ClinicalTrials.gov. Publications other than the aforementioned academic society presentations are the responsibility of the principal investigator of the study, regardless of whether the publication was a request or a public offering.
6) It is preferable to submit protocol papers for up to 50% of entries.
7) Submit the manuscript of the main paper within one year of the final analysis.
8) Submit the manuscript of the main paper and press release manuscript to the J-SUPPORT Office. If the results of the study have a particularly large impact on public health, notify the relevant departments prior to the press release, such as the PR staff of the main research facility, J-SUPPORT, Japan Agency for Medical Research and Development (AMED), and Ministry of Health, Labour and Welfare.
9) When the number of entries at one-quarter of the case registration period is less than 15% of the total, the mentor or chief director should discuss actions with the principal investigator to improve recruitment.
   Example: If the case registration period is 24 months, and the target number of registered cases is 120,

but the number of entries has not reached 18 at the end of 6 months

10) When the number of entries at half of the case registration period is less than 25% of the total, the protocol should be revised to extend the registration period or change the target number of cases.
Example: If the case registration period is 24 months, and the target number of registered cases is 120, but the number of entries has not reached 30 at the end of 12 months
11) When the number of entries at half of the case registration period is less than 15% of the total, the mentor or chief director should discuss with the principal investigator on the slow accrual of the study.
Example: If the case registration period is 24 months, and the target number of registered cases is 120, but the number of entries has not reached 18 at the end of 12 months
12) When the number of entries at half of the total case registration period is less than 25% of the total after extension of the period described in 10) above, the mentor or chief director should discuss the slow accrual of the study with the principal investigator.
Example: If the case registration period after extension is 48 months, and the target number of registered cases is 120, but the number of entries has not reached 30 at the end of 24 months

2.2 Definition of End of Research

2.2.1 Basic Concept

Representative research organization

1) The main analysis described in the protocol is complete (not all the analyses written in the protocol needs to be completed).
2) Other operations described in the protocol are complete (e.g., creation of the final analysis report, "database lock" described in 3) below).

Organizations participating in the research (only providing samples/information from their own facility or involved as an organization in charge of analysis)

3) Intervention/observation of the study subjects has been completed, the original data for the study has been collected from the study subject's medical record survey and/or clinical sample measurements (hereinafter, basic dataset), and data cleaning has been completed (known as database lock).
4) Completion of provision of samples/information to the representative research organization (requires consent from the representative research organization)

*The basic dataset is mainly envisioned to be digital data that can be stored in a computer, and has been collected for the research from source material such as medical charts and clinical samples. It also includes paper-based material. Copies of imaging data taken for the research, such as radiology, endoscopy and pathology tests, may also be included in the basic dataset. Specimens such as histopathology and blood samples are not included.

* Representative organizations are requested to manage other organizations participating in the research themselves in accordance with 3) and 4). Organizations participating in the research are requested to explain the necessity of 1) and 2) to the representative organizations.

2.2.2 Tasks that may be performed after research is completed

Matters related to presentation of research results

5) Creation and presentation of material for paper presentations, academic conferences, and other types of conferences, including processing the "basic dataset" mentioned in 3) above, such as simple reaggregation
6) Additional analysis of data based on suggestions from reviewers (however, the scope of this action is limited to the "basic dataset" mentioned in 3) above and "secondary data analysis" described in 7) below, including reanalysis of samples for validation)
7) Analysis conducted within the scope of the "basic dataset" mentioned in 3) above, other than that mentioned in 1) above, using methods described in the research protocol, within the scope of the purpose of the research protocol (known as "secondary data analysis")

Storage and management of samples and information

8) It is based on the research protocol, ethical guidelines, and the National Cancer Center regulations.

2.2.3 Tasks that may not be performed after research is completed

Collection of additional samples and information

9) Addition of new research subjects, addition of research analysis items
10) New intervention/observation for already registered research subjects

11) Addition of new data to the "basic dataset" mentioned in 3) above, such as additional measurements of already collected samples
12) Provision of new samples/information to representative organizations (mentioned in 4) above)

2.2.4 End of clinical trials

The end of the clinical trial at the main research organization shall be as of completion of the final analysis report related to the main analysis, and the end of the clinical trial at the participating organizations shall be as of database lock (no new data is collected after that point).

Both confirmatory and exploratory studies shall follow the same operations.

(Reference) National Cancer Center "Standard Operating Procedures for Life Science and Medical Research Involving Human Subjects" Attachment: Center Operations related to Completion of Research

3. Secondary use of data and accompanying research

Methods for the secondary use of the data collected in J-SUPPORT-approved research (main research) include supplementary analysis as part of the main research, accompanying research conducted in conjunction with the main J-SUPPORT research (J-SUPPORT Accompanying Research), multiple J-SUPPORT-approved research projects, existing data in J-SUPPORT Accompanying Research, integrated analysis (e.g., meta-analysis) conducted using any combination of research data conducted outside J-SUPPORT, and secondary analysis conducted as new research by providing existing data from J-SUPPORT-approved research or J-SUPPORT Accompanying Research to other organizations or individuals.

The handling of secondary data is stipulated in accordance with the following definition of terms within this policy.

[Definition of terms]

Main research: Research implemented to achieve the main purpose of the J-SUPPORT-approved research

Secondary use: Use of existing data already collected in J-SUPPORT-approved research and/or J-SUPPORT Accompanying Research for analysis with a different purpose or in different research. This includes the provision of data to external parties. In J-SUPPORT, this refers to the supplementary analysis, accompanying research, and secondary analysis listed below.

Supplementary analysis: Analysis conducted using only existing data from a single main study

Accompanying research: Research planned for a separate purpose implemented in a format that accompanies the main research. Accompanying research includes exploratory analysis studies, research conducting analysis by collecting samples, integrated analysis of multiple main research studies, and observational studies as preparation for planned J-SUPPORT studies. Supplementary analysis reviewed at the same time as the main research is not included in accompanying research. For research planned at a later date, the plan is to be created after consultation with the principal investigator and mentor, approval by a new institutional review board, and submission to the Office.

Secondary analysis: Analysis conducted using data from multiple studies (main research, accompanying research), and includes research integrating and analyzing data from other research groups outside of J-SUPPORT

3.1 Main research

1) The main research is sufficiently discussed in advance with the mentor at the research planning stage, reviewed by the Scientific Advisory Committee, and approved by J-SUPPORT.
2) The accompanying research protocol approved by the institutional review board is submitted to the Office.
3) The J-SUPPORT study number is to be written in the title of the paper or presentation and in the acknowledgments. The abstract of the published paper/presentation is to be submitted to the Office.

3.2 Secondary use

3.2.1 Supplementary analysis

1) Supplementary analysis planned at the planning stage of the main research is sufficiently discussed in advance with the mentor and principal investigator, and reviewed by the Scientific Advisory Committee of the main research. Supplementary analysis approved by J-SUPPORT will subsequently be handled in the same way as the main research.

2) When new supplementary analysis is planned after completion of the main research, the plan shall be formulated after sufficient discussion with the mentor and principal investigator. The protocol of the accompanying research approved by the institutional review board must be submitted to the Office.
3) The J-SUPPORT study number shall be written in the title of the paper or presentation and in the acknowledgments. The abstract of the published paper/presentation shall be submitted to the Office.

3.2.2 Accompanying research

1) Accompanying research is sufficiently discussed in advance with the mentor and principal investigator at the research planning stage of the main research, reviewed by the Scientific Advisory Committee, and approved by J-SUPPORT.
2) The accompanying research shall be approved by the mentor, principal investigator, and statistical analyst.
3) The accompanying research protocol approved by the institutional review board shall be submitted to the Office.
4) The J-SUPPORT study number shall be written in the acknowledgments of the paper/presentation, and the abstract of the published paper/presentation shall be submitted to the Office.

3.2.3 Secondary analysis

1) Secondary analysis must be approved by the mentor, principal investigator, and statistical analyst.
2) The secondary analysis protocol approved by the institutional review board must be submitted to the Office.
3) The J-SUPPORT study number shall be written in the acknowledgments of the paper/presentation, and the abstract of the published paper/presentation shall be submitted to the Office.

4. Publication of research results

When publishing the results of J-SUPPORT research, approval must be obtained from the J-SUPPORT Office as needed. The approval number must be included as a credit notation when publishing the paper or presenting at an academic association (Table 1).

Table 1. Necessity of J-SUPPORT approval and credit notation (Title, Methods, or Acknowledgement)

	J-SUPPORT approval	J-SUPPORT credit notation (paper)	J-SUPPORT credit notation (academic society presentation)
Primary analysis of main research	Required	Required	Required
Supplementary analysis of main research	Not required	Required	Required
Accompanying research	Required	Required	Required
Secondary analysis	Not required	Required	Required

(Description example) This research received support as J-SUPPORT research number [study approval number].

(e.g.) This work was supported by the Research for the Promotion of Cancer Control Programs from the Japanese Ministry of Health, Labour and Welfare (H30-Cancer Control-general-006). The work was endorsed by the Japan Supportive, Palliative and Psychosocial Oncology Group (J-SUPPORT) as J-SUPPORT 1901 study, funded by the National Cancer Center Research and Development Fund (30A-11).

5. Ensuring research transparency and promoting data sharing

Before starting research, researchers must register the research in clinical trials registration systems (e.g., UMIN-CTR, jRCT, ClinicalTrials.gov), state the registration information and data sharing policy in the protocol and informed consent form, and submit the set of documents to the J-SUPPORT Office.

In addition to registering with a data repository system (e.g., UMIN-CTR) after completion of the research (data archive), and after publication of the key findings, anonymized study case data and data specifications are to be submitted to the J-SUPPORT Office.

Supplementary provisions

1. J-SUPPORT Policy Detailed Regulations came into effect on August 19, 2022 as J-SUPPORT Policy No. 2 Detailed Regulations for Research ver. 2.0.
2. J-SUPPORT Policy No. 2 Detailed Regulations for Research ver. 2.1 came into effect on November 15, 2022.