

APPLICATION RESEARCH PROPOSAL

To utilize data from *the COVADIS Microvascular Angina Registry*, researchers are asked to submit this research proposal form to the COVADIS Microvascular Angina Registry Chief Investigator Committee.

This application is applicable when (a) you wish to undertake analyses solely on the *COVADIS Microvascular Angina Registry* data for research/publication purposes or (b) you wish to undertake a sub study and include *COVADIS Microvascular Angina Registry* data as part of the research. All sub studies require approval from the relevant HREC. This is the responsibility of the application's Principal Investigator.

Email proposal to xxxx@yyyy *Subject: COVADIS Microvascular Angina Registry Research Proposal*

I. PROJECT TITLE

Provide a title or brief description of your proposed study.

Provide a keywords description



II. CONTACT INFORMATION of DATA USER

Initial Submission Date:

Revision Date:

Submitting Principal Investigator*:

Institution/Affiliation:

COVADIS Site (if applicable):

Collaborators*:

Name	Institution/Affiliation	E-Mail

****At least one collaborator or the principal investigator must be a COVADIS Microvascular Angina Registry Member***

Relationships with Industry

List all relationships with industry for the Principal Investigator and all collaborators

III. TARGET PUBLICATIONS/PRESENTATIONS

- Abstract: Scientific meeting:
 Submission deadline:
 Date of presentation:
- Manuscript: **Target journal(s) (in order of preference):**
 1.
 2.
 3.

Anticipated date of submission:

IV. COVADIS DATA SOURCES

Identify required data sources

- | | |
|---|--|
| <input type="checkbox"/> Patient Information – Risk Factors | <input type="checkbox"/> Treatment |
| <input type="checkbox"/> Patient Information – Initial Bloods | <input type="checkbox"/> Adverse Events at initial admission |
| <input type="checkbox"/> Seattle Angina Questionnaire | <input type="checkbox"/> Follow-up Examination Data |
| <input type="checkbox"/> Diagnosis of Ischemia | |
| <input type="checkbox"/> Coronary Artery Data | |

V. BACKGROUND/RATIONALE

Briefly explain the background, rationale and significance for your research study.

VI. OBJECTIVES

List the objectives of this study. Clearly identify primary, secondary and tertiary aims. Be specific and concise.

VII. STUDY POPULATION

*Describe the population. List relevant inclusion and exclusion criteria.
E.g. Age, presentation, angiographic evidence of CAD, history of depression*

- Entire Population.
- Subpopulation (specify inclusion/exclusion criteria). Specific Sites

Inclusion

Exclusion:

VIII. STUDY VARIABLES

List all required variables. Identify primary, secondary and any exploratory outcomes.

Please utilize the COVADIS Data Collection Form or Outcomes Study Forms as a reference to delineate groups for comparison, to list the primary and secondary outcomes of interest, any covariates of interest, and any other variables that may need to be considered (e.g. for adjustment) in the analysis.

To obtain a copy of the data collection form or outcomes forms, email shimo@cardio.med.tohoku.ac.jp

Independent/predictor variables:

Dependent/outcome variables:

Primary:

Secondary:

Exploratory:

IX. DATA ANALYSIS PLAN

Outline the general analytic approach.

Provide a brief description of the proposed statistical methodology that could be considered for your proposal based on the data requested above.

X. SAMPLE TABLES AND FIGURES

Draft sample tables & figures as you intend to present them. Specify preferences for labels, legends, axes, etc.

XI. ETHICAL REVIEW

List all the relevant Ethics Committee that you require ethics approval from, the date of submission and whether approval has been granted. Please attach copies of any relevant ethics approvals.

XII. COVADIS PATIENT REQUIREMENTS

*Explain all the relevant COVADIS patient contact or activities that this research proposes.
E.g. blood samples to be taken, questionnaires to be administered etc.*

XII. FUNDING SOURCE

- | | |
|---|------------------|
| <input type="checkbox"/> Grant not yet awarded. | Please describe: |
| <input type="checkbox"/> Grant awarded | Please describe: |
| <input type="checkbox"/> Institutional or departmental funding: | Please describe: |
| <input type="checkbox"/> Industry (pharma, medical device etc): | Please describe: |
| <input type="checkbox"/> Other | Please describe: |

XIII. REFERENCES

List all references cited in this proposal.

XIV. SPECIAL CONDITIONS

To be advised by the COVADIS Microvascular Angina Registry Chief Investigator Committee