The Japan Society of Coloproctology

Journal of the Anus, Rectum and Colon

Application for Ethics Review/Checkbox for Paper Submissions

Manuscript Title:

The corresponding author should upload the form online.

Q1. Select one from the following study contents.

☐ A1. Non-researchable case reports summarizing 9 or fewer cases.
*Required to comply with the Personal Information Protection Law and Guidelines for the Appropriate Handling of Personal Information for Medical and Nursing Care Providers.

☐ A2. Maintenance and promotion of human health through understanding the causes and pathology of injury and disease, improving methods of prevention, diagnosis, and treatment of injury and disease, and verifying the effectiveness and safety of such methods, and reports, etc. not intended to acquire knowledge that contributes to recovery from injury or illness or improves the quality of life*.
*Examples: (1) Only the introduction of treatment methods, education and training methods; (2) Introduction about the institution's medical system and efforts to improve medical examination rates.

☐ A3. Research using only articles, published databases, and guidelines.

☐ A4. Research using samples and information that have already proven academic value, are widely utilized for research purposes and are accessible to the general public.

☐ A5. Research using information that does not include the information on individuals (personal information, anonymized information, pseudonymized information, personally identifiable information, and equivalent information on the dead).

☐ A6. Research using anonymized information that has already been created.

☐ A7. Research based on laws and regulations (excluding the Clinical Trials Act and the Act on Ensuring Regenerative Medicine, Safety, etc.).

☐ A8. Research that only analyzes microorganisms such as bacteria, molds, and viruses isolated from the human body and that does not involve research on events related to human health.

☐ A9. Basic research using animal experiments and generally available cells (including iPS cells and tissue stem cells).

☐ A10. Research conducted overseas (excluding those in which the specimens/information subject to the research were obtained in Japan). However, it is necessary to comply with the regulations of the country where the research was conducted.

☐ B1. **-Observational studies using existing samples and information.**
The use of information from routine medical care or surplus biological specimens collected during medical care is acceptable, regardless of whether it is prospective or retrospective provided it does not affect the routine medical practice (judgment) in any way.
-Observational research that obtains new information only for research purposes and does not involve invasive procedures.
This includes ECG, body surface US tests, and noncardiac invasive questionnaires.

☐ B2. **-Observational studies that involve invasive or minimally invasive procedures in obtaining new information for research purposes.**
Research that does not affect normal medical practice (judgment) in any way but in which radiography, CT, etc., are performed for research purposes.
-Observational research in which samples are obtained in addition to new information for research purposes.
Some of them are invasive or slightly invasive, such as CT, blood sampling (may include others on top of the usual medical care), tissue collection, etc., for research purposes, while others are non-invasive, such as collection of excretions.

☐ C. **Interventional research to which the "Clinical Research Act" does not apply.**
This includes interventional studies using in vitro diagnostics and studies evaluating medical procedures and surgical methods.

☐ D1. **Clinical research other than specific clinical research (research subject to the obligation to make efforts to comply with the "Clinical Research Act").**
Interventional research that evaluates the efficacy and safety of approved drugs and medical devices without funding from related companies.

☐ D2. **Specified clinical research (research obliged to comply with the "Clinical Research Act").**
Research using unapproved or off-label drugs, medical devices, or interventional research funded by companies falls under this category.

☐ E. **Research that meets the following criteria.**
-Research that falls under the Act on Ensuring Regenerative Medicine Safety, etc.
-Research on Human Gene Therapy.

Q2. Studies that checked B1, B2, C, D1, D2, and E in Question 1 require a committee review based on the regulations that apply to each study.

The required review has been undergone, and approval has been obtained.

☐ a: Ethical review board of the author's affiliated facility

IRB number: _____

☐ b: Other ethical review board (name:_____)

IRB number: _____

*If unapproved or off-label medical treatment is performed as a medical treatment rather than as research, each institution must perform the procedure per the Medical Care Act.

*The above ethical information may be revised per changes in national laws, regulations, and guidelines in the future (as of June 2022).

* This guideline is based on the ethical guidelines prepared by the Japanese Society for Abdominal Emergency Medicine and the Japan Diabetes and Digestive Welfare (JDDW) Society.

Corresponding author's name: _____

Date: _____
(MM/DD/YYYY)