

The Japan Society of Coloproctology
Journal of the Anus, Rectum and Colon
Ethical Review Application Checklist for Submission of Academic Papers

Manuscript Title:

The corresponding author should upload the form online.

Q1. Does your study correspond to one of the following types?

- A1. Case report without medical intervention summarizing no more than nine cases
- A2. Study using only anonymized data with no correspondence table (limited to data that prevent specific individuals from being identified) *If your study is performed at a single institution, do not select this.
- A3. Study using only anonymized or unidentifiable data
- A4. Study using only molecular biological data, such as that on genes or proteins
- A5. Study using only papers or published databases and guidelines or study based on laws and regulations
- A6. Study not using specific patient data for basic research and using widely-used cultured cells [such as embryonic stem (ES) cells, induced pluripotent stem (iPS) cells, and tissue stem cells]
- A7. Study conducting only experiments on animals

Yes: No need for ethical review. You do not need to answer the following questions (Q2-Q4).
Select one from above (A1-A7).

No: Answer the following questions (Q2-Q4).

Q2. Select one from the following study contents.

- B1: Observational study not using samples collected from humans or retrospective observational study using samples collected from humans
- B2: Prospective observational study using samples collected from humans
- C1. Case report involving medical action (intervention or off-label use) for the purpose of study beyond the scope of routine care
- C2. Prospective interventional study
- C3. Study involving invasive treatment (however, a new study using samples collected by invasive means and stored for the purpose of another study shall correspond to option B1 if general consent was obtained during sample collection)
- C4. Study on genetic mutations or polymorphisms of human germ lines passed on to progeny
- D1. Clinical study using human embryonic stem (ES) cells, human induced pluripotent stem (iPS) cells, or human tissue stem cells
- D2. Study into human gene therapy

Q3. Select one from the followings.

- 1. Observational study approved following an ethical review.
- 2. Interventional study approved following an ethical review*.
Registration in a public database is complete.
*For specified clinical trials, an approval by a certified review board must be obtained.
- 3. Study in another category approved following an ethical review.
In addition, approved by the Minister for Health, Labour and Welfare if the study corresponds to D in the previous section.

Q4. Ethical review board* that conducted the review

*For specified clinical trials, it must be a certified review board.

A: Ethical review board of the author's affiliated facility

IRB number: _____

B: Other ethical review board (name: _____)

IRB number: _____

Corresponding author's name: _____

Date: _____

(MM/DD/YYYY)