

TERRITORIAL ETHICS COMMITTEE AREA SOUTH WEST VENETO

*Established by Decree of the Director General of the Health and Social Area n. 330 of 29 March 2023
with operational headquarters c/o Azienda Ospedaliera Universitaria Integrata Verona
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Prot. no. 5495 of 28/01/2026

Investigator: Dr. Federica Pederiva, CENTER: Azienda Ospedaliera Universitaria Integrata di Verona - Chirurgia Pediatrica

Director UO: Prof. Luca Giacomello, CENTER: Azienda Ospedaliera Universitaria Integrata di Verona - Chirurgia Pediatrica

Promoter: Azienda Ospedaliera Universitaria Integrata di Verona

URC: Azienda Ospedaliera Universitaria Integrata di Verona

Oggetto: Prog. 882CET - Studio clinico: GASPOUT (Global Assessment of Spontaneous Pneumothorax: Outcomes and Treatment): International prospective cohort study on spontaneous pneumothorax: treatment and outcomes - Protocol code: GASPOUT

With reference to the request for authorization of the study in question, the decisions of the Territorial Ethics Committee of the South-West Veneto Area, which met on **20-01-2026**, are transmitted via web conference.

The requested clarifications and/or modifications must be provided as soon as possible to the relevant Clinical Research Unit, which will forward them to the Technical-Scientific Secretariat of CET ASOV. Following the verification of the conditions set by the Territorial Ethics Committee, the Office of the Secretariat will send applicants and the URC an acknowledgement.

**The Territorial Ethics Committee
in compliance with the provisions of current legislation on
observational studies
examined this request, and in particular the following:**

General documentation:

- Transmittal letter for CE Coordinator - date: 06/10/2025
- Statement on the observational nature of the study - verse: 1 - date: 10/06/2025
- Synopsis of the study - verses: 1 - date: 10/06/2025
- Data Collection Sheet (CRF) - vers: 1 - date: 10/06/2025
- Statement of the sponsor for non-profit studies - vers: 1 - date: 10/06/2025
- List of participating centers - vers: 1 - date: 10/06/2025
- Protocol of the study - verse: 1 - date: 10/06/2025

Specific centre documentation:

- Investigator's CV - date: 10/06/2025
- Statement on the investigator's conflict of interest - date: 10/06/2025
- Local Feasibility Study Module - vers: 1 - date: 12/10/2025

- Information sheet and informed consent form - vers: 1 - date: 10/06/2025 - notes: Informed consent for adults
- Information sheet and informed consent form - vers: 1 - date: 10/06/2025 - notes: Less than mature informed consent
- Information sheet and informed consent form - vers: 1 - date: 10/06/2025 - notes: Minor informed consent
- Information sheet and informed consent form - vers: 1 - date: 10/06/2025 - notes: Legal parent-guardian consent form
- Form for consent to the processing of personal data - vers: 1 - date: 06/10/2025
- Letter to the primary care physician - vers: 1 - date: 10/06/2025 - notes: Letter to the attending physician
- Letter to the primary care physician - vers: 1 - date: 10/06/2025 - notes: Letter to the pediatrician
- Draft economic convention

Date of arrival complete documentation: 12/29/2025

HAS DELIVERED THIS OPINION:

Approved on condition

Notes/requests: CET ASOV proceeds with the approval of the study subject to receiving the following amendments/additions:

- Please clarify how many people will be enrolled at the AOUI VR center, as conflicting information is provided: 25 people are listed in the transmittal letter, 20 in the synopsis and 10 in the local feasibility document;
- In the information sheet for children aged 6-11, V1 of 10/06/2025:
 - Page 1 asks to explain what is meant by "collapse of the lung"
 - Page. 2 is asked to rewrite the sentence "No identifying data will be sent apart from gender and age and in any case the data will be managed in a protected way and in full anonymity according to the highest international standards" with a simpler language suitable for minors
- In the information sheet for children aged 12-17, V1 of 10/06/2025:
 - Page 3 of the sentence "[...] hundreds of patients of the same age as you who have had spontaneous pneumothorax will be included" please specify that recruitment of adult patients is also planned
 - On page 3, it is asked to amend the paragraph "Whether or not to participate is my free choice?" in such a way that it is clear that the child may or may not express a wish to participate in the study, but that the ultimate decision rests with the parents. It is recommended to take as a reference the CNCC model
 - A page 5 paragraph "What happens if I come of age while studying?" asks to replace "parental authority" with "parental responsibility"
 - Page. 5 paragraph B2, asks to choose only one of the two options regarding the destruction of personal data: "They will not be destroyed only in the event that a) it is no longer possible to trace them back to your identity, because anonymized during the study itself; b) in the presence of your specific informed consent."
- The information sheet and informed consent form for parents/legal guardians, V1 of 10/06/2025, is very long and in some parts redundant. It is recommended to streamline the information by deleting/modifying concepts that are repeated (e.g. paragraphs B1, B3, B4). In addition:
 - Page. 8 asks to delete the sentence "No compensation is provided, but participation does not entail any additional cost for the family", information not relevant with the paragraph and already provided
 - Please specify that the data collected will be in pseudonymised form (and explain what is meant) and not in anonymous form, as reported instead.

- The information sheet and informed consent form for adults, V1 of 10/06/2025, is very long and in some parts redundant. It is recommended to streamline the information by deleting/modifying concepts that are repeated (e.g. paragraphs C1, C3, C4). In addition:
 - Please specify that the data collected will be in a pseudonymised form (and explain what is meant) and not in an anonymous form, as instead reported
 - p. 5 paragraph "Are there any reasons why the study could be interrupted not by my will (early conclusion)?" asks to review/delete the point "parents/guardians no longer wish to cooperate in collecting the necessary data"
 - The following sentences are requested to be modified for the adult subject only: "Doctors will continue to treat your child according to best practices and available guidelines" (p. 4); "If possible, researchers will still ask you to complete the visits [...]" (p. 5); "If you wish, researchers can provide [...]" (page 8)
 - pag. 8 asks to delete the sentence "No compensation is provided, but participation does not entail any additional cost for the family", information not relevant with the paragraph and already provided
- There is a possible discrepancy between the retention period for personal data indicated in the information notice for the processing of personal data (page 4, paragraph 7, retention is indicated as 3 years) and the retention period indicated in the protocol. (page 22, paragraph "data retention and archiving", the storage of data for at least 5 years). Clarification on this point is requested.

The CET ASOV proceeds with approval on condition of study.

APPROVED UNDER CONDITIONS

Members of the Territorial Ethics Committee for South-West Veneto present at the discussion:

- BONETTI Andrea, Clinical expert on clinical trials
- BONINSEGNA Fernando, Representative of patient associations or citizens committed to health issues
- BRESOLIN Chiara, clinical engineer
- CASTELLO Roberto, Clinical expert on clinical trials
- DEL BIANCO Paola, Biostatistician
- DE BERNARDO M. Gloria, Esperto di bioetica
- GAJOFATTO Alberto, Clinical expert on clinical trials
- GANGEMI Michele, Pediatrics
- INNO Alessandro, Clinical expert on clinical trials
- LEONE Roberto, Pharmacologist
- MALLEO Giuseppe, Clinical expert in the study of new technical, diagnostic and therapeutic procedures, invasive and semi-invasive
- MELOTTI Paola, Expert in genetics, in relation to genetic studies
- RIGON Giulio, Territorial General Practitioner
- SPONGA Matteo, Medical Examiner
- STRINI Veronica, Representative of the area of health professions concerned with experimentation

Members of the Territorial Ethics Committee absent:

- BRUGNARO Pierluigi, Clinical expert on clinical trials
- CORDIANO Alessandra, Expert in legal matters

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- DI FRANCESCO Vincenzo, expert in nutrition, in relation to the study of food products on humans
- GIRI Maria Grazia, Medical Physicist
- RANIERO Dario, Insurance expert
- VENTURINI Francesca, Hospital pharmacist
- ZUPPINI Teresa, Medical device expert

The above-mentioned members of the Committee declare that they will refrain from taking a position on those trials for which there may be a direct or indirect conflict of interest.

Verona, 20-01-2026

Order of the President of the Ethics
Committee
Territorial Area South-West Veneto
The Office of Secretary
Dr. Roberta Fraccaroli

**Digitally signed by:
FRACCAROLI ROBERTA
Signed on 28/01/2026 15:43
28.01.2026 14:43:35 UTC**

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Prot. no. 14924 of 10/03/2026

Investigator: Dr. Federica Pederiva, CENTER: Azienda Ospedaliera Universitaria Integrata di Verona -
Chirurgia Pediatrica

Director UO: Prof. Luca Giacomello, CENTER: Azienda Ospedaliera Universitaria Integrata di Verona -
Chirurgia Pediatrica

Promoter: Azienda Ospedaliera Universitaria Integrata di Verona

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**Subject: Acknowledgement by the Scientific Secretariat of the CET ASOV regarding the clinical trial:
GASPOUT (Global**

**Assessment of Spontaneous Pneumothorax: Outcomes and Treatment): Studio internazionale prospettico di
Spontaneous pneumothorax cohort: treatment and outcomes - Protocol code: GASPOUT- Prog. 882CET**

The Territorial Ethics Committee South West Veneto (CET ASOV), in its meeting of 01/20/2026 approved the study under condition.

Following this decision, the following amended documentation was forwarded to the Office of the Scientific Secretariat of CET ASOV on 25/02/2026:

- Transmittal letter for approved on condition - date: 02/02/2026
- Synopsis of the study - verse: 2 - date: 02/02/2026 - clean + TC
- Information sheet and informed consent form - verse: 2 - date: 02/02/2026 - notes: adult consent - clean + TC
- Information sheet and informed consent form - verses: 2 - date: 02/02/2026 - notes: less mature consent - clean + TC
- Information sheet and informed consent form - verse: 2 - date: 02/02/2026 - notes: minor consent - clean + TC
- Information sheet and informed consent form - verse: 2 - date: 02/02/2026 - notes: parental consent - clean + TC
- Information notice and consent form for the processing of personal data - version: 2 - date: 02/02/2026 - clean + TC

This documentation is noted, which meets the requirements of ASOV TEC.

It is recalled that:

- For the activation of the trial, it is necessary to wait, if required, for receipt of authorization from its own administration.
- The Investigator is required to report to the Ethics Committee the recruitment of the first patient.
- At the end of the study, the investigator must send the final report to the Ethics Committee.

Trial Prog. **882CET**

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The CET ASOV Secretariat Office
Dr. ssa Roberta Fraccaroli

Digitally signed by:
FRACCAROLI ROBERTA
Signed on 10/03/2026 15:06
10.03.2026 14:06:44 UTC

Trial Prog. **882CET**

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