EUCROF
European CRO Federation

20 February 2025

EUCROF Code of Conduct for Service Providers in Clinical Research

Call for candidates for the Governance Body:

The Supervisory Committee (COSUP)

Following the adoption of opinion 12/2024 by the EDPB (European Data Protection Board) on June 18, the EUCROF Code has been definitely adopted on September 12, 2024 (deliberation 2024-64 of CNIL). **This Code is the first GDPR transnational code in the area of health**. It is the specific interpretation, **approved by the supervisory authorities of the 27 EU Member States**, of how the GDPR should be implemented for clinical research. The documents of the Code are now public and can be downloaded from EUCROF web site (https://cro.eucrof.eu/gdpr-form).

The Code is a unique tool to ensure security and transparency, and build trust and confidence towards patients, investigational sites, pharma, biotechs, medtechs, ethics committees, authorities and reduce the burden of audits and vendor assessments in an harmonized EU landscape.

Now, EUCROF releases this call for candidates, to appoint the **EUCROF Code of Conduct Supervisory Committee (COSUP)** constituting the **Governance Body of the Code**. The COSUP is the only body entitled to exercise operational decision-making regarding the adherence of CROs to the Code, in an impartial and independent manner. Candidates should have 10 years of experience in at least one of the following domains: (1) research in the domains of health, epidemiology, genetics, biostatistics, human and social sciences, (2) protection of Personal Data, (3) health information systems, (4) the protection of the rights of patients, or (5) relevant experience of audit, inspection, or certification processes.

To ensure a balanced, impartial and independent decision making, candidates should have a documented experience in one of the areas:

- CROs,
- Patient associations or advocates,
- Healthcare Professionals (Investigational Sites)
- Organisations developing, producing or commercialising health products, including pharmaceutical companies, manufacturers of medical devices and biotechnology; and
- Independent experts with documented experience in one or more of the above domains.

Every member of the COSUP shall complete a declaration of interests as in appendix 3 of the Code. Candidates may be excluded in case of insufficient documented experience, overlap with other candidates or in case of prohibitive conflict of interest.

As a member of the COSUP, you will have the opportunity to engage in a privileged collaboration scheme with the supervisory authorities, and to influence future adaptations of the Code, for instance to facilitate the wider adoption of decentralized trials, or the secondary use of health data for clinical research in the context of the European

Health Data Space (EHDS), the development of Artificial Intelligence in clinical research or simplify the relationship between CROs and all other stakeholders of clinical research: sponsors, patient advocacy groups, investigational sites, ethics committees etc.…

The term of office for Members of the COSUP is 3 years. The term of office of the Chairman and Vice-Chairman can be extended only one time. Regular Members can have their term of office extended for 3 successive terms of 3 years. The COSUP will start operation as soon as the first 8 members are found and the maximum number of members is 12.

Decisions of the COSUP are taken by simple majority vote of its Members, provided that the quorum is achieved. The COSUP is expected to meet 11 times per year, including 10 remote meetings (2 hours videoconferencing) and 1 in person meeting, representing an estimated workload of 7 days per year. Members of the COSUP will receive a compensation fee for their participation and any travel expenses will be taken in charge by the COSUP's budget.

Please submit your candidacy by sending a CV and a motivation letter to info@eucrof.eu. Use the same email address for any questions you may have in relation with the subject.

Your candidacy will be assessed by the ad hoc committee setup by EUCROF for this purpose. EUCROF wishes to have the COSUP in operation at the end of Q1 2025 or beginning of Q2 2025.

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Yoanni Th. MATSAKIS

EUCROF Vice-President & chairman of the ad hoc committee

21/02/2025

Members of the ad hoc committee:

- Dimitris Athanassiou
- Pierre-Henri Bertoye
- Magnus Johanssen
- Dipak Kalra
- Stefano Marini
- Yoanni Th. Matsakis
- Doris Wiegel

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Powers of the COSUP

(powers of the COSUP are defined in Chapter 5 of the Code)

- Assess the applications of CROs willing to adhere to the Code and decide on the Compliance Mark for successful applicants.
- Deliver appropriate instructions for the update of the online Public Register of adhering CROs.
- Make decisions regarding the selection of Auditors.
- Organises and approves the allocation of Auditors to assess CROs who have applied for adherence to the Code.
- Makes decisions regarding the selection of the Risk and Compliance Officer whose role is to prepare and document the decisions of the COSUP.
- Organises and monitors the maintenance of compliance by adherent CROs at regular intervals as defined in the Code's procedures regarding the process of controlling and maintaining compliance with the Code.
- Establishes procedures and structures to deal with complaints about infringements of the Code or the manner in which the Code has been, or is being, implemented by CROs.
- Investigates and adjudicates complaints about infringements of the Code by adherent CROs.
- Takes appropriate action against a CRO in the case of an infringement of the Code or in the event that a CRO is not providing the information necessary to investigate a possible infringement of the Code to the COSUP.
- Informs the competent supervisory authority of final actions taken against CROs and the reasons for taking them. Informs the competent supervisory authority in case the CRO is suspended or excluded.
- Implements procedures and structures that prevent conflicts of interests.
- Communicates with the wider public as required to ensure appropriate transparency.
- Performs appropriate financial management.
- Takes any appropriate decision to maintain its accreditation by the competent authority.
- Monitors changes in European Union data protection laws and other relevant laws and proposes relevant changes to the Code. For this purpose, the COSUP has the capacity to activate relevant EUCROF working groups or set-up ad hoc working groups as necessary.
- Contributes to the continuous improvement of the Code and elaborates recommendations for improvements.
- Reviews updates to the Code, before their submission to the competent supervisory authority by the Code owner (EUCROF).

About EUCROF

EUCROF is a not-for-profit legal entity registered in the Netherlands whose objectives are, among others, to contribute to high quality Clinical Research in humans and to promote the excellence of European Clinical Research to the public and the media, as well as on the international stage.

The members of EUCROF are national CRO associations as well as individual CROs established in one or more European countries or outside Europe, as defined in its Bylaws. Today EUCROF has more than 450 affiliated companies, in 31 countries. The list of EUCROF members, as well as EUCROF Bylaws, are public and can be freely downloaded from EUCROF's website (www.eucrof.eu).

About GDPR Codes of Conducts

Article 40 of Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, also known as "GDPR", "*[…] encourages drawing up of code of conducts intended to contribute to the proper implementation of this Regulation, taking account of the specific features of the various processing sectors and the specific needs of micro, small and medium-sized enterprises*."

Monitoring of compliance with a code of conduct pursuant to Article 40 must be implemented according to article 41 GDPR and *may be carried out by a body which has an appropriate level of expertise in relation to the subject-matter of the code and is accredited for that purpose by the competent supervisory authority*.

Clinical research is a field with highly specific features, where a number of dedicated Regulations apply, and the vast majority (over 90%) of Service Providers for Clinical Research, also known as "CROs" – Contract Research Organizations" are micro, small, and medium-sized enterprises.

Development of the Code was triggered by the clear identification of the lack of harmonised approaches with regards to the application of the requirements of the GDPR to the data processing in which CROs are engaged.
Inviting CROs to comply with the requirements established by the Code promotes better safeguards for data subjects in Clinical Research. A Code of Conduct contributes to transparency of the practices employed by CROs and also offers better protection for data subjects if the adhering CROs implement the principles of the GDPR. The demand for a Code for CROs was scrutinised in discussions with privacy and clinical experts, confirmed and recognised by the authorities, including by the representative of the European Data Protection Supervisor (EDPS). Clinical Research is mentioned twice in the EDPB Guidelines 1/2019 on Codes of Conduct and Monitoring Bodies as a domain that should benefit from a Code of Conduct.