Annex to the **TEF-Health Consortium Agreement**
Based on Template EN_Muster_Joint_Controller_FoKo_202103.docx; changes marked Green.

Agreement on joint control over the processing of personal data in accordance with Article 26 of the General Data Protection Regulation (GDPR)

between the following Parties (individual parties are hereinafter referred to by their short name indicated in brackets):

1. **Charité – Universitätsmedizin Berlin** (CHARITE), Charitéplatz 1, 10117 Berlin, Germany, represented by the Faculty Business Director Anne Großkopff
2. **TECHNISCHE UNIVERSITAET MUENCHEN** (TUM), acting here through its Chair for Robotics, Artificial Intelligence and Embedded Systems, Prof. Dr. Alois Christian Knoll, established in Arcisstrasse 21, 80333 MUENCHEN, Germany
3. **KAROLINSKA INSTITUTET** (KI), Department of Clinical Neuroscience, reg. no. 202100-2973, 171 77 STOCKHOLM, Sweden
4. **PHYSIKALISCH-TECHNISCHE BUNDESANSTALT** (PTB), BUNDESALLEE 100, 38116 BRAUNSCHWEIG, Germany
5. **LABORATOIRE NATIONAL DE METROLOGIE ET D'ESSAIS** (LNE), Rue Gaston Bossier 1, 75724 PARIS, France
6. **COMMISSARIAT A L'ENERGIE ATOMIQUE ET AUX ENERGIES ALTERNATIVES (CEA),** a French state-owned research entity with a scientific, technical or industrial activity duly organised under the laws of France, declared at the Paris Register of Commerce and Trade under the following registration number: R.C.S. Paris B 775 685 019, established at 25 rue Leblanc Bâtiment « Le Ponant D » - 75015 Paris – FRANCE, acting for its "Laboratoire d'électronique et de technologie de l'information" (LETI), and represented by Mrs Julie GALLAND, Director of DRT
7. **CENTRE HOSPITALIER UNIVERSITAIRE DE GRENOBLE ALPES** (CHUGA), BOULEVARD DE LA CHANTOURNE CS 10217, 38700 L1A TRONCHEF, GRENOBLE CEDEX 9,, France
8. **UNIVERSITE GRENOBLE ALPES (UGA)**, established in 621 AVENUE CENTRALE, GRENOBLE 38058, France
9. HOSPICES CIVILS DE LYON (HCL), a Public Health Establishment having its registered office at 3, Quai des Célestins, 69002 LYON, FRANCE, represented by its General Manager, Mr. Raymond LE MOIGN
10. **FONDATION DE COOPERATION SCIENTIFIQUE** (IHU STRASBOURG), 1 PLACE DE L'HOPITAL, 67000 STRASBOURG, France
11. **RISE RESEARCH INSTITUTES OF SWEDEN AB** (RISE), Sven Hultins plats 5, 412 58 Göteborg, Sweden
12. **UNIVERZITNA NEMOCNICA MARTIN** (University Hospital Martin), Ul. Kollárova 4248/2, 036 59, Martin, Slovakia
13. **UNIVERZITA KOMENSKEHO V BRATISLAVE** (UK BA), SAFARIKOVO NAM 6, 814 99 BRATISLAVA, Slovakia
14. **ZILINSKA UNIVERZITA V ZILINE** (UNIZA), UNIVERZITNA 8215/1 000, 01026 ZILINA, Slovakia
15. **EBRAINS** (EBRAINS), CHAUSSEE DE LA HULPE 166, GLAVERBEL 0001170, BRUXELLES, Belgium
16. **INSTITUTO PEDRO NUNES ASSOCIACAO PARA A INOVACAO E DESENVOVIMENTO EM CIENCIA E TECNOLOGIA** (IPN), RUA PEDRO NUNES 000, 3030-199 COIMBRA, Portugal
17. **Health Cluster Portugal – Associação do Polo de Competitividada da Saude** (HCP), Rua da Lionesa nº446 Loja K, 4465-671 Leça do Balio, Portugal
18. **CENTRO HOSPITALAR E UNIVERSITARIO DE COIMBRA EPE** (CHUC EPE), AV DE BISSAYA, PRACETA DE

MOTA PINTO, 3000-075 COIMRRA, Portugal

19. **CENTRO HOSPITALAR DE SAO JOAO EPE** (CHSJ), ALAMEDA DO PROFESSOR HERNANI MONTEIRO 000, 4200 319, PORTO, Portugal
20. **SERVIÇOS PARTILHADOS DO MINISTÉRIO DA SAÚDE E.P.E** (SPMS), a state owned enterprise nr 509540716, established under the laws of Portugal, with its registered office at Avenida da República, 61, 1050-189 Lisbon, legally represented by the President of the Board of Directors.
21. **FRIEDRICH-ALEXANDER-UNIVERSITAET ERLANGEN-NUERNBERG** (FAU), SCHLOSSPLATZ4, 91054 ERLANGEN, Germanv
22. **FRAUNHOFER GESELLSCHAFT ZUR FORDERUNG DER ANGEWANDTEN FORSCHUNG EV** (Fraunhofer), HANSASTRASSE 27C 000, 80686 MUNCHEN, Germany
23. **HUMANI SC (HUmani),** BOULEVARD ZOE DRION 1 1, 6000, CHARLEROI, Belgium
24. **MULTITEL** (MULTITEL), RUE PIERRE ET MARIE CURIE 2, 7000 MONS, Belgium
25. **UNIVERSITE DE NAMUR ASBL** (UNamur), RUE DE BRUXELLES 61 000, 5000, NAMUR, Belgium
26. **CENTRE D'EXCELLENCE EN TECHNOLOGIES DE L'INFORMATION ET DE LA COMMUNICATION** (CETIC), AVENUE JEAN MERMOZ 28 000, 6041, CHARI FROI Belgium
27. **TUV AI.Lab**, Max-Urich-Straße 3, 13355 Berlin, Germany
28. **EIT HEALTH EV** (EIT HEALTH EV), MIES-VAN-DER-ROHE-STRASSE1 C, 80807 MUNCHEN, Germany
29. **EIT HEALTH SI GMBH** (EIT H SI GmbH), MIES VAN DER ROHE STRASSE 1C 000, 80807 MUNCHEN, Germany
30. **PLATEFORME DES DONNEES DE SANTE** (Health Data Hub), 9 RUE GEORGES PITARD 000, 75015, Paris, France
31. **CENTRE HOSPITALIER UNIVERSITAIRE DE RENNES** (CHU RENNES), RUE HENRI LE GUILLOUX -HOPITAL 2, 35033 RENNES (FDFX 9 France
32. **EIT HEALTH HUB FRANCE** (EIT Health FR), 187 RUE DU CHEVALERET 000, 75013, PARIS, France
33. **EIT HEALTH INNOSTARS EV** (InnoStars), MIES VAN DER ROHE STRASSE 1/C 000, 80807 MUNCHEN Germany
34. **UNIVERSITA DEGLI STUDI DI PAVIA** (UNIPV), STRADA NUOVA65, 27100 Lombardia, PAVIA Italy
35. **FONDAZIONE BRUNO KESSLER** (FBK), VIA SANTA CROCE 77, 38122, TRENTO Italy
36. **POLITECNICO DI MILANO DEIB** (POLIMI), PIAZZA LEONARDO DA VINCI 32 000, 20133 MILANO, Italy
37. **ISTITUTO SUPERIORE DI SANITÀ** (ISS), Viale Regina Elena 299, 00161, ROMA Italy
38. **FONDAZIONE ISTITUTO ITALIANO DI TECNOLOGIA** (IIT), VIA MOREGO 30, 16163, GENOVA Italy
39. **POLE MECATECH** (POLE MECATECH), RUE JEAN SONNET 21, LES ISNES, Belgium
40. **BioWin (BIOWIN)**, Business Village Ecolys, Avenue d'Ecolys 2, 5020 Namur, Belgium
41. **WSL** (WSL), RUE DU BOIS SAINT JEAN 15/1, SERAING Belgium
42. **BERLIN PARTNER FUR WIRTSCHAFT UND TECHNOLOGIE GMBH** (BPWT), FASANENSTRASSE 85,10623 BERLIN, Germany
43. **HUS GROUP** (HUS), STENBACKINKATU 9 PO box: 100, 00029, HELSINKI Finland
44. **METROPOLIA AMMATTIKORKEAKOULU OY** (METROPOLIA), MYLLYPURONTIE1, PO box: 4000 00920 HELSINKI Finland
45. **HELSINGIN KAUPUNKI** (HELSINGFORS), POHJOIS ESPLANADI 15-17, 00099, HELSINKI Finland
46. **Masarykova univerzita** (MU), 7erotinovo namesti 9, 601 77 BRNO, Czechia
47. **KI Park e.V.** (KI Park e.V.), Lankwitzer Str. 45-57, 12107 Berlin, Germanv
48. **SLOVENSKA TECHNICKA UNIVERZITA V BRATISLAVE** (STUBA), VAZOVOVA 5, 81243 BRATISLAVA, Slovakia
49. **VLAAMSE INSTELLING VOOR TECHNOLOGISCH ONDERZOEK N.V.** (VITO), BOERETANG 200, 2400 MOL Belgium
50. **ISTITUTO GIANNINA GASLINI** (IGG), VIA GEROLAMO GASLINI 5, 16147. GENOVA, Italy
51. **INNOVAAL AGGREGAZIIONE PUBBLICO-PRIVATA PER L'ACTIVE & ASSISTED LIVING SOCIETA CONSORTILE A RESPONSIBILITA LIMITATA** (INNOVAAL SCARL), VIA MONTERONI CAMPUS ECOTEKNE C O CNR, 73100, LECCE Italy
52. **VERENIGING EIT HEALTH BELGIE-NEDERLAND** (EIT Health BeNe), TATIONSPLEIN 45

All Parties act as joint controller within the meaning of the GDPR hereinafter collectively referred to as the "**Parties**"

Preamble

The Parties intend to cooperate within the framework of the TEF-Health Project (tefhealth.eu; hereinafter referred to as the "**Project**") and concluded the TEF-HEALTH CONSORTIUM AGREEMENT (hereinafter referred to as the "**Main Agreement**") for this purpose on 12.02.2024. The cooperation in the context of the Project requires the processing of personal data in respect of which the Parties – at least in part – jointly determine the purposes and means of the data processing and to that extent consider themselves as joint controllers within the meaning of Article 26 GDPR. For this reason, the Parties enter into the present agreement on joint control over the processing of personal data in accordance with Article 26 of the General Data Protection Regulation (hereinafter the "**Agreement**"):

1. General remarks

(1) This Agreement governs the rights and obligations of the Parties in relation to the joint processing of personal data. This Agreement applies to all activities in the course of which employees of the Parties or processors engaged by them process personal data in the context of the Project. The Parties have jointly determined the means and purposes of the processing activities described in more detail in section "Data processing operations, legal bases and tasks of the Parties".

(2) The subject matter of this Agreement is the processing of personal data by the Parties for the purpose of implementing the Project. The Parties hereby determine the processing steps in which personal data are processed under their joint control (Article 26 GDPR).

(3) For the avoidance of doubt, with respect to any processing that falls outside the scope of this Agreement, each of the Parties shall remain solely responsible and fully liable as independent controller within the meaning of Article 4 GDPR and, to that extent, no responsibilities or obligations of any Party towards the respective other Party shall arise under this Agreement.

(4) Unless otherwise specified in this Agreement, the terms used herein shall have the meaning ascribed to them in Article 4 GDPR.

2. Data processing operations, legal bases and tasks of the Parties

(1) The responsibilities and competences in the context of the implementation of the Project are set out in Annex 1.

(2) The subject matter of the processing, the type of data and categories of data subjects, and the purposes of the processing, are set out in Annex 2 and in the study protocol, to be annexed to the Main Agreement where available.

(3) If necessary because of a data processing operation, the Parties will adapt the provisions of this Agreement accordingly. In view of the obligations of the Parties as joint controllers, each of the Parties is responsible for informing the other Parties if it deems it necessary to adapt the Agreement.

3. Principles relating to the processing

(1) Each Party shall ensure compliance with the statutory provisions, in particular the lawfulness of the data processing operations it carries out, including in the context of joint control. The Parties affirm and shall ensure that all personal data will be collected and further processed in accordance with the provisions of this Agreement and applicable data protection laws.

(2) The Parties shall at all times ensure that they comply with the principles relating to the processing of personal data under Article 5 GDPR.

(3) If any of the Parties considers that, in the course of the performance of the present Agreement, any/the other Party is in breach of the provisions of this Agreement or of the applicable data protection laws, it shall immediately notify the other Party/Parties of this.

4. Expediency and data minimisation

(1) The Parties shall store the personal data for which they are responsible in structured, commonly used and machine-readable formats as defined by the World Wide Web Consortium (W3C), IETF (Internet Engineering Task Force) RFC Database, ISO, Schema.org, and OpenAPI initative including JSON, XML, YAML, RDF, CSV, Markdown, HTML, PDF, ODF, DOCX, XSLX, Dockerfile, FHIR, DICOM, BIDS, iCal, VCard, ZIP, MP4, MP3, SVG, WAV, TIFF, X.509, JWT, Git, PEM, and HDF5.

(2) Each Party that collects data shall ensure that only those personal data are collected that are consistent with the specified, clear and legitimate purposes for the implementation of the Project and are strictly necessary.

(3) None of the Parties shall make copies or duplicates of the personal data processed under this Agreement unless necessary for the implementation of the Project (including data backups) or for the purpose of complying with legal retention obligations.

5. Location of the data processing

Processing within the EU/EEA

(1) The Parties shall process personal data in the course of the implementation of the Project exclusively in the Member States of the European Union or in another state that is a party to the Agreement on the European Economic Area.

(2) Paragraph 1 shall apply accordingly to the use of processors in accordance with section "Commissioned Data Processing - Use of Processors".

6. Information to be provided to data subjects

(1) The Parties undertake to provide data subjects free of charge with the information required under Articles 13 and 14 GDPR in a concise, transparent, intelligible and easily accessible form, using clear and plain language. This information shall inform the data subjects about the allocation of responsibility for the processing of the personal data. In particular, information shall be provided on which Party is responsible for the identifying data or the process of re-identification. This Party should also be named as the contact person for safeguarding the rights of data subjects.

(2) The Parties agree that the Party collecting the personal data from the data subjects shall provide the information referred to in paragraphs 1 and 2.

7. Contact point for data subjects and reciprocal information requirement

(1) The Parties shall take all necessary technical and organisational measures to ensure that the rights of the data subjects, in particular under Articles 12 to 22 GDPR, can be or are guaranteed at all times within the statutory time limits, in so far as these rights are not restricted by statutory provisions.

(2) The Party that is to process the identifying data in accordance with the Agreement shall be responsible for responding to requests from data subjects for the purpose of asserting their rights under Articles 15 to 22 GDPR. The Parties agree that in each case this Party shall be named as the contact point for the data subjects. Data subjects may assert the rights to which they are entitled under Articles 15 to 22 GDPR against all Parties. Data subjects shall be informed of the contact point responsible for them and of their rights by the responsible Party in accordance with section "Information to be provided to data subjects".

(3) The Parties will assist each other in responding to requests and giving effect to data subject rights. If a Party receives a complaint, request, or notice from a data subject whose data it did not collect,

it will promptly notify the Party that collected the data of the data subject's request. If a data subject contacts one of the Parties regarding the exercise of his or her data subject rights, in particular for information or the rectification or erasure of his or her personal data, the Parties undertake to forward this request without delay to those Parties whose sphere of activity is affected by the request, irrespective of the obligation to ensure the data subject right.

(4) The Parties' responsible contact persons are:

#	Party	Function	Surname, first name	Email	Phone
1	CHARITE	Coordinator	Ritter, Petra	petra.ritter@bih-charite.de	+49 30 450 560 005
2	TUM	Project Manager	Knoll, Alois	knoll@in.tum.de	+49 (89) 289 - 18104
3	KI	Swedish TEF-Health node coordinator, TEF-Health project leader (PI)	Daniel Lundqvist	daniel.lundqvist@ki.se	+46 709 640 339
4	PTB	Coordinator Digital Medicine	Schwabe, Daniel	Daniel.schwabe@ptb.de	+49 30 3481 7802
5	LNE	French Node coordinator, Project Manager	Bernard, Guillaume	guillaume.bernard@lne.fr	+33 673073786
6	CEA	Manager	Hihi, Madjid	Abdelmadjid.HIHI@cea.fr	+ 33 43 87 89 658
7	CHUGA	Project Manager	Moreau-Gaudry, Alexandre	Tef-health@chu-grenoble.fr	+3376767614
8	UGA	Project Leader	Pierre Gillois	tef-health-uga@univ-grenoble-alpes.fr dpo@grenet.fr	
9	HCL	MD, PhD	Pr Marc COLOMBEL	Marc.colombel@chu-lyon.fr	
10	IHU STRASBOURG	Project Manager	Exter, Jeremie	jeremie.exter@ihu-strasbourg.eu	+33 3 90 41 36 18
11	RISE	Senior Project Manager	Salehi, Alireza	alireza.salehi@ri.se	+46 730429867
12	UHM	Data Protection Officer and Project Manager	Rastislav Igliar	gdpr@unm.sk Rastislav Igliar	+42143420 3 512 +421 905 93 50 60
13	UK BA	Data Protection Officer	Ondrej Zimen	dpo@uniba.sk	+421 904 914 198
14	UNIZA	Project leader	Róbert Hudec	robert.hudec@uniza.sk	+421 917 742 737
15	EBRAINS	Technical Project Manager	Ciprian Ciulpan	ciprian.ciulpan@ebrains.eu	N/A

16	IPN	Legal	Henrique Neves	hneves@ipn.pt	+351917167829
17	HCP	Innovation director	Patrícia Patrício	ppatricio@healthportugal.com	+351 912 318 566
18	CHUC EPE	Project Manager	Seringa, Joana	60128@ulscoimbra.min-saude.pt	+351 910 417 628
19	CHSJ	Senior Project Manager	Afonso Pedrosa	Jose.pedrosa@ulssaojoao.min-saude.pt	+351964884656
20	SPMS	Data Protection Officer	NA	DPO@spms.min-saude.pt	NA
21	FAU	Principal Investigator	Bjoern Eskofier	Bjoern.Eskofier@fau.de	+49 9131 8527297
22	Fraunhofer	Project Manager	Jackie Ma	jackie.ma@hhi.fraunhofer.de	+49 30 31002 461
23	HUmani	Chief Innovation Officer	Maxime Rossi	Maxime.rossi@humani.be	+32 (0)71 92.00.38
24	MULTITEL	Project manager	Anne-Laure Cadji	cadji@multitel.be	+32 65 34 27 57
25	UNamur	DPO	Karen Rosier	dpo@unamur.be	
26	CETIC	Project manager	Nikolaos Matskanis	nikolaos.matskanis@cetic.be	+32 486 87 69 68
27	VdTÜVTÜV AI.Lab	Project Leader	Alexander von Janowski	Alexander@tuev-lab.ai	+49 151 55205611
28	EIT HEALTH EV	Projecct Manager	Omolol Adanlawo	omolola.adanlawo@eithealth.eu	+491753265458
29	EIT HSI GmbH				
30	Health Data Hub				
31	CHU RENNES	Project Manager DPO	Baujard-Lamotte Lucie Hespel Anne	Tef-health@chu-rennes.fr Dpo@chu-rennes.fr	+33 (0)2 99 28 25 55
32	EIT Health FR				
33	InnoStars	Health Community Lead	Ricardo Pires	ricardo.pires@eithealth.eu	+351 912 697 922
34	UNIPV	Principal Investigator	D'Angelo Egidio Ugo	dangelo@unipv.it	+390382987606
35	FBK	Data Protection Officer	Anna Benedetti	privacy@fbk.eu	+390461314370
36	POLIMI	Data Protection officer	N/A	privacy@polimi.it	N/A

37	ISS	Principal Investigator	Evaristo Cisbani	evaristo.cisbani@iss.it	+390649902847
38	IIT	Data Protection Officer	N/A	dpo@iit.it	+39 010 28961
39	POLE MECA TECH				
40	BIOWIN				
41	WSL				
42	BPWT	Project Manager	Jasmin Podufall	jasmin.podufall@berlin-partner.de	+49 30 46302-122
43	HUS				
44	METROPOLIA	Project manager	Kari Heikkilä	kari.heikkila@metropolia.fi	+358452693125
45	HELSINKI	Senior Advisor	Sanna Hartman	Sanna.hartman@hel.fi	+358406341594
46	MU	Principal Investigator	Michal Kozubek	kozubek@fi.muni.cz	+420549494023
47	KI Park e.V.				
48	STUBA				
49	VITO				
50	IGG				
51	INNOVAAL SCARL				
52	EIT Health BeNe				

The other Parties shall be notified without delay of any change to the respective contact person.

(5) If a Party uses a processor and the processor receives a complaint, request or notice from a data subject, the Party that engaged the processor shall ensure that the processor notifies the Party that collected the data subject's data of the request.

8. Erasure of personal data

(1) If personal data are to be erased, the Parties shall inform each other in advance. The Parties may object to the erasure for a legitimate reason, for example if they have a legal obligation to retain the data or if the right to erasure is restricted by law.

(2) Regardless of a request for erasure, the Parties shall erase the data when the project objective has been achieved and if there is no right to further retention.

(3) Each Party shall keep a record of the erasure of personal data, which is to be provided to the other Parties upon request.

(4) Paragraphs 1 and 3 shall apply accordingly in the event of requests for rectification or restriction of processing from data subjects.

9. Communication and notification obligations

The Parties shall inform each other without delay if they discover errors or irregularities with regard to data protection provisions when reviewing the processing activities within the scope of the Project.

10. Procedure in the event of data protection incidents

(1) The Parties are responsible for the notification and communication obligations resulting from Articles 33 and 34 GDPR vis-à-vis the supervisory authority and the data subjects affected by a personal data breach under their respective responsibility. Any required notification to the supervisory authority shall be the responsibility of the Party under whose responsibility the personal data breach occurred. If the breach occurs under the responsibility of more than one Party, the Parties shall consult with each other on how to proceed.

(2) The Parties shall notify each other without delay, and in no circumstances more than 36 hours, after becoming aware of a possible personal data breach under their responsibility. If possible, this notification should already contain the information required under Article 33(3) GDPR.

(3) Any required notification to the supervisory authority shall be the responsibility of the Party under whose responsibility the personal data breach occurred. If the breach occurs under the responsibility of more than one Party, the Parties shall consult with each other on how to proceed. The Parties shall comply with the statutory time limit for notification within 72 hours. Any deviation from the time limit must be justified and documented.

(4) If, due to a risk to the rights and freedoms of natural persons, data subjects are to be informed pursuant to Article 34 GDPR, the Party that collected the personal data shall be responsible for this. The respective other Parties shall assist the Party responsible under the first sentence to the best of their abilities in fulfilling its notification obligations and shall forward the information required to carry out the notification to the Party in question without delay.

(5) Where possible, the Parties shall coordinate with each other on any communication with the competent supervisory authority and/or the data subjects relating to a personal data breach before it is sent. The Parties shall promptly take all measures within their areas of responsibility that are necessary to address or prevent data protection breaches and violations.

11. Data protection impact assessment (DPIA)

If a DPIA is required pursuant to Article 35 GDPR, the Parties shall assist each other and provide each other with the information necessary for its preparation. Projects for which a DPIA is to be carried out may only be started once the DPIA has been completed.

12. Documentation/accountability

Documentation within the meaning of Article 5(2) GDPR which serves to demonstrate proper data processing shall be prepared by each Party in accordance with its legal powers and obligations and, if necessary, shall be retained beyond the end of this Agreement.

13. Confidentiality, retention, state of the art, protection

(1) The Parties shall ensure, within their area of responsibility, that all employees involved in data processing maintain the confidentiality of the data in accordance with Articles 28(3), 29 and 32 GDPR for the duration of their employment as well as after termination of the employment relationship and that these persons have committed themselves to confidentiality and been informed of the data protection provisions relevant to them prior to commencing their employment.

(2) The Parties shall independently ensure that they comply with all statutory retention obligations existing in relation to the data. To this end, they shall take appropriate data security precautions (Article 32 et seq. GDPR). This applies in particular in the event of termination of the cooperation.

(3) The implementation, pre-setting and operation of the systems shall be carried out in compliance with the requirements of the GDPR and other legislation, in particular in compliance with the principles of data protection by design and by default, as well as using appropriate technical and organisational measures in line with the state of the art.

14. Commissioned Data Processing - Use of Processors

(1) The Parties are entitled to use processors within the meaning of Article 28 GDPR for processing operations under their respective responsibility. The Parties shall each keep a list of processors engaged by them for processing operations under this Agreement. In the event of a legitimate interest (e.g. monitoring compliance with the obligations under this Agreement, request from a supervisory authority or a data subject), the Parties shall make the lists available to each other, unless the request can be answered by means of direct information provided by the respective Party to the requesting person.

(1) Processors already entrusted with processing operations at the time of conclusion of the Agreement and also used by the respective Party to provide the processing operations under this Agreement shall be deemed to be approved by the other Parties.

(2) The Parties shall inform each other in good time, and in any event at least one month in advance, of any intended changes concerning the addition or replacement of subcontracted processors for the processing operations for which the Parties are joint controllers pursuant to section "Data processing operations, legal bases and tasks of the Parties" and shall only use subcontractors that comply with the requirements of data protection law and the provisions of this Agreement. For the purposes of this provision, subcontracted services do not include services that the Parties obtain from third parties as ancillary services in support of the performance of the contract, such as telecommunications services and maintenance. However, the Parties are obliged to make appropriate and legally compliant contractual agreements and to take control measures to ensure the protection and security of personal data, even in the case of externally contracted ancillary services.

(3) The Parties undertake to conclude a contract in accordance with Article 28 GDPR when using processors within the scope of this Agreement. The Party engaging the processors must impose obligations on these processors regarding data protection, confidentiality and data security that meet the requirements of Articles 28 and 29 GDPR and are at least as stringent as those set out in this Agreement. If subcontracting is allowed, the Parties shall ensure that the processors impose corresponding obligations on these subcontractors.

15. Record of processing activities

Each Party shall, in accordance with Article 30(1) GDPR, keep a record of the processing operations it carries out, including and in particular a note on the nature of the processing operation under its joint or sole control.

16. Audit rights

(1) Each Party shall have the right to audit the compliance of the other Parties with this Agreement if this is necessary in order to fulfil an obligation vis-à-vis a supervisory authority or to satisfy itself that the other Party/Parties has/have adapted its/their operations to the provisions of this Agreement following a data protection incident.

(2) If and to the extent that such an audit requires the performance of on-site inspections, such inspections shall ordinarily take place during normal business hours and without unnecessary disruption to operations. The Party conducting an audit shall give reasonable advance notice to the other Parties of all circumstances related to the audit (at least 20 days).

(3) A Party may engage a third party to carry out the audit. In such a case, the third party must be bound in writing to maintain secrecy and confidentiality, unless the third party is subject to a professional duty of confidentiality.

17. Liability

(1) Without prejudice to the provisions of this Agreement, in the event of unlawful data processing, the Parties shall, in accordance with Article 82(4) in conjunction with the first sentence of Article 82(2) GDPR, in relation to third parties, be jointly liable vis-à-vis the data subjects for any damage caused by processing which infringes the GDPR, unless any of the Parties can prove that it is not in any way responsible for the event giving rise to the damage (Article 82(3) GDPR).

(2) In their internal relationship, the Parties shall, without prejudice to the provisions of this Agreement, only be liable for damage that has occurred within their respective area of responsibility.

(3) If, pursuant to Article 82(4) GDPR, a Party has paid the entire compensation to a data subject for the damage suffered, that Party shall be entitled to recover from the other Parties that part of the compensation which corresponds to those other Parties' share in the responsibility for the damage.

(4) Paragraph 3 shall apply accordingly in the event that a supervisory authority has imposed a fine on a Party if and to the extent that the breach giving rise to the fine is based, in whole or in part, on a breach of this Agreement or the applicable data protection laws by one or more of the other Parties. Without prejudice to the foregoing, a Party may seek indemnification for a fine only if it has made all reasonable efforts to defend against or reduce that fine in the context of administrative proceedings.

18. Miscellaneous

(1) This Agreement shall remain in force, irrespective of the duration of the Project, until all data processed jointly by the Parties and/or any processors engaged have been erased, at which time it shall automatically cease to be in force.

(2) In all other respects, the final provisions of the Main Agreement shall apply accordingly.

19. Amendments

The Parties agree that any of the following conditions shall necessitate the execution of a new or amended agreement:

(1) Change in Processing Purpose: Any modification to the fundamental purpose of the data processing activities.

(2) Introduction of New Data Types and Processing of New Categories of Personal Data: The inclusion of new types of data and the processing of additional categories of personal data, particularly special categories as defined under Article 9 of the GDPR.

(3) New Third-Party Involvement: The engagement of additional joint controllers, processors, or sub-processors that influence the data flows or change the allocation of responsibilities among the Parties.

(4) Change in Data Subject Rights Impact: Any modification that may affect the manner in which data subjects can exercise their rights under the GDPR, such as rights of access, rectification, or erasure.

(5) Cross-Border Data Transfers: The implementation of data transfers outside the European Economic Area (EEA) that necessitate new or updated safeguards, including but not limited to Standard Contractual Clauses (SCCs).

(6) Change in Data Processing Means: The adoption or use of new technologies, software, or methodologies that could alter the risk profile of the data processing, such as the use of artificial intelligence to process sensitive data.

(7) Significant Risk Increase: Any change that results in a higher level of risk to the data subjects, as determined by a Risk Analysis or a Data Protection Impact Assessment (DPIA).

(8) Change in Data Security Measures: Revisions to the technical and organizational security measures, including but not limited to encryption standards, access controls, or breach response protocols, that impact the commitments outlined in this Agreement.

Annex 1 (to section Data processing operations, legal bases and tasks of the Parties: Responsibilities and competences of the Parties

Editing note: Please mark with [X] to indicate who is responsible for which tasks and with [Y] to indicate merely a support function.

The table below delineates the allocation of responsibilities among all parties. All parties acknowledge that joint control may apply only to specific aspects of the data processing activities, and in such cases, the parties share responsibility for fulfilling the associated obligations. For processing activities conducted by one or more joint controllers independently, as outlined in Annex 2, those parties bear sole responsibility for ensuring compliance with all relevant obligations and requirements. Annex 2 includes a Record of Processing Activities, which provides a comprehensive mapping of processing activities attributed to each partner.

Tasks according to GDPR	All Parties
Determination of the purpose and means of data processing	X
Determination of the type of personal data	X
Article 26(2): Informing the data subjects about the essence of this Agreement*	X
Article 13: Information to be provided where personal data are collected from the data subject*	X
Article 14: Information to be provided where personal data have not been obtained from the data subject	X
Articles 15-18, 20: Data subject's rights of access, rectification and erasure/restriction of processing and data portability*	X
Article 19: Notification obligation regarding rectification or erasure of personal data or restriction of processing**	X
Article 21: Right to object, if applicable (not in case of consent)	X
Articles 24, 32, 35, 36: Determination/documentation of technical and organisational measures, risk assessment, data protection impact assessment, where applicable, and consultation with the supervisory authority	X
Article 28: Engaging processors	X
Article 30: Maintaining the records of processing activities	X
Article 33: Notification of personal data breaches*,**	X
Article 34: Communication of a personal data breach to the data subject*,**	X

* Communication with the data subjects shall be carried out exclusively by the body that may lawfully access identifying data, sections 7 to 10 of the Agreement.
** Communication between the Parties shall, where appropriate, take place in pseudonymised form, see sections 7 to 10 of the Agreement.

Annex 2 (to section "Data processing operations, legal bases and tasks of the Parties" paragraph (2)): Description of the processing activity and categories of personal data

The descriptions of all processing activities, the performing partners, and categories of personal data are provided in the accompanying TEF-Health Records of Processing Activities.

Signature Template

Please use the following template

Authorized to sign on behalf of

Party Number: **<index as per list of Parties above>**

Party Short Name: **<short name as per list of Parties above>**

Signature: ……

Name: ……

Title: ……

Date: ……

Stamp (if applicable): ……