

ETHOS Digital Health Ltd

Terms and Conditions

G-Cloud 15 Service Delivery

Version 1.0

Effective Date: January 2026

Table of Contents

1. Definitions and Interpretation
2. Scope of Services
3. Engagement and Commencement
4. Service Delivery
5. Fees and Payment
6. Intellectual Property Rights
7. Confidentiality and Data Protection
8. Warranties and Representations
9. Liability and Indemnification
10. Term and Termination
11. Professional Standards and Conduct
12. Dispute Resolution
13. General Provisions

1. Definitions and Interpretation

1.1 Definitions

In these Terms and Conditions, unless the context requires otherwise:

- **"Agreement"** means the contract between ETHOS and the Client comprising these Terms and Conditions, the Statement of Work, and any other documents incorporated by reference.
- **"Client"** means the organisation or entity purchasing Services from ETHOS via the G-Cloud 15 framework.
- **"Deliverables"** means the outputs, documentation, reports, and other materials to be provided by ETHOS as specified in the Statement of Work.
- **"ETHOS"** means ETHOS Digital Health Ltd, a company registered in England and Wales.
- **"Framework Agreement"** means the Crown Commercial Service G-Cloud 15 Framework Agreement RM1557.15.
- **"Professional Standards"** means applicable regulatory and professional standards, including DCB 0129/0160, ISO standards, MHRA regulations, and professional body codes of conduct.
- **"Services"** means the clinical safety, regulatory compliance, information security, data protection, training, and related services provided by ETHOS as described in the Service Definition and Statement of Work.
- **"Statement of Work" or "SOW"** means the document specifying the scope, deliverables, timeline, and fees for specific Services.
- **"Virtual Officer Services"** means ongoing Virtual CSO, Virtual CISO, Virtual DPO, or Virtual Regulatory Lead services provided on a retainer basis.
- **"Working Day"** means Monday to Friday, 9 am to 6 pm, excluding UK public holidays.

1.2 Interpretation

- References to statutory provisions include those provisions as amended or re-enacted.
- Headings are for convenience only and do not affect interpretation.
- Words in singular include plural and vice versa.

2. Scope of Services

2.1 Services Provided

ETHOS shall provide Services in accordance with:

- The G-Cloud 15 Service Definition
- The agreed Statement of Work
- These Terms and Conditions
- Applicable Professional Standards and regulatory requirements

2.2 Service Categories

Services may include, but are not limited to:

- Clinical Safety Officer (CSO) services and DCB 0129/0160 compliance
- Medical Device Regulatory Affairs (UK MDR, EU MDR/IVDR, FDA)
- Information Security Management (ISO 27001, Cyber Essentials, DSPT)
- Data Protection and Privacy (GDPR, Virtual DPO services)
- Digital Technology Assessment Criteria (DTAC) support
- Training and capacity building programmes
- Strategic Digital Clinical Safety Model (SCSM) deployments
- Post-market surveillance and vigilance services
- Research and innovation partnership services

2.3 Service Variations

Any variations to the Services must be agreed in writing via a change order or amended Statement of Work signed by both parties.

3. Engagement and Commencement

3.1 Call-Off Contract

Engagement commences upon Client acceptance of the ETHOS proposal and execution of the Statement of Work via G-Cloud 15 Framework Agreement call-off procedures.

3.2 Initial Assessment

ETHOS may conduct an initial complimentary consultation to assess Client requirements and develop a tailored Service proposal.

3.3 Statement of Work

Each engagement shall be governed by a Statement of Work specifying:

- Scope of Services and deliverables
- Timeline and key milestones
- Resource allocation and personnel
- Fees and payment terms
- Client responsibilities and dependencies
- Success criteria and acceptance procedures

4. Service Delivery

4.1 Professional Standards

ETHOS shall provide Services:

- With reasonable skill and care consistent with industry standards
- In compliance with applicable Professional Standards and regulatory requirements
- Using appropriately qualified and experienced personnel

- In accordance with agreed timelines and milestones

4.2 Personnel

ETHOS personnel shall:

- Hold appropriate professional qualifications and registrations (e.g., NMC, GMC, HCPC for CSO services)
- Maintain professional indemnity insurance
- Undergo security screening in accordance with BS 7858:2019
- Comply with Client site access and security requirements

4.3 Client Responsibilities

The Client shall:

- Provide timely access to personnel, systems, and documentation
- Designate appropriate stakeholders and decision-makers
- Respond to ETHOS requests for information within agreed timeframes
- Provide a suitable working environment for on-site delivery where required
- Review and approve Deliverables within agreed timeframes

4.4 Delivery Methods

Services may be delivered remotely, on-site, or via a hybrid model, as agreed in the Statement of Work. Default delivery is remote via secure online platforms unless otherwise specified.

4.5 Communication and Reporting

ETHOS shall provide regular progress updates, reporting, and communication in formats and frequencies agreed with the Client.

5. Fees and Payment

5.1 Fee Structure

Fees are calculated based on:

- Day rates: £650 to £950 per Working Day, depending on service complexity and seniority
- Fixed-fee project pricing as specified in Statement of Work
- Retainer-based pricing for Virtual Officer Services
- Training course fees: £408 per delegate for accredited Foundation CSO course

5.2 Invoicing

- Invoices issued monthly in arrears for day-rate services
- Milestone-based invoicing for fixed-fee projects
- Advance invoicing for training courses and retainer services
- All fees are exclusive of VAT unless otherwise stated

5.3 Payment Terms

- Payment due within 30 days of invoice date
- Late payment subject to interest at 4% above Bank of England base rate
- ETHOS may suspend Services if payment is overdue by more than 14 days

5.4 Expenses

Reasonable expenses (travel, accommodation, materials) invoiced at cost with prior Client approval for expenses exceeding £200.

5.5 Fee Variations

Fees may be adjusted annually with 60 days' written notice. Change orders for scope variations shall specify fee adjustments.

6. Intellectual Property Rights

6.1 Client Deliverables

Upon full payment, Client shall own all Deliverables created specifically for Client, including documentation, reports, and compliance systems.

6.2 ETHOS IP

ETHOS retains ownership of:

- Pre-existing intellectual property and methodologies
- Proprietary ETHOS regulatory tools and software platforms
- Training materials and course content
- Templates, frameworks, and reusable components

6.3 License

Client granted a non-exclusive, non-transferable license to use ETHOS tools and methodologies for internal compliance purposes during engagement and ongoing compliance maintenance.

6.4 Third-Party IP

Where Services incorporate third-party intellectual property, appropriate licenses shall be obtained, or Client shall procure necessary permits.

7. Confidentiality and Data Protection

7.1 Confidential Information

Each party shall maintain the confidentiality of the other party's information, using the same degree of care as for its own confidential information, a minimum reasonable care.

7.2 Permitted Disclosures

Confidential information may be disclosed:

- To employees, subcontractors, and professional advisors on a need-to-know basis
- As required by law or regulatory authority
- With prior written consent

7.3 Data Protection

Both parties shall comply with UK GDPR and the Data Protection Act 2018. Where ETHOS processes personal data on behalf of the Client, the parties shall execute a Data Processing Agreement specifying data protection obligations.

7.4 Security Measures

ETHOS maintains information security controls, including:

- ISO 27001-aligned information security management
- Cyber Essentials Plus certification
- Encryption of data in transit and at rest
- Regular security assessments and penetration testing
- Staff security awareness training

8. Warranties and Representations

8.1 ETHOS Warranties

ETHOS warrants that:

- Services performed with reasonable skill and care
- Personnel appropriately qualified and experienced
- Services comply with applicable Professional Standards
- ETHOS has the authority to enter into an agreement and provide Services
- Services will not infringe third-party intellectual property rights

8.2 Client Warranties

Client warrants that:

- Information provided to ETHOS is accurate and complete
- Client has the authority to enter into the Agreement
- Client will comply with applicable laws and regulations

8.3 Limitations

Except as expressly stated, all warranties, conditions, and representations (express or implied, statutory or otherwise) are excluded to the maximum extent permitted by law.

9. Liability and Indemnification

9.1 Professional Indemnity Insurance

ETHOS maintains professional indemnity insurance with a minimum of £5,000,000 per claim and in aggregate per policy year.

9.2 Liability Cap

ETHOS total aggregate liability under or in connection with the Agreement (whether in contract, tort, negligence, breach of statutory duty or otherwise) shall not exceed:

- For project-based services: the total fees paid or payable under the relevant Statement of Work
- For Virtual Officer Services: fees paid in preceding 12 months
- Minimum £100,000 where fees are less than this amount

9.3 Excluded Losses

Neither party shall be liable for:

- Loss of profits, revenue, business, or anticipated savings
- Loss of use or corruption of data
- Loss of goodwill or reputation
- Any indirect or consequential losses

9.4 Exceptions

Nothing in the Agreement excludes or limits liability for:

- Death or personal injury caused by negligence
- Fraud or fraudulent misrepresentation
- Breach of confidentiality obligations
- Liabilities that cannot be excluded by law

9.5 Indemnification

ETHOS shall indemnify Client against third-party claims arising from ETHOS's negligence, breach of Agreement, or infringement of intellectual property rights, subject to:

- Client promptly notifies ETHOS of the claim
- ETHOS having sole control of defence and settlement
- Client providing reasonable cooperation

10. Term and Termination

10.1 Term

Agreement commences on Start Date specified in Statement of Work and continues until:

- Completion of project-based Services and acceptance of Deliverables

- Termination of Virtual Officer Services retainer
- Earlier termination in accordance with these Terms

10.2 Termination for Convenience

Either party may terminate project-based Services with 30 days' written notice. Client shall pay for Services performed and committed costs up to the termination date.

10.3 Termination for Cause

Either party may terminate immediately by written notice if:

- Other party commits a material breach and fails to remedy within 14 days of notice
- Other party becomes insolvent or subject to insolvency proceedings
- Other party suspends business or ceases trading

10.4 Effect of Termination

Upon termination:

- Client shall pay all outstanding fees for Services provided
- Each party shall return the other party's Confidential Information
- ETHOS shall deliver work-in-progress and documentation
- Clauses intended to survive termination shall continue (confidentiality, IP, liability)

10.5 Transition Support

ETHOS shall provide reasonable transition support for up to 30 days post-termination to facilitate handover, charged at standard day rates.

11. Professional Standards and Conduct

11.1 Regulatory Compliance

ETHOS personnel providing Clinical Safety Officer services shall:

- Maintain current professional registration (NMC, GMC, HCPC as applicable)
- Comply with professional codes of conduct
- Maintain fitness to practice
- Undertake continuing professional development

11.2 Independence

ETHOS shall maintain professional independence and objectivity in providing Services, particularly for statutory roles (CSO, DPO, PRRC, UK Responsible Person).

11.3 Conflicts of Interest

ETHOS shall disclose any actual or potential conflicts of interest and implement appropriate management measures with the Client's agreement.

11.4 Standards Compliance

Services shall comply with applicable standards, including DCB 0129/0160, ISO 13485, ISO 14971, ISO 27001, MHRA regulations, and other relevant regulatory frameworks.

12. Dispute Resolution

12.1 Escalation

Disputes shall first be escalated to the senior management of both parties for resolution within 14 days.

12.2 Mediation

If unresolved, the parties shall attempt mediation through CEDR or a similar body before litigation.

12.3 Jurisdiction

Agreement governed by the laws of England and Wales. Parties submit to the exclusive jurisdiction of the English courts.

13. General Provisions

13.1 Framework Terms

These Terms are subject to the Crown Commercial Service G-Cloud 15 Framework Agreement RM1557.15. In the event of a conflict, Framework terms prevail.

13.2 Entire Agreement

The Agreement constitutes the entire understanding between the parties and supersedes any prior agreements, representations, and understandings.

13.3 Amendments

Amendments must be in writing and signed by authorised representatives of both parties.

13.4 Assignment

Neither party may assign the Agreement without the other party's prior written consent, except that ETHOS may assign it to its affiliated companies.

13.6 Force Majeure

Neither party is liable for failure to perform due to events beyond reasonable control (pandemic, natural disaster, war, government action), provided the affected party promptly notifies the other party.

13.7 Notices

Notices under the Agreement shall be in writing to the addresses specified in the Statement of Work, deemed delivered:

- Hand delivery: upon delivery
- Email: upon transmission confirmation
- Post: 3 Working Days after posting

13.8 Waiver

Failure to enforce any provision does not constitute waiver. Waivers must be in writing.

13.9 Severability

If any provision is held invalid or unenforceable, the remaining provisions continue in full effect.

13.10 Third Party Rights

No third party has rights under the Contracts (Rights of Third Parties) Act 1999 to enforce the terms of the Agreement.

13.11 Counterparts

The Agreement may be executed in counterparts, each constituting an original, but together forming one agreement.

ETHOS Digital Health Ltd

Terms and Conditions - G-Cloud 15

Version 1.0 | January 2026

Crown Commercial Service Supplier | SGS Consultants Connect Standard Member