



G-CLOUD 14 SERVICE DEFINITION DOCUMENT

DATA PROTECTION	2
Data Protection Advice and Consultancy	2
Data Protection Impact Assessment (DPIA)	2
External Independent Reviews	2
Training	3
Data Protection Officer Services	3
Fair Processing Materials	4
Data Protection Health Check	4
Assistance With Policy Development	4
Data Security and Protection Toolkit (DSPT)	5
Record of Processing Activities (ROPA) & Information Asset Registers	5
Other Services	6
RESEARCH	6
Support for sponsors and Clinical Research Organisations (CROs)	6
Support for Participating Sites	7
Support for Suppliers	7
ARTIFICIAL INTELLIGENCE	8
AI Advice and Consultancy	8
AI Assessment	8
AI Training	8
AI Policy Development	8
DATA ETHICS	9
External Independent Reviews	9
Ethics Policy Development	9
Data Ethics Training	9
SECURE DATA ENVIRONMENTS	10
HEALTHCARE LEGACY CONSULTANCY	10
CORPORATE GOVERNANCE	11
PACKAGED SERVICES	11
SERVICE LEVELS	11
Telephone availability	11
Email availability and tailored service solutions	11
Performance Monitoring	11

We provide a full data protection and information governance consultancy service to all our clients who engage with us. We provide flexible packages and services to make sure that you only pay for what you need, and so you aren't paying for unnecessary services. Whatever you and your organisation need, we are here to help.

DATA PROTECTION

Data Protection Advice and Consultancy

Whilst we provide many services to our clients, one of our core services is general data protection/information governance consultancy support. The issues which an organisation may face, and the gaps and weaknesses they may have are often varied and bespoke. Having us engaged as consultants means you can turn to us to discuss any new or existing projects, policies, practices and make sure you are on the right side of the law.

If your organisation does not have any oversight on its data handling practices, or has concerns on how you handle personal data, or you are looking to bolster your existing practices and want support, we are here to support you.

Data Protection Impact Assessment (DPIA)

As an organisation, before you begin processing personal data for a particular project or function, you may be required to undertake a data protection risk assessment (DPIA) under Article 35 of the UK GDPR. With us, you get the safety and security of trained professionals undertaking a true deep dive in a particular project to assess any associated risks, before they develop. We will undertake a full, comprehensive report of the whole project and feedback the risks you will need to be aware of, and anything which you need to action before the project goes live.

In the event that you need to consult the supervisory authority of a particular project due to a risk that cannot be mitigated, we are able to undertake that consultation for you.

- ✓ We start by talking with you to better understand your organisation, the services you provide, the project itself, and any third party organisations involved in the project. We work by getting as much information as possible from you from the outset, to avoid you spending more time than you communicating unnecessarily with us throughout the review.
- ✓ Once we have everything we need, we are off to work. We will undertake a full DPIA of the project and turn it around in a reasonable amount of time. The time of each DPIA differs depending on the complexity and scope of each project.
- ✓ If we discover anything new throughout our investigations which require more information, we will engage with you to get everything we need to undertake the review.
- ✓ Once we have completed the DPIA, we will send it across and arrange for a meeting with any relevant stakeholders with the projects to explain our findings. In the event and issue a second version of the DPIA which you can share both internally, and externally.

External Independent Reviews

There is a multitude of reasons why an issue may have occurred, and we will help you figure out where the issue has occurred and present recommendations around how to mitigate the chance of the issue happening again. Our reviews are objective, informative and aim to provide you with as much information as possible to fix the issue without overwhelming you. We always ensure that our reviews have a series of recommendations and actions which you

should take to improve your organisation's practices or to mitigate the likelihood of something going wrong again.

Ultimately, every case is different, and we will tailor our investigation to best handle each case. Notwithstanding the above, we have a general approach to cases which involves the following:

- ✓ First, we need to fully understand the issue. We will review all the relevant materials and have discussions with all the relevant people pertinent to the issue.
- ✓ After we understand the issue, we will cross-reference the facts of the case against the policies and procedures which ought to have been in place to analysis where procedure was or was not followed.
- ✓ After we have ascertained all the facts and understood where the issues are, we will draft a detailed report of the case, explaining our investigation, the issues we picked up and any recommendations and actions we have to mitigate the issue from never happening again, or, how to improve practices at your organisation.

Training

Having worked with a variety of organisations in all sectors, we understand what is expected of an organisation and how this may differ from company to company, depending on their size and scope. We provide bespoke training to organisations in a variety of areas specific to data protection and information governance.

We offer the following types of training:

- ✓ Staff-wide data protection training, including compliance certification upon completion: The training course will cover a wide remit of the GDPR/UK GDPR, Data Protection Act, Information Governance best practices and procedures – all tailored to your organisation. Detailed training needs analysis on the results of staff training can be made available.
- ✓ Board members/senior staff with data protection responsibility training: the training will be aimed at staff who have more organisational responsibilities for data protection. This is a more in-depth and detailed training on how they can fulfil their roles and have the knowledge to do so.
- ✓ Bespoke training of identified areas of support and need: your organisation may have a gap, weakness, or an area where your team need some specific training in relation to information governance.

Data Protection Officer Services

Our trained consultants are experts in data protection law, and we offer a DPO service for organisations.

- ✓ One of our experienced consultants will be appointed as the named DPO for your organisation.
- ✓ We will carry out all the statutory responsibilities of the DPO so you don't have to.
- ✓ We will communicate with the regulatory on your behalf, be someone for your customers to contact and complain to about data protection matters, and generally be the face of your organisation when it comes to data protection.
- ✓ We will meet with stakeholders and board members and report to your Senior Information Risk Officer regarding data protection activities in your organisation.

When we are a DPO for an organisation, we set out to make that organisation more compliant and ethical than when we joined. We will work with you to help you achieve your objective, whilst keeping you within the confines of the law.

Fair Processing Materials

- ✓ We provide clear, concise privacy materials for our clients to use so that they can be transparent with users on how they use their data.
- ✓ We provide general and layered privacy policies, explaining how an organisation uses data as a whole, and how particular projects and applications collect data.
- ✓ We re-draft existing policies, provide recommendations on existing policies as well as drafting policies from scratch.
- ✓ We will work with you to ensure that the privacy materials are accurate and reflect how your data processing truly works.

If we find any compliance issues along the way, we will let you know and make recommendations on how you can be compliant.

Data Protection Health Check

Before you can address any issues which may exist, you will need to have a health check or a gap analysis of your organisation. This will help you understand what is and isn't working, what is and isn't lawful, and encompass all the recommendations and actions which you need to take to improve your practices and be compliant with the law.

We provide thorough gap analyses and health checks for organisations, regardless of your size or industry. We ensure that all our health checks are unique to each client.

What we will check for in our health checks:

- ✓ A review of your organisation structure to ensure that there are proper data protection roles and responsibilities in place;
- ✓ A review of the processes in which you collect, capture and process data, including any further processing your organisation takes.
- ✓ A review of your data protection/ information governance policy documentation;
- ✓ A review of your fair processing materials;
- ✓ A review of your record of processing activities and information asset registers;
- ✓ A review of your data storage processes;
- ✓ A review of your engagement with third party processors;
- ✓ A review of your internal organisational information governance practices;
- ✓ A review of your template forms, standard operating procedures (relevant to data protection); and
- ✓ Specific aspects of compliance you are concerned about.

For each area, we will undertake a comprehensive review to capture any strengths and weaknesses within your organisation, providing recommendations and outputs against each area for you to consider and take action on (as necessary).

Assistance With Policy Development

At IGS, we specialise in drafting data protection and information governance policy documentation. We can draft policies from scratch, or we can review and revise current policies you already have. We work with you to ensure that the policies are not only as they are on paper, but they dictate real practices that people in your organisation follow, and help you mobilise those policies so that they are followed.

A non-exhaustive list of policies we typically consult on includes:

- ✓ Freedom of Information Policies/Standard Operating Procedures;
- ✓ Data Subject Access Requests Policies/Standard Operating Procedures;
- ✓ Information Governance Policies;
- ✓ Data Protection Policies;
- ✓ Information Security Policies;
- ✓ Information Management Policies;
- ✓ Information Quality Policies;
- ✓ Acceptable Use Policies;
- ✓ Clear Desk Policies;
- ✓ Privacy Policies;
- ✓ Data Security Incident/Breach Policies;
- ✓ Record of Processing Activities;
- ✓ Information Asset Registers;
- ✓ De-identification/pseudonymisation policies;
- ✓ Individual Rights Request Policies; and
- ✓ Opt-Out and National Data Opt-Out Policies.

Data Security and Protection Toolkit (DSPT)

We go every extra mile to complete the toolkit to the very best of our ability, and using us to complete your DSPT gives you the peace of mind that you are in safe hands and that you will meet the standards of the DSPT. Where you don't have a practice in place which is required, we will draft any necessary documentation and work with you to get that practice in place before the submission is due.

DSPT submissions cannot be completed overnight, so the earlier you get in contact with us, the better your submission and overall practices is going to be.

When it comes to DSPTs, we offer two main styles of services:

- ✓ **Full DSPT Service Package:** We will take a proactive approach to work with you to ensure that we have all of the evidence required to submit the DSPT and we will complete the toolkit on your behalf.
- ✓ **DSPT Support Package:** If you are comfortable taking the lead in providing the evidences, we will assist you in checking the evidences against the requirements and reviewing the documentation and evidences you present. We will advise any recommendations and changes to be made for the submission.

Record of Processing Activities (ROPA) & Information Asset Registers

We can help train and teach your staff to learn how to update the record of processing activities and ensure it truly is a living document. We can either improve your existing ROPA, or work with you to build one from scratch.

Having an IAR helps your organisation improve its understanding and visibility about all the information assets you hold. This can help you find documents quickly, and help demonstrate compliance to organisations you partner with, or where you are required to show such documentation to the ICO or statutory bodies in your field.

We can assist you in the following ways:

- ✓ Provide you with templates;

- ✓ Train your staff on what information assets are, what an information asset register should look like;
- ✓ Work with staff to complete an information asset from scratch; and
- ✓ Work with staff to improve and expand upon existing IARs.

Other Services

In addition to these services, we provide many more consultancy services in the field of data protection. We can also help you with:

- ✓ Freedom of Information Requests;
- ✓ Subject Access Requests;
- ✓ Data Security Incidents/Data Breaches;
- ✓ Data Protection Contract Clause Assistance;
- ✓ Data Sharing and Processing Agreements;
- ✓ International Transfer Risk Assessments;
- ✓ Communicating with the Data Protection Supervisory Authority on your Behalf;
- ✓ UK Representative for non-UK organisations; and
- ✓ Administering and advising in IG forums and IG Steering Groups.

RESEARCH

Support for sponsors and Clinical Research Organisations (CROs)

We offer comprehensive compliance support to commercial companies, such as pharmaceutical companies or medical device manufacturers, and non-commercial organisations, such as NHS Trusts, academic institutions and charities, whether based in the UK or overseas, that wish to set up research studies.

Our support may include:

- ✓ Supporting the drafting of the information governance elements relating to:
- ✓ Research documents, such as study protocols and integrated research application system (IRAS) forms;
- ✓ Legal documents, such as patient information sheets (PIS) and informed consent forms (ICF) to ensure these documents meet the appropriate legal standards;
- ✓ Contractual arrangements, including HRA-approved model contracts (e.g. Model clinical trial agreement – MCTA; model non-commercial agreement – MCA) and bespoke agreements (e.g. data sharing agreements and data processing agreements);
- ✓ Data capturing documents, such as case report forms (CFR) templates and questionnaires;
- ✓ Documentation required for applications to research ethics committees (REC);
- ✓ Drafting documentation required for the confidentiality advisory group (CAG) application process;
- ✓ Drafting data protection impact assessments (DPIA) for research projects;
- ✓ Carrying out vendor risk management for the purposes of assuring systems, applications and services provided by third-parties, including:
 - Electronic data capture (EDC) systems;
 - Interactive response technology (IRT);
 - Randomization and trial supply management (RTSM);
 - Electronic patient-reported outcomes (EPRO) systems;
 - Transcription services;
- ✓ Advising on pseudonymisation and anonymisation techniques from a data protection perspective as well as from a confidentiality standpoint;

- ✓ Advising on technical and organisational measures applicable to data transfers and data storage from a data protection perspective;
- ✓ Advising on international transfers of data and how to satisfy the corresponding requirements under data protection legislation;
- ✓ Designing procedures for compliance with data subjects' rights under the data protection laws and providing advice thereafter.

Support for Participating Sites

We provide extensive support to public and private providers of health and social care, including General Practices (GPs), NHS Trusts, private hospitals and local authorities, that are asked to act as participating sites in health research studies sponsored or managed by commercial or non-commercial organisations.

Whether commissioned for a specific project or offered as part of a service package comprised of end-to-end support for the entire research process, our support may include:

- ✓ Developing procedural mechanisms for the purpose of assuring, from an information governance standpoint, research studies that require access to individuals' data;
- ✓ Drafting Data Protection Impact Assessments (DPIA) to risk assess each individual research study;
- ✓ Reviewing Study Protocols, Integrated Research Application System (IRAS) forms, Patient Information Sheets (PIS) and Informed Consent Forms (ICF) to ascertain their compliance with legal and regulatory requirements;
- ✓ Drafting and reviewing contractual arrangements, including HRA-approved model contracts (e.g. model Clinical Trial Agreement – mCTA; model Non-commercial Agreement – mNCA) and bespoke agreements (e.g. Data Sharing Agreements and Data Processing Agreements), from a data protection standpoint; and
- ✓ Drafting and reviewing International Data Transfer Agreements (IDTA) and carrying out Transfer Impact Assessments (TIA) to ensure compliance with the law in regard to international transfers of data.

Support for Suppliers

Our consultancy services include compliance support to commercial and non-commercial suppliers of systems, applications and services, whether based in the UK or overseas, that wish to make their products or services available to organisations undertaking research.

Our support may include:

- ✓ Supporting with Data Protection by Design and Default, ensuring that data protection is embedded in the creation of new products and services;
- ✓ Drafting Data Protection Impact Assessments (DPIA) for these products or services;
- ✓ Drafting Data Processing Agreements or, depending on the nature of the services, Data Sharing Agreements that comply with the law and best practices;
- ✓ Advising on pseudonymisation and anonymisation techniques from a data protection perspective as well as from a confidentiality standpoint;
- ✓ Advising on technical and organisational measures applicable to data transfers and data storage from a data protection perspective; and
- ✓ Advising on international transfers of data and how to satisfy the corresponding requirements under data protection legislation.

ARTIFICIAL INTELLIGENCE

AI Advice and Consultancy

IGS consult and assist our clients from various sectors in the field of AI to reduce any barriers in innovation and invention, all whilst addressing privacy related risks. Our team of trained lawyers and consultants offer clients a holistic understanding of the privacy issues surrounding the use of AI systems and help identify mitigating measures.

- ✓ Different AI systems may either exacerbate or mitigate particular privacy issues, there is no one-size-fits-all when it comes to ensuring regulatory compliance. This means we don't just apply a "tick box" exercise to assess whether an AI can be safely implemented.
- ✓ Instead, we take a risk-based approach and help our clients implement appropriate measures in the context of their particular AI systems and uses.

AI Assessment

Regulators are looking at new ways to control and assess AI models because AI systems' eventual failures and weaknesses may have dramatic consequences. Potential harms may be caused to individuals, society, your organisation or an entire ecosystem. For example, it can have an impact on civil rights and freedoms, discrimination towards sub-groups, your organisation's reputation, or the public trust.

Various countries have implemented, or are looking at implement, new regulatory frameworks that apply to AI systems. As organisations around the world adapt to the GDPR, organisations may need to consider the requirements of the EU AI Act or US Executive Orders.

We can support organisations assessing and developing an AI system – building, feature engineering, training, testing and validation – based on:

- ✓ Safety, security and robustness;
- ✓ Fairness;
- ✓ Transparency;
- ✓ Accountability; and
- ✓ Governance.

AI Training

We can provide and tailor:

- ✓ Staff-wide training focused on the legal issues around the adoption of AI. It will cover the scope of the GDPR/UK GDPR and any additional obligations and advise on best practices for your organisation.
- ✓ Training for technical teams. If you are collecting data to support and train an AI, we can offer training to ensure your company is aware of the best practices in data collection and security.
- ✓ Bespoke training of identified areas of support and need: you may want to target a specific gap or weakness in your AI strategy such as automated profiling or AI in health care analytics for example. We are here to adapt to your needs and requirements.

AI Policy Development

Organisations need to plan and scope their AI strategy, from defining business cases to establishing an adequate level of human oversight in the decision-making process. You may

need to review your existing documentation to include AI-specific provisions that can adapt over time.

We can help you with:

- ✓ Determining responsibilities across your organisation based on your objectives and requirements
- ✓ Defining an AI governance structure
- ✓ Setting common terms and standards for your organisation
- ✓ Implementing a data strategy to include privacy by design
- ✓ Adapting your privacy and data practices for AI management
- ✓ Maintaining an inventory of AI and ML applications
- ✓ Managing third-party risks and ensuring accountability

DATA ETHICS

External Independent Reviews

Our general approach to data ethics cases involves the following:

First, we need to fully understand the issue, challenge, or obstacle. We will review all the relevant materials and have discussions with all people pertinent to whatever matter needs to be resolved.

Next, having understood the matter to which a solution is sought, we will cross-reference the facts of the case against any guidance and policies for ethical data governance that were in place, to assess whether the required procedures were followed.

Finally, we will draft a detailed report of the case, explaining our investigation, the issues we picked up and recommendations for action that we can make, so that your organisation can prevent the same problem from occurring again. A key part of our report will be an assessment of the adequacy of the data ethics guidance and policies that exist in your organisation, if they exist at all. Where guidance and policies are inadequate, we will recommend how they should be improved, and if none exist, we can work with you to develop these, so that you and your organisation can implement them into its practices.

Ethics Policy Development

We specialise in drafting robust, coherent, implementable policy documentation for ensuring ethical data governance. We can draft policies from scratch, or we can review and revise current policies you already have. We work with you to ensure that the policies not only appear to be sound on paper, but provide practical, effective guidance that people in your organisation are able to follow and understand, and we can help you to mobilise those policies so that they are followed as they should be.

Data Ethics Training

We offer a wide range of training, which includes the following:

- ✓ Staff-wide, general training in principles of data ethics, including how these principles intersect with the demands of the GDPR/UK GDPR and Data Protection Act.

- ✓ Tailored training about ethical best practice and procedures in information governance, developed specifically for the specific needs of your organisation.
- ✓ Senior staff training, for those at board level with overall data protection responsibility in your organisation. This is more in-depth, detailed training on how senior staff with greater responsibility for ethical data governance can ensure their organisation meets its obligations, giving them the confidence and the knowledge needed for implementing relevant procedures across the organisation.
- ✓ Explaining the ethical implications of consent for data use, re-use, sharing, and linkage; including how these implications vary according to different models of consent, for instance: informed consent, broad consent, blanket consent, and meta-consent. This training is particularly relevant to organisations which use machine learning and AI-driven tools, given that the utility of such tools depends in part on the unpredictability of the outcomes that they can produce. This unpredictability can undermine the standard model of informed consent, where one agrees to the collection, use, and possible re-use of one's data on the basis of relatively accurate predictions about the possible consequences of doing so. Ensuring ethical practice in the context of big data, machine learning, and AI is complex and requires input from trained experts who are able to provide training based on the cutting edge of such developments.

SECURE DATA ENVIRONMENTS

We can help private and public providers of health and care services adapt to a changing health and care industry by leveraging data-driven technologies and systems.

Our team of experts has a track record of working with clients to design and implement effective information governance models that are tailored to their needs and capable of supporting the successful implementation of SDEs in compliance with data protection regulation and information governance principles, whilst preserving public trust and confidence in the process.

HEALTHCARE LEGACY CONSULTANCY

We provide specialist holistic legal consultancy services for the healthcare sector which focus on compliance recommendations for improvement, efficiency and financial savings in mind. We assess key areas and metrics to provide an actionable roadmap that will guide improvements, reduce costs and provide assurances.

Through our consultancy, we focus on:

- External Spending and Costs Reduction;
- Team structure and opportunities for change;
- Improving Relationships internally and externally;
- Increasing triangulation of working with governance and complaints;
- GIRFT reviews/NHSR Scorecard analysis;
- Datix/InPhase redesign for data capture and reporting;
- Streamlined processes, SOPs and KPIs; and
- Value for money assessments.

CORPORATE GOVERNANCE

We provide expert governance services by building clear yet comprehensive governance structures and processes for organisations to implement in their corporate services. We provide flexible consultancy to fit your organisation and requirements, including:

- ✓ Governance Framework Development;
- ✓ Governance Framework Audit and Assessment;
- ✓ Board Training and presentation of proposed and implemented frameworks; and
- ✓ Compliance and Risk Management support.

PACKAGED SERVICES

Whilst we offer services and projects individually, we do offer packages services to clients so that they can receive guaranteed data protection support on a regular, discounted rate.

We can be flexible with our packages, and are always willing to meet and discuss the needs of your organisation and what we can provide for you.

SERVICE LEVELS

Telephone availability

Our consultants all have direct contact numbers which buyers will be able to contact for support. We will ensure that there is a dedicated member of staff available between 9 to 5 so that routine support can always be provided between those hours. We will also make the telephone number of our Lead Consultant available, so he can be reached out of hours for any urgent matters, i.e. suspected data breaches or actual data breaches.

Email availability and tailored service solutions

As many routine queries don't always require phone support and likely need to be considered properly on paper, we suspect that many queries and support request will be sent by email. We will adopt a practice of acknowledging your email as soon-as-possible (but always within 24 hours) and then provide you with timeframe when it will be answered/completed.

IGS can create a designated mailing addresses for buyers to use so that your enquiry can be easily monitored and accessed by our consultants. This will allow all relevant contract delivery consultants to be able to review any requests, and allocate them to a designated member.

Performance Monitoring

IGS will ensure that we provide the highest level of service possible. We are committed to ensuring that we monitor these service levels so that they meet the buyer's expectations throughout the contract.

To achieve this, we can commit to the following:

- ✓ Consultants' work will be supervised by the Lead Consultant, who will have the ultimate responsibility for their advice/work. More complex and nuanced pieces of work will always be reviewed by the relevant members of the contract team with particular expertise in that area to ensure that our consultants agree on the advice we are providing to yourselves;
- ✓ Internally, we have one-to-one supervisions, where we will discuss our performance during the contract. This will allow us to evaluate how we have provided the service to you, and if required, implement any necessary changes;

- ✓ We can have quarterly contract reviews with the buyer to obtain feedback on our performance (or at any frequency required by the buyer). If there is any feedback which requires us to make any changes as to how we provide you with the service, then we commit to implementing those changes in as far as they are reasonably possible and within the scope of our contract; and
- ✓ If the buyer has any complaints or issues about the performance of our Consultants, you will be able to contact the Lead Consultant directly to discuss the details of your complaint or issue.