Chapter 8

Third-Party Agreements

Anne Emmett

Gentlemen's Agreement

In the past, many issues were resolved following discussion and a handshake between two parties (Fig. 8.1). Nothing was written down and progress depended on continued verbal agreement. In some cases, the reason for the original agreement is lost and things just 'carry on'. This is NOT acceptable within JACIE, nor any professional environment.

Memoranda of Understanding (MoU) [1]

This is a more formal written arrangement between two, or more, parties. It may take the format of a completed form with basic information, or may just be a formal letter, but would be signed by both parties.

A MoU (Table 8.1) can be the first step in establishing a process or partnership. However, MoUs are not legally binding and so cannot be deemed to be a suitable process for maintaining services between parties. They do indicate a degree of seriousness and mutual respect. They imply that a formal written contract, agreement – either technical or third party – or a service-level agreement is to follow.

A MoU can be assessed as a 'first step' towards a formal agreement. It can be terminated without legal consequence in most circumstances.

A. Emmett (✉)

BMT, Blood, Cells and Cancer, Great Ormond Street Hospital for Children NHS Foundation Trust, London, UK

e-mail: Anne.emmett@gosh.nhs.uk

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Fig. 8.1 Gentleman's Agreement

Table 8.1 Outline of MoU

Name of contracting organisation:	Address:
Designated contact person:	
Name of third party:	Address:
Designated contact person:	
Activity/activities MoU covers:	
E.g. <ul style="list-style-type: none">• Procurement• Testing• Processing• Distribution• Export• Supplies goods or services that affect quality or safety	
Reference to protocols and SOPs to be followed to meet the required performance specification (attach copies)	
Where applicable, reference to control measures or audits to be carried out by the contracting organisation and which the third party agrees to support (e.g. on-site audit at specified intervals and audit of reports to be provided by third party)	
Reference to reporting requirements of the third party to the contracting organisation	
Reference to systems for managing adverse events and incidents	
Date on which the agreement will be reviewed:	
Details of the person with responsibility to review the agreement:	
Signed: Contracting organisation	Date:
Signed: Third party:	Date:

Fig. 8.2 Contract

Contract/Commercial Agreement (Fig. 8.2)

A contract is the main document governing the deal between you and another organisation. It is the written formal agreement between the two parties. It stipulates each party's legal responsibilities, obligations, governance, contract length, financial details and liabilities within the agreement. It will include the commercial agreements and does not go into the purely technical aspects of the manufacturing, supply or outsourcing of the product or process (Table 8.2). Where possible, sections should not be reproduced in multiple documents, as this can lead to contradictions and conflicts. Where appropriate, cross references to relevant sections in different documents should be made.

As such, it is typically drafted by the legal, financial and management teams of the contractual parties.

Service-Level Agreements (SLAs)

An SLA focuses on measuring performance and quality, as agreed between you and another organisation. The SLA should not determine governance arrangements, financial arrangements, contract lengths, etc. (see Contract section), though these are often incorrectly included in SLAs, making the SLA very long and overcomplicated.

Creating an SLA as well as a contract allows you to revise the SLA without changing the contract. Though the contract may be for 5 years, the SLA may be reviewed and amended as frequently as required and at least every 2 years for JACIE.

The SLA (Table 8.3) should include a description of the services to be provided and their expected service levels, metrics or key performance indicators (KPIs) by which the services are measured, the duties and responsibilities of each party, the remedies or penalties for breach, process for disagreements and a protocol for adding and removing metrics.

Table 8.2 Typical contract contents

1.	Definitions and interpretation
2.	Contract period
3.	Services
4.	Service amendments
5.	Contract price
6.	Charges and terms of payment
7.	Warranties and representations
8.	Intellectual property
9.	Liability
10.	Quality and safety standards
11.	Freedom of information
12.	Confidentiality
13.	Data protection act
14.	Information security
15.	Force majeure
16.	Assignment
17.	Contracts (rights of third parties)
18.	Complaints
19.	Authorised officers
20.	Health and safety
21.	Publicity
22.	Prohibited acts
23.	The prevention of fraud
24.	Notices
25.	Satutory invalidity and severability
26.	Audit requirements
27.	Law and jurisdiction
Schedule 1	Authorised officers
Schedule 2	Charging structure
Schedule 3	Prices

Table 8.3 Typical SLA contents

1.	Definitions and interpretation
2.	Named contacts and responsibilities
3.	Services being provided and key performance indicators
4.	Service amendments and variations, including metrics
5.	Quality and safety standards
6.	Termination
7.	Consequences of termination
8.	Dispute resolution

Technical Agreement

A technical agreement (Fig. 8.3) (also known as a quality agreement) is a written contract that is required whenever you outsource an activity covered by quality guidelines – often good manufacturing practice (GMP) guidelines for pharmaceutical products, but equally JACIE, HTA, FACT and other national and international quality standards. It sets out the quality management responsibilities of each of the parties, both quality control and quality assurance (Table 8.4).

Even though there is an outsourcing of a process, the organisation contracting the process is still accountable for outcomes and is therefore responsible for the activities of the contracted organization. Make sure there is involvement in change control, including assurance that any appropriate validation and qualification are carried out and documented; that there is involvement in any major or critical investigations, and in any other critical issues that require both parties’ input; and ensure that the level of involvement is detailed in the Technical Agreement. The contracting organisation needs to also define how often there will be audits, or audits requested, and if it is intended to send in an independent auditor; this too needs to be specified.

Fig. 8.3 Technical agreement

Table 8.4 Typical technical agreement

1.	Definitions and interpretation
2.	Named contacts and responsibilities
3.	Services being provided
4.	Service amendments
5.	Accessing service(s)
6.	Quality and safety standards responsibilities
7.	Policies, procedures and documentation responsibilities
8.	Information security responsibilities
9.	Health and safety responsibilities
10.	Incident and risks responsibilities
11.	Audit requirements and responsibilities

The technical agreement spells out the *technical specifications and responsibilities* of the parties required for the technical or outsourcing activities and processes. It is to ensure compliance with various QC (quality control) and QA (quality assurance) requirements of the technical process or the outsourcing [2].

It is typically drafted by the technical teams in each organization. It is not usually necessary to get legal advice on a technical agreement because a lawyer will not usually be able to advise on the actual details of a technical agreement.

Third-Party Agreement

Third-party contracts are agreements that involve a person who is not a party to the contract but is involved with the transaction. This could, for example, be that an organisation is contracted to carry out viral analysis in which case the organisation will then contract the staff to do the work. The staff completing the viral analysis have not directly signed the contract but are involved with the transaction. This can get very confusing within the clinical environment if the staff doing the work also have honorary, or permanent, contracts with the contracting organisation.

Quick Checklist [2]

The contract should always refer to the technical agreement for technical matters related to quality control and assurance. As such, the technical agreement should not contain “legal” or “commercial” terminology.

No duplication of provisions should relate to the same subject matter, so that one document simply refers to the relevant provisions in the other document, i.e. instead of repeating or restating the same thing. This is to avoid accidental conflicts or contradictions.

There should be consistency in nomenclature, definitions, and duration such as the same name of the parties in both documents, the same process, the same definitions for terminology and expressions, and the same duration of each agreement.

There should be no “legal” or “commercial” terms in the technical agreement. The job of the technical agreement is to set out technical parameters. It is not intended to set out the commercial relationship between the parties that should go into the contract instead.

That means that the contract is the right place to cover things like patient confidentiality terms, warranties, indemnities, liability limitations, pricing, scheduling, etc.

Fig. 8.4 Communication

Communication Is Critical [3] (Fig. 8.4)

Define:

- Who
- When
- What
- Where
- Why

Make sure that the contacts are clear to both parties and that their communication channels are open.

Ensure there are nominated single points of contact in each organisation for key matters, plus 'local' contacts as required, e.g. HTA lead, quality manager, service manager, accounts. Ensure that, where necessary, there are secure email connections, or use encryption for any emails containing personal or patient data. Ensure this is made clear in all joint documents.

Try to avoid 'scatter gun' communications between the organisations when setting up the agreement and then running the process as this can lead to either key communications being lost or email overload. When necessary, have face-to-face meetings, even if this is by video conference.

References

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3. Calcott P. www.calcott-consulting.com/en/2011/what-does-a-quality-or-technical-agreement-have-to-contain/ 2011.

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