

Chapter title: **Brexit and biobanking: GDPR perspectives**

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Abstract

It is almost impossible to write a legal analysis of an event (Brexit) that has not happened and may never happen. This chapter nonetheless reports on the current legal position in the UK, and presents an analysis of two possible immediate post-Brexit legal futures, for data protection law as applicable to biobanking in the UK. These post-Brexit futures are the position if the draft Withdrawal Agreement is ratified and comes into force, and the position if it does not (a so-called 'No Deal' Brexit). The chapter concludes with some thoughts on possible longer term futures.

Summary

Introduction and key legal provisions

A biobank is an entity which collects and stores human biological materials, and data about such materials, organises them on the basis of population, disease type or other pertinent typology, and provides bio specimens and data for both exploratory research and clinical trials.¹ There are five main models for biobanks (small scale/university, governmental/institutional, population, commercial and virtual), four of which are present in the UK.² All UK biobanks work collaboratively, often with entities in other countries.

Several pieces of UK legislation have relevance to the governance of biobanks in the UK. The focus in this chapter is primarily on data protection. The key current legal instrument here is the EU's General Data Protection Regulation (GDPR),³ which replaced the earlier Data Protection Directive. As a Regulation, from the point of view of EU law, the GDPR is 'directly applicable' in the Member States,⁴ which means it has legal effect irrespective of any act of transposition.

¹ Geneticist (31 May 2018) <https://www.geneticistinc.com/blog/the-importance-of-biorepositories>. Last accessed 18 June 2019.

² The UK does not have a population biobank.

³ Regulation (EU) 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, and repealing Directive 95/46/EC (General Data Protection Regulation) OJ 2016 L 119/1.

⁴ Article 288 TFEU.

In principle, the GDPR protects the fundamental rights of natural persons whose data are ‘processed’ within the material scope of EU law,⁵ where the entity processing the data is within the EU, or the data subjects are within the EU, if the entity processing the data is not, and the processing activities are ‘related to the offering of goods or services, irrespective of whether a payment of the data subject is required’.⁶ Thus the GDPR applies in principle to all UK-based biobanks, which must comply with the GDPR’s terms on lawful data processing.⁷ The GDPR also provides for the free movement of data both within and into the EU. It does so by providing harmonised minimum level standards of data protection, by requiring Member States to have a ‘supervisory authority’ to oversee their application,⁸ and by setting up institutional fora within which EU Member States cooperate. The UK is currently obliged to participate in those institutional arrangements. Its supervisory authority is the Information Commissioner’s Office (ICO).

The GDPR permits Member States to derogate from its terms in various respects. The UK’s Data Protection Act 2018 (DPA) both implements the GDPR in domestic law and specifies how the UK takes advantage of this permission. The DPA also outlines how various aspects of the GDPR apply in practice in the UK.⁹

Lawfulness of processing, transfer of data within the EU, and transfer to ‘third countries’ in the context of biobanking in the UK

UK biobanks rely on two main grounds for lawfully processing data: consent or legitimate public interest.¹⁰

Where data is lawfully processed within the EU, it may be lawfully transferred anywhere within the EU. This is one of the key aims of the GDPR, to allow the flow of data within the EU’s ‘single market’. UK-based biobanks, like UK Biobank, that transfer data *out* to other EU countries, and other EU countries that transfer data *in* to the UK, currently rely on these provisions. Further, under the GDPR, standard contractual clauses provide a lawful basis for transfer of data to ‘third countries’ (ie non-EU countries), or international organisations.

Adequacy decisions, ‘appropriate safeguards’ (standard contractual clauses and binding corporate rules), and special circumstances as a basis for transfer of data to ‘third countries’

Under the GDPR, and Data Protection Act, it is unlawful to transfer personal data to a ‘third country’ unless there is a lawful basis for such transfer.¹¹ While the UK remains a Member State of the EU, organisations (including biobanks) processing data in the UK may rely on

⁵ GDPR, Article 2 (2) (a).

⁶ GDPR, Article 3.

⁷ GDPR, Articles 6 ff.

⁸ GDPR, Article 51.

⁹ See section 22 of the Data Protection Act 2018: Section 22 (1) The GDPR applies to the processing of personal data to which this Chapter applies but as if its Articles were part of an Act extending to England and Wales, Scotland and Northern Ireland. (2) Chapter 2 of this Part applies for the purposes of the applied GDPR as it applies for the purposes of the GDPR.

¹⁰ UK Biobank (2019) GDPR <https://www.ukbiobank.ac.uk/gdpr/> Last accessed 14 June 2019; also see their guidance document, UK Biobank (30 May 2018) Information notice for UK Biobank participants: the General Data Protection Regulation (GDPR) <http://www.ukbiobank.ac.uk/wp-content/uploads/2018/10/GDPR.pdf>. Last accessed 18 June 2019.

¹¹ DPA, section 73.

the grounds set out in chapter V of the GDPR, and chapter 5 of the DPA, as a basis for the lawful transfer of data *out of* the UK to ‘third countries’ (ie non-EU countries).

Biobanks in the UK may lawfully transfer personal data to a third country where the transfer is based on an ‘adequacy decision’.¹² Such adequacy decisions are taken by the European Commission.

In the absence of an adequacy decision, transfer may take place where ‘appropriate safeguards’ are provided. One such appropriate safeguard is the use of standard contractual clauses. Another is a code of conduct. A third is ‘binding corporate rules’.¹³

It is also permissible for a UK-based biobank to transfer data to a third country on the basis of special circumstances.¹⁴ The most relevant circumstances that could be relied upon are those set out in DPA, section 76(1) (a) and (b), which allow for transfer in order to ‘protect the vital interests of the data subject or another person’ or ‘to safeguard the legitimate interests of the data subject’. Explicit consent of the data subject to the transfer is another possible ‘special circumstance’ but this would not be practical for biobanks to secure.

The legal position for GDPR aspects of biobanking post-Brexit

All of the different types of biobank structures in the UK will be affected by Brexit, but in different ways. Smaller biobanks that collect, process or share data solely within the UK will be affected less, although the applicable law will change. Larger, networked, UK-based biobanks that share data *outward* to the EU and other countries, and those which receive *inward* coming data from the EU and other countries will be affected more, because at present the basis on which the lawfulness of data protection in those transactions is secured is the UK’s membership of the EU. Some biobanks, for instance, commercial operators, may be able to circumvent the inconvenience of Brexit, and continue to operate as now within the EU, by incorporating in an EU Member State. This approach will not be open to university-based or governmental/institutional UK biobanks. Those biobanks that rely on EU networks and funding may find that they are totally excluded from such access, depending on the form that Brexit takes.

Domestic legislation, statutory instruments, ‘soft law’, guidance

Soft law and guidance on data protection post-Brexit

In December 2018, the UK government issued a technical note giving guidance on data protection post-Brexit. That guidance was withdrawn on 1 March 2019,¹⁵ and replaced with revised guidance adopted on 6 February 2019.¹⁶ It complements guidance from the ICO¹⁷ on

¹² DPA, section 74.

¹³ GDPR, Article 47.

¹⁴ GDPR, Article 49; DPA, section 75.

¹⁵ Department for Digital, Culture, Media & Sports (13 September 2018, this guidance was withdrawn on the 1st of March 2019) Data protection if there’s no Brexit deal. <https://www.gov.uk/government/publications/data-protection-if-theres-no-brexite-deal/data-protection-if-theres-no-brexite-deal>. Accessed 17 June 2019.

¹⁶ Department for Digital, Culture, Media & Sports (6 February 2019) Using personal data after Brexit. <https://www.gov.uk/guidance/using-personal-data-after-brexite>. Last accessed 17 June 2019. We make no further comment on the obvious unsatisfactory nature of guidance from 6 February 2019 not replacing guidance from December 2018 until 1 March 2019.

the future data protection regime in case of a No Deal Brexit, which remains in place. The guidance applies to all organisations to which the GDPR applies, so it applies to UK biobanks.

Data protection under the EU (Withdrawal) Act 2018

Whether the Withdrawal Agreement is adopted or not, as ‘retained EU law’, the GDPR will in principle be part of UK law on Exit Day, under the terms of the EU (Withdrawal) Act 2018.

However, the GDPR (as a source of ‘retained EU law’) will be subject to future amendments made by the UK legislator. Any such amendments are legally authorised on the basis of powers set out in the EU (Withdrawal) Act 2018, the Data Protection Act 2018, and the European Communities Act 1972. These powers allow the UK government to act unilaterally to remedy any ‘deficiencies’ in ‘retained EU law’. These amendments will take effect through secondary legislation: the Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019,¹⁸ and any subsequent secondary legislation. The EU (Withdrawal) Act 2018 makes no provision for UK compliance with the Withdrawal Agreement (see further below in section 4.2.3).

The Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019

The Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019¹⁹ (hereafter, ‘the EU Exit Regulations’) amend various parts of legislation to take account of the UK leaving the EU. They come into force on Exit Day. In summary, the Regulations amend the Data Protection Act 2018, the GDPR as ‘retained EU law’ (known in the Regulations as ‘the UK GDPR’), and merge provisions of the two.²⁰ Schedule 1 lists the amendments to the UK GDPR, while schedule 2 deals with the amendments to the Data Protection Act 2018. Schedule 3 deals with consequential amendments to other legislation, and schedule 4 addresses amendments consequential on provisions of the 2018 Act.

The UK government claims²¹ that the majority of the changes to the existing law involve removing references to EU institutions and procedures that will not be directly relevant when the UK is outside the EU. This is accurate. Many changes, for instance, simply change ‘the Union’ or ‘a Member State’ for ‘the UK’; or ‘the competent authority’ for ‘the Commissioner’, that is, the Information Commissioner as referred to in the Data Protection Act, section 114 and schedule 12.

¹⁷ICO, Data protection and Brexit <https://ico.org.uk/for-organisations/data-protection-and-brexit/>. Last accessed 17 June 2019.

¹⁸ SI No 419 28 February 2019 http://www.legislation.gov.uk/uksi/2019/419/pdfs/ukxi_20190419_en.pdf. Last accessed 19 June 2019.

¹⁹ Ibid.

²⁰ The Explanatory Note to the SI reads ‘Among other things, changes made by Schedules 1 and 2 have the effect of merging two pre-existing regimes for the regulation of the processing of personal data – namely that established by the GDPR as supplemented by Chapter 2 of Part 2 of the DPA 2018 as originally enacted, and that established in Chapter 3 of Part 2 of the DPA 2018 as originally enacted (the applied GDPR). The applied GDPR extended GDPR standards to certain processing out of scope of EU law and the GDPR. Regulation 5 makes provision concerning interpretation in relation to processing that prior to exit day was subject to the applied GDPR.’

²¹ Department for Digital, Culture, Media & Sports, Data protection if there’s no Brexit deal (n 15).

However, the EU Exit Regulations do make some changes to the legal position beyond removing references to the EU and its institutions and procedures. The key changes of relevance or potential relevance to biobanking are as follows:

- (a) Adequacy decisions
- (b) Standard data protection contractual clauses
- (c) Information exchange and cooperation
- (d) Removal of procedural and remedial safeguards
- (e) General principles of EU law.

The EU-UK Withdrawal Agreement and biobanking

Data protection Law under the Withdrawal Agreement

We note at the start of this section that aspects of the Withdrawal Agreement’s text on data protection are difficult to interpret.²² Of course, as the Withdrawal Agreement has not been formally agreed, ratified, or entered into force, there are no binding judicial rulings on the meaning of its text. The underlying aim of the Withdrawal Agreement is to ensure an orderly withdrawal of the UK from the EU, and to avoid disruption during the transition period by ensuring that EU law applies to and in the UK during that period.²³ The Withdrawal Agreement’s provisions should thus be interpreted with that aimed-for continuity in mind.

In general, the Withdrawal Agreement provides that the UK is to be treated as a Member State of the EU during the transition period.²⁴ So, in general, EU law continues to apply to and in the UK, as if the UK were still a Member State, from Exit Day until the end of transition.²⁵ Thus, the GDPR will continue to apply in and to the UK during that period. Biobanks in the UK will continue to be required to comply with the GDPR. The Withdrawal Agreement also provides that references to competent authorities of Member States in provisions of EU law made applicable by the Withdrawal Agreement are to include UK competent authorities.²⁶ This means that the UK’s ICO will continue to be recognised as an institution of a Member State, even though the UK will no longer be a Member State of the EU.

However, this continuity rule applies *only* ‘unless otherwise provided’ in the Withdrawal Agreement.²⁷ One of the key exclusions concerns the UK’s participation in EU institutions, and in decision-making and governance of the bodies, offices and agencies of the Union. The UK will no longer participate in such entities.²⁸ The European Data Protection Board,

²² See, for instance, <https://privacylawblog.fieldfisher.com/2018/what-does-the-draft-withdrawal-agreement-mean-for-data-protection>. Accessed 19 June 2019: “During the transition period the UK loses its seat at the table in the European Data Protection Board (“EDPB”). But that doesn’t necessarily mean that all the provisions which have a link to the EDPB fall away. So, for example, it’s not clear how the one stop shop will work during the transition period. Just because the UK Information Commissioner loses her seat at the table doesn’t necessarily mean that the entire one stop shop mechanism simply won’t apply to the UK. If that were the case it would undermine the central policy of the transition period, which is to maintain consistency as between the regimes in the UK and the EU. The detail of how all this will work in practice is still very unclear.”

²³ WA, recitals 5 and 8.

²⁴ WA, Article 127 (6).

²⁵ WA, Article 127 (1)

²⁶ WA, Article 7.

²⁷ WA, Article 127.

²⁸ WA, Article 7 (1) (b). This is not the hoped-for outcome that the UK’s Information Commissioner would continue to be part of the EDPB post-Brexit (the so-called ‘adequacy plus’ scenario), see <https://www.dpnetwork.org.uk/opinion/brexit-data-protection-update/>, Last accessed 19 June 2019.

established under the GDPR,²⁹ is (presumably³⁰) a ‘body’ of the Union for these purposes. The Withdrawal Agreement makes no explicit provision for the UK’s continued participation in the European Data Protection Board or its information sharing systems. The precise modalities of the situation where the UK Information Commissioner is excluded from the European Data Protection Board, but the ICO is still recognised as a competent national authority under the GDPR, are far from clear. This may have practical implications for UK-based biobanks, for instance seeking to rely on the European Data Protection Board’s guidance on the ‘one stop shop’ principle, in terms of which national supervisory authority should be the lead supervisory authority after Exit day and during transition. Biobanks which operate across the EU and the UK may find themselves subject to parallel proceedings.³¹

The Withdrawal Agreement has a separate title (Title VII) on data processing. It covers ‘Union law on the protection of personal data’, which includes the GDPR,³² but excludes the GDPR’s Chapter VII, which covers cooperation between supervisory authorities in the EU, consistency, dispute resolution and the European Data Protection Board. Title VII of the Withdrawal Agreement also includes ‘any other provisions of Union law governing the protection of personal data’.³³ Other relevant provisions of Union law include the EU CFR, and ‘general principles’ of EU law, both of which include the right to protection of personal data³⁴ and the right to privacy.³⁵ There is an unresolved question here about whether the EU Exit Regulations’ exclusion of general principles of EU law ‘not relevant to’ the GDPR as it applied immediately before Exit Day³⁶ is compliant with the UK’s obligations under the Withdrawal Agreement.

Title VII consists of just four provisions, two of which are not relevant to biobanking.³⁷

The Withdrawal Agreement, Article 71 is very difficult to understand. One way to make sense of this provision, therefore, is that it is an exception to the general rules in the Withdrawal Agreement. For the purposes of transfer of data of a data subject in an EU Member State from that EU Member State to the UK for processing, during transition, the UK is *not* to be treated as if it were a Member State, and the GDPR does *not* apply. But if this is the intention of the provision, its drafting is far from clear.

Article 71 covers *only* personal data of *data subjects outside the UK* processed or obtained before the end of the transition period, or on the basis of the Withdrawal Agreement. In effect, it operates as if it were an adequacy decision. It does not cover personal data of data subjects within the UK. The majority of data held by UK-based biobanks is personal data of UK-based data subjects. But, especially given the way in which biobanks are networked, some of their data is personal data of data subjects outside the UK. If this interpretation is

²⁹ GDPR, Article 68.

³⁰ GDPR, Article 68 provides ‘the European Data Protection Board ... is hereby established as a body of the Union ...’. It is assumed that the interpretation of ‘body’ in this context under the Withdrawal Agreement would be consistent with the use of the term in EU legislation such as the GDPR.

³¹ See, eg, <https://www.twobirds.com/en/news/articles/2018/global/data-protection-and-the-draft-brexit-agreement-first-impressions>, Last accessed 19 June 2019.

³² It also includes a Directive on data processing in the context of criminal offences, Directive 2016/680/EU OJ 2016 L 119/89; and a Directive on e-communications privacy, Directive 2002/58/EC OJ 2002 L 201/37.

³³ WA, Article 70.

³⁴ EUCFR, Article 8.

³⁵ EUCFR, Article 7; ECHR, Article 8; See, eg, Case C-139/01 *Österreichischer Rundfunk and Others*:

ECLI:EU:C:2003:294; Case C-101/01 *Bodil Lindqvist v Åklagarkammaren i Jönköping* ECLI:EU:C:2003:596.

³⁶ Regulation 5 (3).

³⁷ WA, Article 72 applies to entities in the water, energy, transport and postal services sectors; WA, Article 74 applies to classified information concerning national/EU security.

correct, the law applicable to UK-based biobanks would differ, depending on the source of the personal data. This would potentially create difficult – or even impossible – situations for UK-based biobanks in terms of data processing, depending on the extent to which UK data protection law diverges from EU data protection law.

Article 71 (2) provides that paragraph 1 does not apply in the event that the European Commission adopts an adequacy decision under GDPR, Article 45.

Under the Withdrawal Agreement, Article 73, the EU is obliged to continue to treat data obtained from the UK before the end of transition, or after the end of transition on the basis of the Withdrawal Agreement, the same as data obtained from an EU Member State, or rather, not to treat it differently ‘on the sole ground of the UK having withdrawn from the Union’.³⁸ This drafting is unfortunate, given that the text of the GDPR contemplates only two categories of states: EU Member States and ‘third countries’.

The law if ‘No Deal’ Brexit

The EU’s position

As we write, the EU has been consistently clear in its position that, in the event of a No Deal Brexit, the UK will be treated as a ‘third country’. The European Data Protection Board’s February 2019 information note is consistent with this position:

“In the absence of an agreement between the EEA and the UK (No Deal Brexit), the UK will become a third country from 00.00 am CET on 30 March 2019. This means that the transfer of personal data to the UK has to be based on one of the following instruments as of 30 March 2019:

- Standard or ad hoc Data Protection Clauses
- Binding Corporate Rules
- Codes of Conduct and Certification Mechanisms
- Derogations”³⁹

Note that none of the listed bases of lawful transfer of personal data to the UK, in the event of No Deal Brexit, is that of an adequacy decision. The EU’s contingency planning for a No Deal Brexit does not include adopting an adequacy decision with respect to the UK. EU Member States may not lawfully adopt unilateral adequacy decisions: the power to do so rests with the European Commission only.

According to Article 44 of the GDPR, in the absence of a formal adequacy decision taken by the European Commission, or other basis for the lawful transfer of personal data, all data flows from the EU to the UK would immediately be unlawful under the GDPR.⁴⁰ Given that there is unlikely to be an adequacy decision, biobanks seeking to lawfully transfer personal data to UK-based biobanks must therefore rely on alternative bases for that data transfer.

³⁸ WA, Article 73.

³⁹ European Data Protection Board, *Information note on data transfers under the GDPR in the event of a No Deal Brexit*, 12 February 2019, https://edpb.europa.eu/sites/edpb/files/files/file1/edpb-2019-02-12-infonote-nodeal-brexite_n.pdf. Accessed 19 June 2019.

⁴⁰ GDPR, Article 44. See Mc Cullagh, Karen. UK: GDPR adaptations and preparations for withdrawal from the EU. (n

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As noted above, these include binding corporate rules; standard contractual clauses; codes of conduct; and ‘special circumstances’. We have been unable to locate examples of binding corporate rules in the context of biobanking which are in the public domain, or plans for adopting such rules in the event of No Deal Brexit. Several multinationals in the pharmaceutical and biomedical industry have successfully adopted such binding corporate rules.⁴¹ Given that this approach is more likely to be adopted by commercial biobanks, it is not a surprise that such plans are not available for us to scrutinize. In general, they are costly and time-consuming to put in place.

The most likely mechanism for lawful data transfer from an EU Member State to a non-commercial biobank in the UK in the event of No Deal Brexit is on the basis of standard contractual clauses. However, the status of standard contractual clauses as a basis for data transfer to third countries is currently the subject of litigation before the CJEU. This litigation process may not be completed before Exit Day, adding to the levels of uncertainty. Case C-311/18 *Schrems II* was referred to the CJEU for a preliminary ruling by the Irish High Court on 9 May 2018. As we write, there is as yet no AG Opinion, and the case is not listed in the publicly available judicial calendar.

In view of those concerns, it may be preferable for the biobanking sector to move expeditiously to adopt a sector-specific code of conduct for health research, and have this code approved under Article 40 of the GDPR. Such a code of conduct would provide a lawful basis for transfer of data to UK-based biobanks from the EU in a No Deal Brexit scenario.

One final possibility is that EU-based biobanks transfer data to UK-based biobanks on the basis of ‘special circumstances’.⁴² This may be the most appropriate basis for lawful transfer following No Deal Brexit where data is being shared in the context of an on-going clinical trial.

The position with regard to personal data *that has already been transferred* from the UK to the EU remains uncertain. By analogy with the revocation of an adequacy decision under Article 45 (5) GDPR, the effects of the UK leaving the EU on the lawfulness of the transfer of the data should not have retroactive effect. In practice, unless the European Data Protection Board or European Commission takes a decision applicable to the whole EU, it is likely to depend on the view adopted by the supervisory authority in the relevant EU Member State. Hence, it may be that data is processed by biobanks in the EU in a situation that is technically unlawful, or perhaps better described as a situation of ‘a-legality’,⁴³ following a No Deal Brexit.

The UK position

The UK government’s position is to seek to secure as much continuity as possible in the event of No Deal Brexit. The UK government claims that under a No Deal Brexit there would be no immediate change to data protection law.⁴⁴ The EU (Withdrawal) Act and secondary

⁴¹ See list at https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection/binding-corporate-rules-bcr_en, Last accessed 20 June 2019.

⁴² GDPR, Article 49.

⁴³ T Hervey and E M Speakman, ‘The Immediate Futures of EU Health Law in the UK after Brexit: Law, ‘a-legality’ and uncertainty’ 18 (2-3) *Medical Law International* (2018) 65-109.

⁴⁴ Department for Digital, Culture, Media & Sports, Data protection if there’s no Brexit deal. (n 15).

legislation based on it, such as the Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019, make no distinction between different types of Brexit. The Data Protection Act 2018 would remain in place, and the GDPR would change from being EU law to being ‘retained EU law’. For data transfers from the UK to the EU, EEA and third countries deemed adequate by the EU at point of exit, the UK has in effect taken an adequacy decision under the Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) (No. 2), Regulations 2019, schedule 2, article 102, inserting a new Schedule 21 into the UK GDPR.

The assertion that there would be no immediate change to data protection law is self-evidently not the case with regard to data transfer from the EU to the UK, as without an adequacy decision, or other basis on which data may lawfully be transferred to a UK-based entity, such as ‘appropriate safeguards’ (standard contractual clauses, a code of conduct, or binding corporate rules), or ‘special circumstances’, the EU will treat the UK as non-compliant with its data protection law. This is also the case for data transfer from other countries which currently rely on the UK’s membership of the EU to allow data transfer into the UK.

However, even with regard to data protection law *as applicable solely within the UK*, a better description of the legal position is that there would be no immediate change to the *content* of data protection law, but that the *source* of data protection law would change. With this change of source, there may also be implications for the effects of the relevant law. Indeed, the UK government’s December 2018 guidance⁴⁵ itself described the GDPR as ‘sitting alongside’ the Data Protection Act, which is a quite different to the current legal position to the effect that the GDPR is a source of supreme EU law.

Conclusion

Since the EU referendum vote in June 2016, despite the considerable uncertainties, many of which are outlined above, biobanks in the UK are adopting a ‘business as usual’ approach.

This ‘biobanking business as usual’ approach makes good sense. The UK has not left the EU; as things stand will not do so until 31 October 2019; may secure another extension after that date; and (though politically speaking a remote possibility) legal speaking may in the end decide to remain in the EU.⁴⁶ If the Withdrawal Agreement is agreed, ratified and enters into force, significant levels of continuity will be secured until the end of the transition period (currently until end December 2020, although could be extended). By contrast, under a No Deal Brexit, legal continuity is far from guaranteed, although sharing of data with UK-based biobanks may be able to continue on the basis of appropriate safeguards, including possibly a code of conduct for biomedical research, or even perhaps a (temporary) adequacy decision.

Given the uncertainty, inflexibility, cost and time investment that surrounds other types of appropriate safeguards, prompt moves towards a code of conduct, within the context of BBMRI-ERIC, would offer timely reassurance to the biobanking sector, both within the UK and on a European and international level, given the ways in which UK biobanks are nested within European and global networks.

⁴⁵ Department for Digital, Culture, Media & Sports, Data protection if there’s no Brexit deal. (n 15)

⁴⁶ Case C-621/18 *Wightman and Others v Secretary of State for Exiting the European Union* ECLI:EU:C:2018:999.

All that said, given that prominent biobanks in the UK are continuing to collaborate internationally, it seems likely that such collaborations and data transfer will also continue both in to the UK and outwardly to the EU, in one way or another. Nevertheless, the chilling effect of the uncertain legal basis on which future collaborations involving data transfer will take place, is undoubtedly having implications for the biobanking sector in the UK.