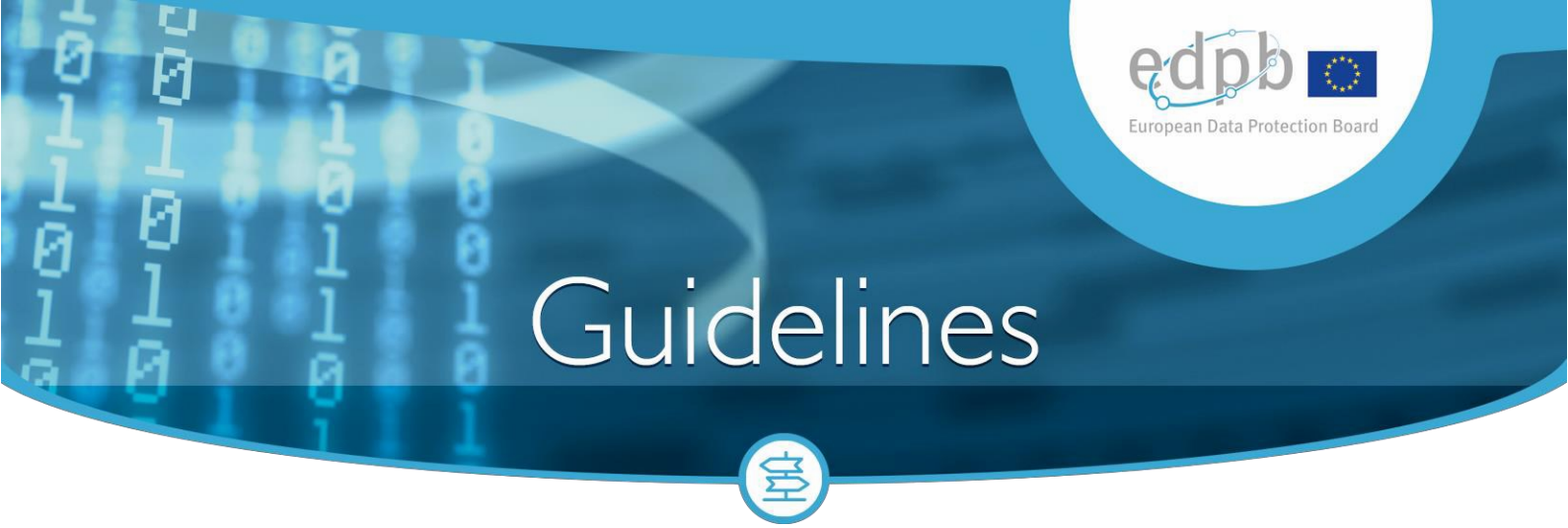

Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak

關於在新冠肺炎（COVID-19）防疫期間為科學研究目的運用健康資料之指引03/2020

Adopted on 21 April 2020

2020年4月21日通過

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The European Data Protection Board

Having regard to Article 70 (1) (e) of the Regulation 2016/679/EU 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, (hereinafter "GDPR"),

Having regard to the EEA Agreement and in particular to Annex XI and Protocol 37 thereof, as amended by the Decision of the EEA joint Committee No 154/2018 of 6 July 2018,

Having regard to Article 12 and Article 22 of its Rules of Procedure,

HAS ADOPTED THE FOLLOWING GUIDELINES

歐盟個人資料保護委員會

依據歐洲議會與歐盟理事會於2016年4月27日通過之「關於運用*個人資料時對自然人之保護與確保此等資料之自由流通，以及廢除指令95/46/EC的歐盟規則2016/679/EU」（下稱GDPR）第70條第1項第e款；

依據歐洲經濟區聯合委員會於2018年7月6日第154/2018號決定修改之歐洲經濟區（EEA）協議，尤其是附件11及其議定書37；

依據「歐盟個人資料保護委員會議事規則」第12條和第22條；

通過以下指引：

* 譯註：我國個資法將個資之使用分為蒐集(collection)、處理(processing)、利用(use)等不同行為態樣，且有相應之適用要件，而GDPR對個資之蒐集、處理、利用任一行為，皆統稱為processing。為與我國個資法中之「處理」有所區隔，本文因此將GDPR中的processing譯為「運用」，processor譯為「受託運用者」。

1. INTRODUCTION
導言

1. Due to the COVID-19 pandemic, there are currently great scientific research efforts in the fight against the SARS-CoV-2 in order to produce *r*esearch results as fast as possible.
由於新冠肺炎（COVID-19）疫情蔓延，許多對抗新型冠狀病毒（SARS-CoV-2）科學研究正在進行之中，以求盡快產出研究結果。

2. At the same time, legal questions concerning the use of health data pursuant to Article 4 (15) GDPR for such research purposes keep arising. The present guidelines aim to shed light on the most urgent of these questions such as the legal basis, the implementation of adequate safeguards for such processing of health data and the exercise of the data subject rights.
於此同時，關於GDPR第4條第15款所規範的健康資料之運用，許多法律問題不斷產生。本指引旨在釐清其中最具緊迫性的問題，如法律依據、運用此等健康資料時採行之適當安全維護措施，以及當事人權利之行使等。

3. Please note that the development of a further and more detailed guidance for the processing of health data for the purpose of scientific research is part of the annual work plan of the EDPB. Also, please note that the current guidelines do not revolve around the processing of personal data for epidemiological surveillance.
請注意，為科學研究目的運用健康資料議題，制定一個進一步的、更為詳盡的指導，乃歐盟個人資料保護委員會（EDPB）年度工作計畫之一部分。此外，請注意本指引並未涉及為流行病學監測目的運用個人資料。

2. APPLICATION OF THE GDPR
GDPR之適用

4. Data protection rules (such as the GDPR) do not hinder measures taken in the fight against the COVID- 19 pandemic.[1] The GDPR is a broad piece of

legislation and provides for several provisions that allow to handle the processing of personal data for the purpose of scientific research connected to the COVID-19 pandemic in compliance with the fundamental rights to privacy and personal data protection.[2] The GDPR also foresees a specific derogation to the prohibition of processing of certain special categories of personal data, such as health data, where it is necessary for these purposes of scientific research. [3]

資料保護規範（如GDPR）並不妨礙實施疫情防控措施[1]。GDPR係一部廣泛法律，其部分規定皆容許在遵循隱私之基本權利與個人資料保護下，為新冠肺炎防疫相關之科學研究目的運用個人資料[2]。GDPR亦預見，為科學研究目的[3]之必要，對部分特種個資(如健康資料)運用之禁止會有具體的例外。

5. Fundamental Rights of the EU must be applied when processing health data for the purpose of scientific research connected to the COVID-19 pandemic. Neither the Data Protection Rules nor the Freedom of Science pursuant to Article 13 of the Charter of Fundamental Rights of the EU have precedence over the other. Rather, these rights and freedoms must be carefully assessed and balanced, resulting in an outcome which respects the essence of both.

為新冠肺炎防疫相關之科學研究目的運用健康資料時，須保障歐盟承認之基本權利。資料保護規範和歐盟「基本權利憲章」第13條規定的科學自由間，並無何者優先之關係。而是須審慎評估和平衡這些權利與自由，以求兩者之本質皆獲得尊重之結果。

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[1] See the Statement of the EDPB from 19.3.2020 on the general processing of personal data in the context of the COVID-19 outbreak, available at https://edpb.europa.eu/our-work-tools/our-documents/other/statement-processing-personal-data-context-covid-19-outbreak_en.
見EDPB「關於新冠肺炎防疫期間一般性運用個人資料之聲明」（2020年3月19日版），請參閱：https://edpb.europa.eu/our-work-tools/our-documents/other/statement-processing-personal-data-context-covid-19-outbreak_en。

[2] See for example Article 5 (1) (b) and (e), Article 14 (5) (b) and Article 17 (3) (d) GDPR.
示例見GDPR第5條第1項第b款和第e款，第14條第5項第b款和第17條第3項第d款。

[3] See for example Article 9 (2) (j) and Article 89 (2) GDPR.
示例見GDPR第9條第2項第j款和GDPR第89條第2項。

3. DEFINITIONS
定義

6. It is important to understand which processing operations benefit from the special regime foreseen in the GDPR and elaborated on in the present guidelines. Therefore, the terms "data concerning health", "processing for the purpose of scientific research" as well as "further processing" (also referred to as "primary and secondary usage of health data") must be defined.
重要的是瞭解哪種運用作業得受益於GDPR預見並在本指引中闡明之特殊制度。因此，須定義「健康資料」、「為科學研究目的運用」與「進階運用」（亦稱健康資料之初級使用（primary usage）和次級使用（secondary usage））。

3.1 "Data concerning health"
「健康資料」

7. According to Article 4 (15) GDPR, "data concerning health" means *"personal data related to the physical or mental health of a natural* person*, including the provision of health care services, which reveal information about his or her health status"*. As indicated by Recital 53, data concerning health deserves higher protection, as the use of such sensitive data may have significant adverse impacts for data subjects. In the light of this and the relevant jurisprudence of the European Court of Justice ("ECJ"),[4] the term "data concerning health" must be given a wide interpretation.
依據GDPR第4條第15款，「健康資料」係指「*與自然人之身體或精神健康有關之個人資料，包括揭示其健康狀況之健康照護服務之提供*」。如前言第53點所述，健康資料需要更高程度之保護，因運用這些敏感資料可能對當事人造成重大不利影響。有鑑於此，並依歐洲法院（ECJ）[4]之相關實務見解，「健康資料」須作廣義解釋。

[4] See for example, regarding the Directive 95/46/EC ECJ 6.3.2003, C-101/01 (Lindqvist) paragraph 50.
示例見，關於指令95/46/EC，歐洲法院2003年11月6日（譯註：原文3月6日應為誤植）第C-

8. Data concerning health can be derived from different sources, for example:
健康資料可取自多種來源，例如：

1. Information collected by a health care provider in a patient record (such as medical history and results of examinations and treatments).
健康照護提供者自病患檔案中蒐集之資訊（如病史、檢查和治療結果）。

2. Information that becomes health data by cross referencing with other data thus revealing the state of health or health risks (such as the assumption that a person has a higher risk of suffering heart attacks based on the high blood pressure measured over a certain period of time).
透過與其他資料交叉比對，並因此揭示健康狀況或健康風險而構成健康資訊（如基於一定期間內對特定個人測得之偏高血壓數值，推測該人有較高心臟病發作風險）。

3. Information from a "self check" survey, where data subjects answer questions related to their health (such as stating symptoms).
經「自我評估」調查獲知之資訊，該等調查中，由當事人回答與其健康相關問題（如描述症狀）。

4. Information that becomes health data because of its usage in a specific context (such as information regarding a recent trip to or presence in a region affected with COVID-19 processed by a medical professional to make a diagnosis).
因特定情形下使用而成為健康資料之資訊（如醫療人員為作出診斷而運用「最近曾前往新冠肺炎疫區」或位於疫區之資訊）。

3.2 "Processing for the purpose of scientific research"
「為科學研究目的運用資料」

9. Article 4 GDPR does not entail an explicit definition of "processing for the

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101/01號案件（Lindqvist）判決，第50段。

purpose of scientific research". As indicated by Recital 159, *"the* term *processing of personal data for scientific research purposes should be interpreted in a broad manner including for example technological development and demonstration, fundamental research, applied research and privately funded research. In addition, it should take into account the Union's objective under Article 179 (1) TFEU of achieving a European Research Area. Scientific research purposes should also include studies conducted in the public interest in the area of public health."*

GDPR第4條並未明確定義「為科學研究目的運用資料」。如前言第159點所述，「『*為科學研究目的運用資料』此一術語應做廣義解釋，包括技術開發和演示、基礎研究、應用研究和私人資助之研究等。此外，應考量歐盟運作條約（TFEU）第179條第1項規定之構建歐洲研究區之歐盟目標。科學研究目的還應包括公共衛生領域符合公共利益之研究。*」

10. The former Article 29-Working-Party has already pointed out that the term may not be stretched beyond its common meaning though and understands that "scientific research" in this context means *"a research project set up in accordance with relevant sector-related methodological and ethical standards, in conformity with good practice"*.[5]

雖前第29條工作小組已指出，該術語之擴張解釋尚不得超出其通常含義；且該小組認為，此時「科學研究」係指「*依相關行業方法與道德標準建構，且符合最佳實務的研究計畫*」[5]。

3.3 "Further processing"
「進階運用」

11. Finally, when talking about "processing of health data for the purpose of scientific research", there are two types of data usages:

[5] See the Guidelines on Consent under Regulation 2016/679 of the former Article 29 Working-Party from 6.7.2018, WP259 rev.01, 17EN, page 27 (endorsed by the EDPB). Available at https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=623051.
見前第29條工作小組「關於第2016/679號規則(GDPR)中的同意之指引」（2018年7月6日版），WP259 rev.01, 17EN，頁27（EDPB採認），請參閱：https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=623051。

最後，關於「為科學研究目的運用健康資料」，有兩種使用方式：

1. Research on personal (health) data which consists in the use of data directly collected for the purpose of scientific studies ("primary use").
   為科學研究目的直接蒐集的資料，對個人（健康）資料進行研究（「初級使用」）之使用。

2. Research on personal (health) data which consists of the further processing of data initially collected for another purpose ("secondary use").
   為其他目的而蒐集的資料，對個人（健康）資料進行研究（「次級使用」）之進階運用。

12. **Example 1:** For conducting a clinical trial on individuals suspected to be infected with COVID-19, health data are collected and questionnaires are used. This is a case of "primary use" of health data as defined above.
示例1：為對疑似感染新冠肺炎的個體進行臨床試驗，蒐集其健康資料並使用問卷調查。此即前開定義的健康資料之「初級使用」。

13. **Example 2:** A data subject has consulted a health care provider as a patient regarding symptoms of the SARS-CoV-2. If health data recorded by the health care provider is being used for scientific research purposes later on, this usage is classified as further processing of health data (secondary use) that has been collected for another initial purpose.
示例2：當事人曾以病患身分就新冠肺炎症狀向健康照護者進行諮詢。若該健康照護者記錄之健康資料後來被用於科學研究目的，此種使用會被歸類為其他初始目的蒐集之健康資料的進階運用（次級使用）。

14. The distinction between scientific research based on primary or secondary usage of health data will become particularly important when talking about the legal basis for the processing, the information obligations and the purpose limitation principle pursuant to Article 5 (1) (b) GDPR as outlined below.
當涉及運用資料之法律依據、資訊提供義務（information obligation）

以及GDPR第5條第1項第b款規定之目的限制原則時，區分科學研究中健康資料的初級使用和次級使用尤為重要，詳述如下。

4. LEGAL BASIS FOR THE PROCESSING
運用之法律依據

15. All processing of personal data concerning health must comply with the principles relating to processing set out in Article 5 GDPR and with one of the legal grounds and the specific derogations listed respectively in Article 6 and Article 9 GDPR for the lawful processing of this special category of personal data.[6]
對健康資料之一切運用皆須遵守GDPR第5條規定的運用之各項原則；還須具備GDPR第6條規定的合法要件之一，與第9條規定的合法運用特種個資之明確例外之一[6]。

16. Legal bases and applicable derogations for processing health data for the purpose of scientific research are provided for respectively in Article 6 and Article 9. In the following section, the rules concerning consent and respective national legislation are addressed. It has to be noted that there is no ranking between the legal bases stipulated in the GDPR.
第6條和第9條分別規定了為科學研究目的運用健康資料的法律依據及可適用之例外。本節將討論同意以及個別國家立法的相關規範。應注意，GDPR規定之各項法律依據間並無位階差別。

4.1 Consent
同意

17. The consent of the data subject, collected pursuant to Article 6 (1) (a) and Article 9 (2) (a) GDPR, may provide a legal basis for the processing of data concerning health in the COVID-19 context.
依GDPR第6條第1項第a款和第9條第2項第a款獲得之當事人同意，可

[6] See for example, regarding the Directive 95/46/EC ECJ 13.5.2014, C‑131/12 (Google Spain), paragraph 71.
示例見，關於指令95/46/EC，歐洲法院2014年5月13日第C‑131/12號案件（Google Spain）判決，第71段。

作為在新冠肺炎防疫期間運用健康資料之法律依據。

18. However, it has to be noted that all the conditions for explicit consent, particularly those found in Article 4 (11), Article 6 (1) (a), Article 7 and Article 9 (2) (a) GDPR, must be fulfilled. Notably, consent must be freely given, specific, informed, and unambiguous, and it must be made by way of a statement or "clear affirmative action".
然而，應注意須符合明確同意之各項要件，特別是GDPR第4條第11款、第6條第1項第a款、第7條和第9條第2項第a款規定之要件。尤其是，同意應自主給予、特定、知情且非模糊，且須以聲明或「清楚肯定行為」為之。

19. As stated in Recital 43, consent cannot be considered freely given if there is a clear imbalance between the data subject and the controller. It is therefore important that a data subject is not pressured and does not suffer from disadvantages if they decide not to give consent. The EDPB has already addressed consent in the context of clinical trials.[7] Further guidance, particularly on the topic of explicit consent, can be found in the consent guidelines of the former Article 29-Working-Party.[8]
如前言第43點所言，若當事人與控管者間存在明顯不對等，則不得認為同意係自主給予。因此，有必要確保當事人未被強迫，且不因拒絕同意而承受不利益。EDPB已就臨床試驗所涉之同意發表意見[7]。另可自前第29條工作小組之同意指引獲得進一步指導，特別是關於明確同意[8]。

20. **Example:** A survey is conducted as part of a non-interventional study on

[7] See Opinion 3/2019 of the EDPB from 23.1.2019 on concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR), available at https://edpb.europa.eu/our-work-tools/our-documents/avis-art-70/opinion-32019-concerning-questions-and- answers-interplay_en.
見EDPB「關於臨床試驗規則（CTR）和一般資料保護規則（GDPR）間互動問答集之意見3/2019」（2019年1月23日版），請參閱：https://edpb.europa.eu/our-work-tools/our-documents/avis-art-70/opinion-32019-concerning-questions-and-answers-interplay_en。

[8] Guidelines on Consent under Regulation 2016/679 of the former Article 29 Working-Party from 6.7.2018, WP259 rev.01, 17EN, page 18 (endorsed by the EDPB).
前第29條工作小組「關於第2016/679號規則(GDPR)中的同意之指引」（2018年7月6日版），WP259 rev.01, 17EN，頁18（EDPB採認）。

a given population, researching symptoms and the progress of a disease. For the processing of such health data, the researchers may seek the consent of the data subject under the conditions as stipulated in Article 7 GDPR.

示例：作為非介入性（non-interventional）研究之一部分，對特定群體進行調查，研究某一疾病之症狀與發展。為運用此等健康資料，研究人員得依GDPR第7條所明定之要件徵求當事人同意。

21. In the view of the EDPB, the example above is *not* considered a case of "clear imbalance of power" as mentioned in Recital 43 and the data subject should be able to give the consent to the researchers.[9] In the example, the data subjects are not in a situation of whatsoever dependency with the researchers that could inappropriately influence the exercise of their free will and it is also clear that it will have no adverse consequences if they refuse to give their consent.

EDPB認為，上開示例中並不存在前言第43點所述之「權力明顯不平等」，且當事人應可對研究人員給予同意[9]。該示例中，當事人與研究人員並無任何依賴關係，以致影響其表達自由意志，而且，當事人並不會因拒絕同意而承受不利後果。

22. However, researchers should be aware that if consent is used as the lawful basis for processing, there must be a possibility for individuals to withdraw that consent at any time pursuant to Article 7 (3) GDPR. If consent is withdrawn, all data processing operations that were based on consent remain lawful in accordance with the GDPR, but the controller shall stop the processing actions concerned and if there is no other lawful basis justifying the retention for further processing, the data should be deleted by the controller.[10]

然而，研究人員應注意，若以同意作為運用之合法依據，依GDPR第7條第3項，相關個人須能夠隨時撤回同意。撤回同意後，依GDPR，此

[9] Assuming that the data subject has not been pressured or threatened with disadvantages when not giving his or her consent.
假設當事人未被強迫，且不受拒絕同意時之不利益威脅。

前基於同意實施之一切資料運用作業仍為合法，但控管者須停止相關運用行為，且若無可正當保留資料作進階運用的其他合法依據，控管者應刪除該資料[10]。

4.2 National legislations
國家立法

23. Article 6 (1) e or 6 (1) f GDPR in combination with the enacted derogations under Article 9 (2) (j) or Article 9 (2) (i) GDPR can provide a legal basis for the processing of personal (health) data for scientific research. In the context of clinical trial this has already been clarified by the Board.[11]
GDPR第6條第1項第e款或第f款，結合第9條第2項第j款或第i款之例外規定，能夠作為為科學研究目的運用個人（健康）資料的法律依據。在臨床試驗領域，委員會對此已做說明[11]。

24. **Example:** A large population based study conducted on medical charts of COVID-19 patients.
示例：以新冠肺炎患者之病歷，進行大規模族群（population based）研究。

25. As outlined above, the EU as well as the national legislator of each Member State may enact specific laws pursuant to Article 9 (2) (j) or Article 9 (2) (i) GDPR to provide a legal basis for the processing of health data for the purpose of scientific research. Therefore, the conditions and the extent for such processing *vary* depending on the enacted laws of the particular Member State.
如前所述，歐盟以及各會員國之立法者得依GDPR第9條第2項第j款或第i款制定具體法律，作為為科學研究目的運用健康資料的法律依據。因此，此等運用之條件與程度依具體會員國所制定之法律而*有所不同*。

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[10] See Article17 (1) (b) and (3) GDPR.
見GDPR第17條第1項第b款和第3項。
[11] See Opinion 3/2019 of the EDPB from 23.1.2019, page 7.
見EDPB「意見3/2019」（2019年1月23日版），頁7。

26. As stipulated in Article 9 (2) (i) GDPR, such laws shall provide "*for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy*". As similarly stipulated in Article 9 (2) (j) GDPR, such enacted laws *"shall be proportionate to the aim pursued, respect the essence of the right to data* protection *and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject*".
GDPR第9條第2項第i款規定，此等法律須規定「*保障當事人權利與自由的適當具體措施，特別是職業秘密*」。GDPR第9條第2項第j款也有類似規定，即此等法律「*須與其追求之目的間合乎比例，尊重資料保護權利之本質，且規定保障當事人基本權利和利益之適當具體措施*」。

27. Furthermore, such enacted laws must be interpreted in the light of the principles pursuant to Article 5 GDPR and in consideration of the jurisprudence of the ECJ. In particular, derogations and limitations in relation to the protection of data provided in Article 9 (2) (j) and Article 89 GDPR must apply only in so far as is strictly necessary.[12]
此外，解釋此等法律時，須以GDPR第5條之各項原則為依據，並考量歐洲法院的實務見解。特別是，GDPR第9條第2項第j款和第89條關於資料保護之例外與限制規定，須在絕對必要之情況下始有其適用[12]。

5. DATA PROTECTION PRINCIPLES
資料保護原則

28. The principles relating to processing of personal data pursuant to Article 5 GDPR shall be respected by the controller and processor, especially considering that a great amount of personal data may be processed for the purpose of scientific research. Considering the context of the present guidelines, the most important aspects of these principles are addressed in the following.

[12] See for example, regarding the Directive 95/46/EC ECJ 14.2.2019, C–345/17 (Buivids) paragraph 64.
示例見，關於指令95/46/EC，歐洲法院2019年2月14日第C–345/17號案件（Buivids）判決，第64段。

特別考量到為科學研究之目的，可能運用大量個人資料，因此控管者和受託運用者應遵守GDPR第5條之個人資料運用原則。考量本指引之背景，以下提出這些原則最重要之面向。

5.1 Transparency and information to data subjects
透明化與對當事人提供資訊

29. The principle of transparency means that personal data shall be processed fairly and in a transparent manner in relation to the data subject. This principle is strongly connected with the information obligations pursuant to Article 13 or Article 14 GDPR.
透明化原則係指，個人資料之運用應公平合理並對當事人以透明之方式為之。該原則與GDPR第13條和第14條規定之資訊提供義務密切相關。

30. In general, a data subject must be individually informed of the existence of the processing operation and that personal (health) data is being processed for scientific purposes. The information delivered should contain all the elements stated in Article 13 or Article 14 GDPR.
一般而言，應個別告知當事人資料運用作業之存在，以及個人（健康）資料係為科學目的運用。所提供之資訊應包含GDPR第13條和第14條規定之各項要素。

31. It has to be noted that researchers often process health data that they have not obtained directly from the data subject, for instance using data from patient records or data from patients in other countries. Therefore, Article 14 GDPR, which covers information obligations where personal data is not collected directly from the data subject, will be the focus of this section.
應注意，研究人員所運用之個人資料，往往並非直接取自當事人，如取自病患紀錄之資料，或其他國家病患之資料。因此，GDPR第14條規定之非直接向當事人蒐集資料時的資訊(提供)義務，乃本節焦點。

5.1.1 When must the data subject be informed?
何時須告知當事人？

32. When personal data have not been obtained from the data subject, Article 14 (3) (a) GDPR stipulates that the controller shall provide the information *"within a reasonable period after obtaining the personal data, but at the latest within one month, having regard to the specific circumstances in which the personal data are processed"*.
對於非直接取自當事人的個人資料，GDPR第14條第3項第a款規定，控管者須「*考量個人資料運用之具體情形，在取得該個人資料後的合理期間內，至遲於一個月內*」，提供相關資訊。

33. In the current context, it has to be particularly noted that according to Article 14 (4) GDPR, where *"the controller intends to further process the personal data for a purpose other than that for which the personal data were obtained, the controller shall provide the data subject prior to that further processing with information on that other purpose"*.
於目前情況下，尤應注意，依據GDPR第14條第4項規定，當「*控管者想在個人資料之蒐集目的外，進階運用個人資料，則應在該進階運用前，向當事人提供該其他目的之相關資訊*」。

34. In the case of the further processing of data for scientific purposes and taking into account the sensitivity of the data processed, an appropriate safeguard according to Article 89 (1) is to deliver the information to the data subject within a reasonable period of time *before* the implementation of the new research project. This allows the data subject to become aware of the research project and enables the possibility to exercise his/her rights beforehand.
為科學研究目的進階運用資料時，考量所運用資料之敏感性，第89條第1項規定之適當安全維護措施之一，係在執行新的研究計畫*前*之適當期間內，提供當事人相關資訊。這使當事人得以獲知研究計畫，並使其具有在事前行使其權利之可能性。

5.1.2 Exemptions

例外

35. However, Article (14) (5) GDPR stipulates four exemptions of the information obligation. In the current context, the exemption pursuant to Article (14) (5) (b) ("proves impossible or would involve a disproportionate effort") and (c) ("obtaining or disclosure is expressly laid down by Union or Member State law") GDPR are of particular relevance, especially for the information obligation pursuant to Article 14 (4) GDPR.

然而，GDPR第14條第5項規定了資訊提供義務的四項例外。於目前情況下，尤其是就GDPR第14條第4項規定的資訊提供義務而言，最具關連性者為GDPR第14條第5項第b款（「證明為不可能或將涉及不成比例之付出」）和第c款（「歐盟法或會員國法明文規定之取得或揭露」）的例外。

5.1.2.1 Proves impossible

證明為不可能

36. In its Guidelines regarding the principle of Transparency,[13] the former Article 29-Working-Party has already pointed out that *"the situation where it "proves impossible" under Article 14 (5) (b) to provide the information is an all or nothing situation because something is either impossible or it is not; there are no degrees of impossibility. Thus, if a data controller seeks to rely on this exemption it must demonstrate the factors that actually prevent it from providing the information in question to data subjects. If, after a certain period of time, the factors that caused the "impossibility" no longer exist and it becomes possible to provide the information to data subjects then the data controller should immediately do so. In practice, there will be very few situations in which a data controller can demonstrate that it is actually impossible to provide the information to data subjects."*

在透明化原則之相關指引中[13]，前第29條工作小組已指出，「第14條第5項第b款中所謂當提供資訊被『證明為不可能』之情形，應屬一種或可提供全部資訊、或完全無法提供之情形，因為『不可能』並沒有程度上的區分。因此，若資料控管者試圖援用此項例外，則必須證明有實際上阻止其向當事人提供有關資訊之因素。若在一段期間後，導致『不可能性』之因素已不存在，且可向當事人提供資訊時，資料控管者應立即為之。實際上，僅在少數情況下資料控管者可證明其事實上不可能向當事人提供資訊。」

5.1.2.2 Disproportionate effort

不成比例之付出

37. In determining what constitutes disproportionate effort, Recital 62 refers to the number of data subjects, the age of the data and appropriate safeguards in place as possible indicative factors. In the Transparency Guidelines mentioned above,[14] it is recommended that the controller should therefore carry out a balancing exercise to assess the effort involved to provide the information to data subjects against the impact and effects on the data subject if they are not provided with the information.

於決定如何構成不成比例之付出時，前言第62點提到，當事人之數量、資料之年代和採行之適當安全維護措施是可能的指示性因素。前開透明化指引[14]建議，控管者應進行衡量比較，評估提供資訊予當事人之工作量，以及若未提供該資訊予當事人將對其產生之影響和結果。

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[13] See the Guidelines on transparency under Regulation 2016/679 of the former Article-29 Working-Party from 11.4.2018, WP260 rev.01, 17/EN, page 29 (endorsed by the EDPB). Available at https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=622227.
見前第29條工作小組「第2016/679號規則 (GDPR)的透明化指引」（2018年4月11日版），WP260 rev.01, 17/EN，頁29（EDPB採認），請參閱：https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=622227。

[14] Guidelines on transparency under Regulation 2016/679 of the former Article-29 Working-Party from 11.4.2018, WP260 rev.01, 17/EN, page 31 (endorsed by the EDPB).
前第29條工作小組「第2016/679號規則 (GDPR)的透明化指引」（2018年4月11日版），WP260 rev.01, 17/EN，頁31（EDPB採認）。

38. **Example:** A large number of data subjects where there is no available contact information could be considered as a disproportionate effort to provide the information.
示例：若當事人數量眾多且無可用之聯絡資訊，可認為提供資訊將構成不成比例之付出。

5.1.2.3 Serious impairment of objectives
對目的之嚴重損害

39. To rely on this exception, data controllers must demonstrate that the provision of the information set out in Article 14 (1) *per se* would render impossible or seriously impair the achievement of the objectives of the processing.
為援用此項例外，資料控管者必須證明提供第14條第1項規定之資訊*本身*將使運用資料之目的無法達成或嚴重受損。

40. In a case where the exemption of Article (14) (5) (b) GDPR applies, *"the controller shall take appropriate measures to protect the data subject's rights and freedoms and legitimate interests, including making the information publicly available"*.
若適用GDPR第14條第5項第b款規定之例外，則「*控管者應採取適當措施保護當事人之權利和自由以及正當利益，包括公開該等資訊。*」

5.1.2.4 Obtaining or disclosure is expressly laid down by Union or Member State law
歐盟法或會員國法明文規定之取得或揭露

41. Article 14 (5) (c) GDPR allows for a derogation of the information requirements in Articles 14 (1), (2) and (4) insofar as the obtaining or disclosure of personal data *"is expressly laid down by Union or Member State law to which the controller is subject"*. This exemption is conditional upon the law in question providing *"appropriate measures to protect the data subject's legitimate interests"*. As stated in the above mentioned Transparency Guidelines,[15] such law must directly address the data controller and the obtaining or disclosure in question should be

mandatory upon the data. When relying on this exemption, the EDPB recalls that the data controller must be able to demonstrate how the law in question applies to them and requires them to either obtain or disclose the personal data in question.

依GDPR第14條第5項第c款，若取得或揭露個人資料係「*依據控管者適用之歐盟法或會員國法律明文規定*」，則可免除第14條第1項、第2項和第4項規定之提供資訊要求。此一例外之條件是，相關法律提供「*保護當事人正當利益之適當措施*」。如前開透明化指引[15]所述，此等法律須直接規範資料控管者，且取得或揭露資料應具強制性。援用此一例外時，EDPB重申，資料控管者必須能夠證明其適用該相關法律，且該法律要求其取得或揭露相關個人資料。

5.2 Purpose limitation and presumption of compatibility
目的限制與相容性推定

42. As a general rule, data shall be *"collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes"* pursuant to Article 5 (1) (b) GDPR.

一般而言，依據GDPR第5條第1項b款，資料之「*蒐集須有特定、明確且正當之目的，且不得以該等目的不相容之方式為進階運用*」。

43. However the "compatibility presumption" provided by Article 5 (1) (b) GDPR states that *"further processing for […] scientific research purposes […] shall, in accordance with Article 89 (1), not be considered to be incompatible with the initial purposes"*. This topic, due to its horizontal and complex nature, will be considered in more detail in the planned EDPB guidelines on the processing of health data for the purpose of scientific research.

然而，GDPR第5條第1項第b款之「相容性推定」規定，「*依第89條第1項，為……科學研究目的……之進階運用，不得被視為與初始目的*

[15] Guidelines on transparency under Regulation 2016/679 of the former Article-29 Working-Party from 11.4.2018, WP260 rev.01, 17/EN, page 32 (endorsed by the EDPB).
見前第29條工作小組「關於第2016/679號規則 (GDPR) 中的透明化之指引」（2018年4月11日版），WP260 rev.01, 17/EN，頁32（EDPB採認）。

不相容」。此一議題，由於其水平性（horizontal）和複雜性，將在EDPB計劃發布之關於為科學研究目的運用健康資料的指引中，提供更深入之探討。

44. Article 89 (1) GDPR stipulates that the processing of data for research purposes *"shall be subject to appropriate safeguards"* and that those *"safeguards shall ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation. Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner"*.
GDPR第89條第1項規定，為研究目的運用資料，「*應有適當安全維護措施*」，且此等「*安全維護措施應確保採行技術性和組織性措施，特別是為確保遵守資料最小化原則。在能滿足其目的之前提下，此等措施可能包括假名化處理*」。

45. The requirements of Article 89 (1) GDPR emphasise the importance of the data minimisation principle and the principle of integrity and confidentiality as well as the principle of data protection by design and by default (see below).[16] Consequently, considering the sensitive nature of health data and the risks when re-using health data for the purpose of scientific research, strong measurements must be taken in order to ensure an appropriate level of security as required by Article 32 (1) GDPR.
GDPR第89條第1項之要件強調資料最小化原則、完整性和機密性原則、以及資料保護設計（by design）和預設（by default）原則（見下文）[16]。因此，考量健康資料的敏感本質，以及為科學研究目的再使用健康資料之風險，須採取有力措施，確保實現GDPR第32條第1項規定的適當安全程度。

[16] Also see the Guidelines 4/2019 of the EDPB from 13.11.2019 on Data Protection by Design and by Default (version for public consultation), available at https://edpb.europa.eu/our-work-tools/public-consultations-art- 704/2019/guidelines-42019-article-25-data-protection-design_en
另見，EDPB「關於資料保護設計和預設之指引4/2019」（2019年11月13日，公告徵求意見版），請參閱：https://edpb.europa.eu/our-work-tools/public-consultations-art-704/2019/guidelines-42019-article-25-data-protection-design_en。

5.3 Data minimisation and storage limitation
資料最小化和儲存限制

46. In scientific research, data minimisation can be achieved through the requirement of specifying the research questions and assessing the type and amount of data necessary to properly answer these research questions. Which data is needed depends on the purpose of the research even when the research has an explorative nature and should always comply with the purpose limitation principle pursuant to Article 5 (1) (b) GDPR. It has to be noted that the data has to be anonymised where it is possible to perform the scientific research with anonymised data.
科學研究中，可透過詳細說明研究問題的要求、評估充分解決研究問題所需之資料類型與數量，實現資料最小化。對資料的需求取決於研究目的（即便是探索式研究也是如此），且應始終遵守GDPR第5條第1項第b款規定的目的限制原則。亦應注意，若可使用匿名資料進行該科學研究，則應將資料匿名化。

47. In addition, proportionate storage periods shall be set. As stipulated by Article 5 (1) (e) GDPR *"personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving […] scientific purposes […] in accordance with Article 89 (1) subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject"*
此外，應設定合乎比例之儲存期間。根據GDPR第5條第1項第e款規定，「*專為歸檔……科學目的……運用個人資料，依第89條第1項執行本規則規定之適當技術性和組織性措施以保障當事人之權利與自由者，個人資料得儲存較長時間*」。

48. In order to define storage periods (timelines), criteria such as the length and the purpose of the research should be taken into account. It has to be noted that national provisions may stipulate rules concerning the storage period as well.

為確定儲存期間（時限），應考慮研究之時間長短和目的等標準。應注意，國家法律亦可能就儲存期間明訂相關規定。

5.4 Integrity and confidentiality
完整性和機密性

49. As mentioned above, sensitive data such as health data merit higher protection as their processing is likelier to lead to negative impacts for data subjects. This consideration especially applies in the COVID-19 outbreak as the foreseeable re-use of health data for scientific purposes leads to an increase in the number and type of entities processing such data.
如前所述，由於健康資料等敏感資料之運用更易導致對當事人之不利影響，此等資料需要更高程度之保護。新冠肺炎防疫期間，這一考量尤其重要，因為可以預見為科學目的對健康資料進行再使用，將導致運用此等資料之實體的數量與類型大幅增加。

50. It has to be noted that the principle of integrity and confidentiality must be read in conjunction with the requirements of Article 32 (1) GDPR and Article 89 (1) GDPR. The cited provisions must be fully complied with. Therefore, considering the high risks as outlined above, appropriate technical and organisational up-to-date measures must be implemented to ensure a sufficient level of security.
還應注意，對完整性和機密性原則之理解，須結合GDPR第32條第1項和GDPR第89條第1項。且須完全遵守此兩條文。因此，考量到前述之高度風險，必須實施適當且先進的技術性和組織性措施，以確保足夠的安全程度。

51. Such measures should *at least* consist of pseudonymisation,[17] encryption, non-disclosure agreements and strict access role distribution, restrictions as well as logs. It has to be noted that national provisions may stipulate concrete technical requirements or other safeguards such as adherence to professional secrecy rules.

此等措施至少應包括假名化[17]、加密、保密協議和嚴格存取權限分配、限制措施和日誌（log）。應注意，國家法律亦可能規定具體技術要求或其他安全維護措施，如遵守職業保密規範等。

52. Furthermore, a data protection impact assessment pursuant to Article 35 GDPR must be carried out when such processing is *"likely to result in a high risk to the rights and freedoms of natural persons"* pursuant to Article 35 (1) GDPR. The lists pursuant to Article 35 (4) and (5) GDPR shall be taken into account.
此外，依據GDPR第35條第1項規定，若運用「*可能對自然人之權利和自由造成高風險*」，則應辦理GDPR第35條規定的個資保護影響評估。應考慮GDPR第35條第4項和第5項規定的運用類型清單。

53. At this point, the EDPB emphasises the importance of data protection officers. Where applicable, data protection officers should be consulted on processing of health data for the purpose of scientific research in the context of the COVID-19 outbreak.
於此，EDPB強調個資保護長之重要性。在可行情況下，新冠肺炎防疫期間，為科學研究目的運用健康資料時，應諮詢個資保護長。

54. Finally, the adopted measures to protect data (including during transfers) should be properly documented in the record of processing activities.
最後，所採取之資料保護措施（包括資料傳輸期間的措施），應在運用活動檔案中予以適當記錄。

6. EXERCISE OF THE RIGHTS OF DATA SUBJECTS
當事人權利之行使

55. In principle, situations as the current COVID-19 outbreak do not suspend or restrict the possibility of data subjects to exercise their rights pursuant to Article 12 to 22 GDPR. However, Article 89 (2) GDPR allows the

[17] It has to be noted that personal (health data) that has been pseudonymised is still regarded as "personal data "pursuant to Article 4 (1) GDPR and must not be confused with "anonymised data" where it is no longer possible for anyone to refer back to individual data subjects. See for example Recital 28.
應注意，經假名化之個人資料（健康資料）仍為GDPR第4條第1款定義之「個人資料」，且不應與「匿名資料」(任何人皆無法回復識別個別當事人)混淆。示例見前言第28點。

national legislator to restrict (some) of the data subject's rights as set in Chapter 3 of the regulation. Because of this, the restrictions of the rights of data subjects *may vary* depending on the enacted laws of the particular Member State.

原則上，當前新冠肺炎疫情等狀況不會中止或限制當事人依GDPR第12條至第22條行使權利。然而，GDPR第89條第2項允許國家立法者限制當事人依GDPR第三章享有的（某些）權利。因此，對當事人權利之限制，*可能*因具體會員國所制定之法律而*有所不同*。

56. Furthermore, some restrictions of the rights of data subjects can be based directly on the Regulation, such as the access right restriction pursuant to Article 15 (4) GDPR and the restriction of the right to erasure pursuant to Article 17 (3) (d) GDPR. The information obligation exemptions pursuant to Article 14 (5) GDPR have already been addressed above.

此外，可直接基於GDPR對當事人的權利課予某些限制，如依GDPR第15條第4項限制近用權，以及依GDPR第17條第3項第d款限制刪除權。GDPR第14條第5項規定之資訊提供義務之例外已於上文討論。

57. It has to be noted that, in the light of the jurisprudence of the ECJ, all restrictions of the rights of data subjects must apply only in so far as it is strictly necessary.[18]

應注意，歐洲法院的實務見解認為，對當事人權利之一切限制，皆應限於必要範圍內[18]。

7.INTERNATIONAL DATA TRANSFERS FOR SCIENTIFIC RESEARCH PURPOSES

為科學研究目的實施之國際資料傳輸

58. Within the context of research and specifically in the context of the COVID-19 pandemic, there will probably be a need for international cooperation that may also imply international transfers of health data for

[18] See for example, regarding the Directive 95/46/EC ECJ 14.2.2019, C–345/17 (Buivids) paragraph 64.
示例見，歐洲法院2019年2月14日第C–345/17號案件（Buivids）關於95/46/EC指令判決，第64段。

the purpose of scientific research outside of the EEA.
為研究目的，特別是新冠肺炎防疫相關研究，可能需要進行國際合作，亦可能意味著，為於歐洲經濟區外科學研究之目的，進行健康資料國際傳輸。

59. When personal data is transferred to a non-EEA country or international organisation, in addition to complying with the rules set out in GDPR,[19] especially its Articles 5 (data protection principles), Article 6 (lawfulness) and Article 9 (special categories of data),[20] the data exporter shall also comply with Chapter V (data transfers).[21]
將個人資料傳輸至非歐洲經濟區國家或國際組織時，除應遵守GDPR之相關規定[19]，特別是第5條（資料保護原則）、第6條（合法性）和第9條（特種個資）[20]，資料輸出者還應遵守第五章（資料傳輸）之規範[21]。

60. In addition to the regular transparency requirement as mentioned on page 7 of the present guidelines, a duty rests on the data exporter to inform data subjects that it intends to transfer personal data to a third country or international organisation. This includes information about the existence or absence of an adequacy decision by the European Commission, or whether the transfer is based on a suitable safeguard from Article 46 or on a derogation of Article 49 (1). This duty exists irrespective of whether the personal data was obtained directly from the data subject or not.
除本指引第7頁(譯註：即本翻譯文件第15頁)論及之一般性透明化要求外，資料輸出者還有義務告知當事人，其有意將個人資料傳輸至

[19] Article 44 GDPR.
GDPR第44條。
[20] See sections 4 to 6 of the present Guidelines.
見本指引第4節至第6節。
[21] See the Guidelines 2/018 of the EDPB from 25.5.2018 on derogations of Article 49 under Regulation 2016/679, page 3, on the two-step test, available at https://edpb.europa.eu/our-work-tools/our-documents/smjernice/guidelines-22018-derogations-article-49-under-regulation_en.
見EDPB 2018年5月25日「關於第2016/679號規則第49條的例外情形之指引2/2018（譯註：原文2/018應為誤植）」，頁3，二階段測試，請參閱：https://edpb.europa.eu/our-work-tools/our-documents/smjernice/guidelines-22018-derogations-article-49-under-regulation_en。

第三國或國際組織。告知資訊包括歐盟執委會是否曾就其適足性作出認定，或傳輸是否具有第46條規定的適當安全維護措施或第49條第1項規定的例外。無論個人資料是否直接從當事人取得，都負有此一義務。

61. In general, when considering how to address such conditions for transfers of personal data to third countries or international organisations, data exporters should assess the risks to the rights and the freedoms of data subjects of each transfer[22] and favour solutions that guarantee data subjects the continuous protection of their fundamental rights and safeguards as regards the processing of their data, even after it has been transferred. This will be the case for transfers to countries having an adequate level of protection,[23] or in case of use of one of the appropriate safeguards included in Article 46 GDPR,[24] ensuring that enforceable rights and effective legal remedies are available for data subjects.

一般而言，考量如何處理個人資料傳輸至第三國或國際組織的條件時，資料輸出者應評估每次傳輸對當事人權利和自由之風險[22]，並優先選擇保證對於當事人之資料運用，即使在傳輸後，仍可持續保護當事人基本權利及安全維護措施之方案。例如傳輸目的國具備適足保護程度[23]，或採用GDPR第46條[24]規定的適當安全維護措施之一，從而確保當事人享有可依法行使之權利和有效法律救濟。

62. In the absence of an adequacy decision pursuant to Article 45 (3) GDPR

[22] International Data Transfers may be a risk factor to consider when performing a DPIA as referred to in page 10 of the present guidelines.
實施本指引第10頁(譯註：即本翻譯文件第24頁)所述之個資保護影響評估時，國際資料傳輸可能是需考量的風險因素。

[23] The list of countries recognised adequate by the European Commission Link is available at https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection/adequacy- decisions_en
關於歐盟執委會認定之適足保護國家清單，請參閱：https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection/adequacy-decisions_en。

[24] For example standard data protection clauses pursuant to Article 46 (2) (c) or (d) GDPR, ad hoc contractual clauses pursuant to Article 46 (3) (a) GDPR) or administrative arrangements pursuant to Article 46 (3) (b) GDPR.
如GDPR第46條第2項第c款或第d款規定之標準資料保護條款，GDPR第46條第3項第a款規定之個案專用（ad hoc）契約條款，或GDPR第46條第3項第b款規定之行政安排。

or appropriate safeguards pursuant to Article 46 GDPR, Article 49 GDPR envisages certain specific situations under which transfers of personal data can take place as an exception. The derogations enshrined in Article 49 GDPR are thus exemptions from the general rule and, therefore, must be interpreted restrictively, and on a case-by-case basis.[25] Applied to the current COVID-19 crisis, those addressed in Article 49 (1) (d) ("transfer necessary for important reasons of public interest") and (a) ("explicit consent") may apply.

若欠缺GDPR第45條第3項規定的適足性認定，或GDPR第46條規定之適當安全維護措施，GDPR第49條規定得在特定情形下，例外進行個人資料傳輸。因此，GDPR第49條所列之例外情形，為一般原則之豁免，應根據個案具體情形，予以限縮解釋[25]。對於當前的新冠肺炎危機，可能適用第49條第1項第d款（「基於公共利益之重要原因所為之必要傳輸」）及第a款（「明確同意」）。

63. The COVID-19 pandemic causes an exceptional sanitary crisis of an unprecedented nature and scale. In this context, the EDPB considers that the fight against COVID-19 has been recognised by the EU and most of its Member States as an important public interest,[26] which may require urgent action in the field of scientific research (for example to identify treatments and/or develop vaccines), and may also involve transfers to third countries or international organisations.[27]

新冠肺炎疫情為一場性質與規模皆前所未見的嚴重衛生危機。在此情形下，EDPB認為，對抗新冠肺炎係歐盟及其大多數會員國所承認之重要公共利益[26]，這可能需要科學研究領域迅速採取行動（如確定

[25] See Guidelines 2/2018, page 3.
見「2/2018指引」，頁3。

[26] Article 168 of the Treaty on the Functioning of the European Union recognises a high level of human health protection as an important objective that should be ensured in the implementation of all Union policies and activities. On this basis, Union action supports national policies to improve public health, including in combatting against major health scourges and serious cross-border threats to health, e.g. by promoting research into their causes, transmission and prevention. Similarly, Recitals 46 and 112 of the GDPR refer to processing carried out in the context of the fight against epidemics as an example of processing serving important grounds of public interest. In the context of the COVID-19 pandemic, the EU has adopted a series of measures in a broad range of areas (e.g. funding of healthcare systems, support to cross-border patients and deployment of medical staff, financial assistance to the most

治療方法和（或）開發疫苗），也可能涉及向第三國或國際組織傳輸資料[27]。

64. Not only public authorities, but also private entities playing a role in pursuing such public interest (for example, a university's research institute cooperating on the development of a vaccine in the context of an international partnership) could, under the current pandemic context, rely upon the derogation mentioned above.
當前疫情期間，除公務機關外，追求此等公共利益之私人實體（如與國際夥伴合作開發疫苗的大學研究機構），亦仰賴前開之例外。

65. In addition, in certain situations, in particular where transfers are performed by private entities for the purpose of medical research aiming at fighting the COVID-19 pandemic,[28] such transfers of personal data could alternatively take place on the basis of the explicit consent of the data subjects.[29]
此外，於特定情形下，特別是為對抗新冠肺炎疫情之相關醫學研究目的，由私人實體進行傳輸時[28]，此種個人資料之傳輸亦可能以當事人之明確同意為依據[29]。

66. Public authorities and private entities may, under the current pandemic

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deprived, transport, medical devices etc.) premised on the understanding that the EU is facing a major public health emergency requiring an urgent response.
人類健康之高水準保護係歐盟運作條約第168條認可之重要目標，在實施歐盟各項政策與活動時，皆應確保符合這一目標。因此，歐盟活動支持促進公共衛生之國家政策，包括對抗重大健康危害和嚴重跨境之健康威脅之政策，如增進對其起因、傳播和防範方法之研究。同樣地，GDPR前言第46點和第112點提及，對抗流行病之相關運用，是為重要公共利益服務而運用之示例。新冠肺炎防疫期間，基於歐盟正面臨嚴峻公共衛生危機且需要迅速回應之認知，歐盟在諸多領域廣泛採取了一系列措施（如資助健康照護體系、支援跨境病患和部署醫療人員、向最弱勢群體提供經濟援助、運輸、醫療設備等）。

[27] The EDPB underlines that the GDPR, in its Recital 112, refers to the international data exchange between services competent for public health purposes as an example of the application of this derogation.
EDPB強調，GDPR前言第112點以適格公共衛生服務間的國際資料交換為例，說明了此一例外之適用。

[28] In accordance with Article 49 (3) GDPR, consent cannot be used for activities carried out by public authorities in the exercise of their public powers.
依GDPR第49條第3項，公務機關行使其公權力時，不得以同意為依據。

[29] See EDPB Guidelines 2/2018, section 2.1.
見EDPB「2/2018指引」，第2.1節。

context, when it is not possible to rely on an adequacy decision pursuant to Article 45 (3) or on appropriate safeguards pursuant to Article 46, rely upon the applicable derogations mentioned above, mainly as a temporary measure due to the urgency of the medical situation globally.

當前疫情狀況下，若無法依據GDPR第45條第3項規定的適足性認定，或GDPR第46條規定之適當安全維護措施，公務機關和私人實體得援用前開例外，主要將其作為當前全球緊急醫療狀態下的臨時措施。

67. Indeed, if the nature of the COVID-19 crisis may justify the use of the applicable derogations for initial transfers carried out for the purpose of research in this context, repetitive transfers of data to third countries part of a long lasting research project in this regard would need to be framed with appropriate safeguards in accordance with Article 46 GDPR.[30]

事實上，若新冠肺炎危機得做為適用該項例外，為相關研究目的進行初次傳輸之正當化理由，則作為持續進行中的研究計畫之一部分，後續多次向第三國傳輸資料之行為，須採取GDPR第46條規定的適當安全維護措施[30]。

68. Finally, it has to be noted that any such transfers will need to take into consideration on a case-by-case basis the respective roles (controller, processor, joint controller) and related obligations of the actors involved (sponsor, investigator) in order to identify the appropriate measures for framing the transfer.

最後，應注意，一切傳輸皆應依據個案情形，考量（控管者、受託運用者、共同控管者的）各自角色，以及所涉行動者（贊助者、調查員）之相關義務，以確定建構該項傳輸之適當措施。

[30] See EDPB Guidelines 2/2018, page 5.
見EDPB「2/2018指引」，頁5。

8. SUMMARY
結論

69. The key findings of these guidelines are:
本指引之主要結論如下：

1. The GDPR provides special rules for the processing of health data for the purpose of scientific research that are also applicable in the context of the COVID-19 pandemic.
為科學研究目的運用健康資料，GDPR定有特殊規範，此等規範亦適用於當前新冠肺炎疫情狀況。

2. The national legislator of each Member State may enact specific laws pursuant to Article (9) (2) (i) and (j) GDPR to enable the processing of health data for scientific research purposes. The processing of health data for the purpose of scientific research must also be covered by one of the legal bases in Article 6 (1) GDPR. Therefore, the conditions and the extent for such processing varies depending on the enacted laws of the particular member state.
各會員國的國家立法者得依據GDPR第9條第2項第i款和第j款制定具體法律，允許為科學研究目的運用健康資料。為科學研究目的運用健康資料，須具有GDPR第6條第1項規定之法律依據之一。因此，此種運用之條件與程度依具體會員國所制定之法律而有所不同。

3. All enacted laws based on Article (9) (2) (i) and (j) GDPR must be interpreted in the light of the principles pursuant to Article 5 GDPR and in consideration of the jurisprudence of the ECJ. In particular, derogations and limitations in relation to the protection of data provided in Article 9 (2) (j) and Article 89 (2) GDPR must apply only in so far as is strictly necessary.
依GDPR第9條第2項第i款和第j款制定之各項法律，其解釋須符合GDPR第5條之各項原則，且考量歐洲法院的實務見解。特別是，GDPR第9條第2項第j款和第89條第2項關於個資保護之例外與限制

規定，須以絕對必要為限。

4. Considering the processing risks in the context of the COVID-19 outbreak, high emphasise must be put on compliance with Article 5 (1) (f), Article 32 (1) and Article 89 (1) GDPR. There must be an assessment if a DPIA pursuant to Article 35 GDPR has to be carried out.
   考量新冠肺炎疫情期間資料運用之風險，須著重強調遵守GDPR第5條第1項第f款、第32條第1項和第89條第1項規定。須評估是否應依GDPR第35條規定辦理個資保護影響評估。

5. Storage periods (timelines) shall be set and must be proportionate. In order to define such storage periods, criteria such as the length and the purpose of the research should be taken into account. National provisions may stipulate rules concerning the storage period as well and must therefore be considered.
   應設定合乎比例之儲存期間（時限）。為確定儲存期間，應考慮研究之時間長度和目的等標準。國家法律亦可能包含儲存期間相關規定，此等規定亦須予以考慮。

6. In principle, situations as the current COVID-19 outbreak do not suspend or restrict the possibility of data subjects to exercise their rights pursuant to Article 12 to 22 GDPR. However, Article 89 (2) GDPR allows the national legislator to restrict (some) of the data subject's rights as set in Chapter 3 of the GDPR. Because of this, the restrictions of the rights of data subjects *may vary* depending on the enacted laws of the particular Member State.
   原則上，當前新冠肺炎疫情等狀況不會中止或限制當事人依GDPR第12條至第22條行使權利。然而，GDPR第89條第2項允許國家立法者限制當事人依GDPR第三章享有的（某些）權利。因此，對當事人權利之限制，*可能*因具體會員國所制定之法律而*有所不同*。

7. With respect to international transfers, in the absence of an adequacy decision pursuant to Article 45 (3) GDPR or appropriate safeguards pursuant to Article 46 GDPR, public authorities and private entities may rely upon the applicable derogations pursuant to Article 49 GDPR. However, the derogations of Article 49 GDPR do have exceptional character only.
   國際傳輸方面，若欠缺GDPR第45條第3項規定的適足性認定，或GDPR第46條規定之適當安全維護措施，公務機關和私人實體得援用GDPR第49條之例外條款。但此GDPR第49條之例外條款僅得例外適用。

For the European Data Protection Board
The Chair
(Andrea Jelinek)

歐盟個人資料保護委員會
主席
(Andrea Jelinek)