医療分野の研究開発に資するための匿名加工医療情報に関する法律施行規則

Regulation for Enforcement of the Act on Anonymized Medical Data That Are Meant to Contribute to Research and Development in the Medical Field

（平成三十年五月七日内閣府・文部科学省・厚生労働省・経済産業省令第一号）

(Order of the Cabinet Office; Ministry of Education, Culture, Sports, Science and Technology; Ministry of Health, Labour and Welfare; and Ministry of Economy, Trade and Industry No. 1 of May 7, 2018)

医療分野の研究開発に資するための匿名加工医療情報に関する法律（平成二十九年法律第二十八号）及び医療分野の研究開発に資するための匿名加工医療情報に関する法律施行令（平成三十年政令第百六十三号）の規定に基づき、並びに同法を実施するため、医療分野の研究開発に資するための匿名加工医療情報に関する法律施行規則を次のように定める。

Pursuant to the provisions of the Act on Anonymized Medical Data That Are Meant to Contribute to Research and Development in the Medical Field (Act No. 28 of 2017) and the Order for Enforcement of the Act on Anonymized Medical Data That Are Meant to Contribute to Research and Development in the Medical Field (Cabinet Order No. 163 of 2018), and in order to implement that Act, this Regulation for Enforcement of the Act on Anonymized Medical Data That Are Meant to Contribute to Research and Development in the Medical Field is established as follows.

（定義）

(Definitions)

第一条　この規則において使用する用語は、医療分野の研究開発に資するための匿名加工医療情報に関する法律（以下「法」という。）において使用する用語の例による。

Article 1 The terms used in this Regulation carry the meanings of the terms used in the Act on Anonymized Medical Data That Are Meant to Contribute to Research and Development in the Medical Field (hereinafter referred to as "the Act").

（医療情報）

(Medical Information)

第二条　医療分野の研究開発に資するための匿名加工医療情報に関する法律施行令（以下「令」という。）第一条第二号イの主務省令で定める心身の機能の障害は、個人情報の保護に関する法律施行規則（平成二十八年個人情報保護委員会規則第三号）第五条各号に規定する障害とする。

Article 2 The impairments of physical and mental function specified by Order of the competent ministries that are referred to in Article 1, item (ii), (a) of the Order for Enforcement of the Act on Anonymized Medical Data That Are Meant to Contribute to Research and Development in the Medical Field (hereinafter referred to as "the Order") mean the impairments of physical and mental function prescribed in the items of Article 5 of the Regulation for Enforcement of the Act on the Protection of Personal Information (Rules of the Personal Information Protection Commission No. 3 of 2016).

（認定の申請）

(Application for Certification)

第三条　法第八条第一項の認定を受けようとする者は、様式第一による申請書を主務大臣に提出しなければならない。

Article 3 (1) A person seeking the certification referred to in Article 8, paragraph (1) of the Act must submit a written application based on Form No. 1 to the competent ministers.

２　法第八条第二項の主務省令で定める書類は、次のとおりとする。

(2) The documents specified by Order of the competent ministries that are referred to in Article 8, paragraph (2) of the Act are as follows:

一　申請者に係る次に掲げる書類

(i) the following documents regarding the applicant:

イ　定款及び登記事項証明書又はこれらに準ずるもの

(a) its articles of incorporation and certificate of registered information or documents equivalent thereto; and

ロ　法第八条第三項第一号ハの役員（第八条第二項第一号において単に「役員」という。）及び使用人（次条に規定する使用人をいう。）に係る住民票の写し又はこれに代わる書類

(b) copies of the resident records of any officer as referred to in Article 8, paragraph (3), item (i), (c) of the Act (simply referred to as "officers" in Article 8, paragraph (2), item (i)) or employee as referred to in that clause (meaning an employee as prescribed in the following Article), or documents that stand in place of resident records;

二　申請の日の属する事業年度及び翌事業年度における事業計画書及び収支予算書

(ii) its business plans and income and expenditure budgets for the business year that includes the day of the application and for the following business year; and

三　その他主務大臣が必要と認める書類

(iii) other documents that the competent ministers find to be necessary.

（使用人）

(Employees)

第四条　法第八条第三項第一号ハの主務省令で定める使用人（第八条第二項第一号において単に「使用人」という。）は、申請者の使用人であって、当該申請者の匿名加工医療情報作成事業に関する権限及び責任を有する者とする。

Article 4 The employees specified by Order of the competent ministries that are referred to in Article 8, paragraph (3), item (i), (c) of the Act (simply referred to as "employees" in Article 8, paragraph (2), item (i)) are those employees of an applicant who have authority and responsibility for the applicant's business of producing anonymized medical data.

（法第八条第三項第二号の主務省令で定める基準）

(Standards Specified by Order of Competent Ministries as Referred to in Article 8, Paragraph (3), Item (ii) of the Act)

第五条　法第八条第三項第二号の主務省令で定める基準は、次のとおりとする。

Article 5 The standards specified by Order of the competent ministries that are referred to in Article 8, paragraph (3), item (ii) of the Act are as follows:

一　日本の医療分野の研究開発に資する匿名加工医療情報の作成に関する相当の経験及び識見を有する者であって、匿名加工医療情報作成事業を統括管理し、責任を有するものがいること。

(i) it has a person who has substantial experience and insight in the production of anonymized medical data that contributes to Japan's medical research and development engaged in the overall management of its business of producing anonymized medical data and responsible therefor;

二　匿名加工医療情報作成事業を適正かつ確実に行うに足りる経験及び識見を有する者として次に掲げるものをいずれも確保していること。

(ii) it has secured all of the following persons as persons who have sufficient experience and insight to undertake the business of producing anonymized medical data in a proper and reliable manner:

イ　日本の医療分野の研究開発に資する匿名加工医療情報を作成するための大規模な医療情報の加工に関する相当の経験及び識見を有する者

(a) a person who has substantial experience and insight in the large-scale processing of medical information to produce anonymized medical data that contributes to Japan's medical research and development;

ロ　匿名加工医療情報を用いた日本の医療分野の研究開発の推進に関する相当の経験及び識見を有する者

(b) a person who has substantial experience and insight in the promotion of Japan's medical research and development using anonymized medical data; and

ハ　日本の医療分野の研究開発に資する匿名加工医療情報の作成に用いる医療情報の取得及び整理に関する相当の経験及び識見を有する者

(c) a person who has substantial experience and insight in the acquisition and organization of medical information used to produce anonymized medical data that contributes to Japan's medical research and development;

三　医療情報検索システムその他の匿名加工医療情報作成事業の実施に必要な設備を備えていること。

(iii) it is equipped with a medical information search system and other equipment necessary to implement its business of producing anonymized medical data;

四　匿名加工医療情報作成事業を適正かつ確実に行うための内部規則等を定め、これに基づく事業の運営の検証がされる等、法令等を遵守した運営を確保していること。

(iv) internal rules for carrying out the business of producing anonymized medical data in a proper and reliable manner have been established, it has been verified that its business operation is based on those rules, and it has otherwise been ensured that its operation complies with laws and regulations;

五　匿名加工医療情報作成事業を適正かつ確実に、かつ継続して行うに足りる経理的基礎を有すること。

(v) it has a sufficient financial basis to continuously carry out the business of producing anonymized medical data in a proper and reliable manner;

六　法第四条第一項に規定する基本方針（次号において「基本方針」という。）に照らし適切なものであると認められる匿名加工医療情報作成事業に関する中期的な計画を有すること。

(vi) it has a medium-term plan for the business of producing anonymized medical data that is found to be appropriate in light of the basic policy prescribed in Article 4, paragraph (1) of the Act (referred to as the "basic policy" in the following item);

七　匿名加工医療情報の提供の是非の判断に際して、基本方針に照らし、匿名加工医療情報が医療分野の研究開発に資するために適切に取り扱われることについて適切に審査するための体制を整備していること。

(vii) it has set in place a framework for appropriately examining, when deciding whether or not to provide anonymized medical data, whether anonymized medical data will be handled appropriately so that it will contribute to research and development in the medical field, in light of the basic policy;

八　広報及び啓発並びに本人、医療情報取扱事業者又は匿名加工医療情報取扱事業者からの相談に応ずるための体制を整備していること。

(viii) it has set in place frameworks for public relations, for imparting information, and for responding to requests for consultation from principals, enterprises handling medical information, and enterprises handling anonymized medical data;

九　その取り扱う医療情報の規模及び内容が、匿名加工医療情報作成事業を適正かつ確実に行うに足りるものであること。

(ix) the scale and substance of medical information it handles are sufficient for it to carry out the business of producing anonymized medical data in a proper and reliable manner;

十　医療分野の標準的な規格に対応した医療情報を円滑に取り扱うことができること。

(x) it is able to smoothly handle medical information that complies with normal medical standards; and

十一　申請者が行う匿名加工医療情報作成事業において、特定の匿名加工医療情報取扱事業者に対して不当な差別的取扱いをするものでないこと。

(xi) the applicant, in the business of producing anonymized medical data that it undertakes, does not subject any specific enterprise handling anonymized medical data to undue differential treatment.

（安全管理措置）

(Security Control Measures)

第六条　法第八条第三項第三号及び法第二十条の主務省令で定める措置は、次のとおりとする。

Article 6 The measures specified by Order of the competent ministries that are referred to in Article 8, paragraph (3), item (iii) of the Act and Article 20 of the Act are as follows:

一　組織的安全管理措置

(i) systematic security control measures:

イ　認定事業に関し管理する医療情報等及び匿名加工医療情報（この条において「認定事業医療情報等」という。）の安全管理に係る基本方針を定めていること。

(a) it has established a basic policy regarding security controls for the medical and related information and anonymized medical data that it manages in connection with the certified business (referred to as "medical and related information and anonymized medical data associated with its certified business" in this Article);

ロ　認定事業医療情報等の安全管理に関する相当の経験及び識見を有する責任者を配置していること。

(b) it has assigned a person in charge who has substantial experience and insight in security controls for medical and related information and anonymized medical data associated with its certified business;

ハ　認定事業医療情報等を取り扱う者の権限及び責務並びに業務を明確にしていること。

(c) it has clarified the authority, responsibility, and duties of persons handling medical and related information and anonymized medical data associated with its certified business;

ニ　認定事業医療情報等の漏えい、滅失又は毀損の発生時における事務処理体制が整備されていること。

(d) a framework has been prepared for business processing upon the occurrence of a leak, loss, or damage involving medical and related information and anonymized medical data associated with its certified business;

ホ　安全管理措置に関する規程の策定及び実施並びにその運用の評価及び改善を行っていること。

(e) it has formulated and implemented rules for security control measures security control measure, and has evaluated and improved the operation thereof; and

ヘ　外部の専門家による情報セキュリティ監査の受検又は第三者認証の取得により、安全管理に係る措置の継続的な確保を図っていること。

(f) it continuously seeks to ensure measures for security controls by undergoing information security audits by outside experts or by obtaining a third-party certification;

二　人的安全管理措置

(ii) human security control measures:

イ　認定事業医療情報等を取り扱う者が、法第八条第三項第一号ハ（１）から（４）までのいずれにも該当しない者であることを確認していること。

(a) it has confirmed that persons handling medical and related information and anonymized medical data associated with its certified business do not fall under item (i), (c), 1. through 4. of Article 8, paragraph (3) of the Act;

ロ　認定事業医療情報等を取り扱う者が、認定事業の目的の達成に必要な範囲を超えて、認定事業医療情報等を取り扱うことがないことを確保するための措置を講じていること。

(b) it has taken measures to ensure that persons handling medical and related information and anonymized medical data associated with its certified business do not handle this beyond the scope necessary for achieving the purpose of its certified business;

ハ　認定事業医療情報等を取り扱う者に対する必要な教育及び訓練を行っていること。

(c) it provides the necessary education and training to persons handling medical and related information and anonymized medical data associated with its certified business; and

ニ　認定事業医療情報等を取り扱う権限を有しない者による認定事業医療情報等の取扱いを防止する措置を講じていること。

(d) it has taken measures to prevent persons who do not have the authority to handle medical and related information and anonymized medical data associated with its certified business from handling it;

三　物理的安全管理措置

(iii) physical security control measures:

イ　認定事業医療情報等を取り扱う施設設備を他の施設設備と区分していること。

(a) it has separated the facilities and equipment it uses to handle medical and related information and anonymized medical data associated with certified business from other facilities and equipment;

ロ　認定事業医療情報等を取り扱う施設設備への立入り及び機器の持込みを制限する措置を講じているとともに、監視カメラの設置その他の当該施設設備の内部を常時監視するための装置を備えていること。

(b) it has taken measures to restrict entry and the bringing of devices into facilities and equipment used for handling medical and related information and anonymized medical data associated with certified business, and has installed surveillance cameras or otherwise set up equipment to continuously monitor the interiors of those facilities and equipment;

ハ　認定事業に関し管理する医療情報等の取扱いに係る端末装置は、原則として、補助記憶装置及び可搬記録媒体（電子計算機又はその周辺機器に挿入し、又は接続して情報を保存することができる媒体又は機器のうち、可搬型のものをいう。）への記録機能を有しないものとすること。

(c) the terminal devices associated with the handling of medical and related information that it manages in connection with its certified business do not, in principle, have a function for recording onto auxiliary storage or portable recording media (meaning portable media and devices onto which data can be saved if they are inserted into or connected to a computer or its peripheral equipment); and

ニ　認定事業医療情報等を削除し、又は認定事業医療情報等が記録された機器、電子媒体等を廃棄する場合には、復元不可能な手段で行うこと。

(d) when it deletes medical and related information and anonymized medical data associated with its certified business or disposes of a device, electronic medium, or the like containing medical and related information and anonymized medical data associated with its certified business, it does so in a way that makes it impossible to restore the medical and related information and anonymized medical data associated with its certified business;

四　技術的安全管理措置

(iv) technical security control measures:

イ　認定事業医療情報等を取り扱う施設設備に、不正アクセス行為（不正アクセス行為の禁止等に関する法律（平成十一年法律第百二十八号）第二条第四項に規定する不正アクセス行為をいう。）を防止するため、適切な措置を講じていること。

(a) it takes appropriate measures for facilities and equipment that handle medical and related information and anonymized medical data associated with its certified business to prevent acts of unauthorized computer access (meaning acts of unauthorized computer access as prescribed in Article 2, paragraph (4) of the Act on Prohibition of Unauthorized Computer Access (Act No. 128 of 1999));

ロ　認定事業医療情報等の取扱いに係る電子計算機及び端末装置の動作を記録するとともに、通常想定されない当該電子計算機及び端末装置の操作を検知し、当該操作が行われた電子計算機及び端末装置を制御する措置を講じていること。

(b) in addition to recording the activity of computers and terminal devices used for handling medical and related information and anonymized medical data associated with its certified business, it takes measures to detect if someone has operated those computers and terminal devices in a way that is unexpected and to control computers and terminal devices that someone has operated in an unexpected way;

ハ　認定事業医療情報等の取扱いに係る電子計算機又は端末装置において、第三者が当該電子計算機又は端末装置に使用目的に反する動作をさせる機能が具備されていないことを確認していること。

(c) it verifies that computers and terminal devices used to handle medical and related information and anonymized medical data associated with its certified business have not been equipped with a function that allows a third party to make the computer or terminal device act in a way that is counter to the purpose for which it is being used; and

ニ　認定事業医療情報等を電気通信により送受信するとき、又は移送し、若しくは移送を受けるときは、次に掲げる措置を講じていること。

(d) it takes the following measures when transmitting, receiving, transferring, or being transferred medical and related information and anonymized medical data associated with its certified business via telecommunications:

（１）　外部の者との送受信の用に供する電気通信回線として、専用線等（ＩＰ―ＶＰＮサービス（電気通信事業報告規則（昭和六十三年郵政省令第四十六号）第一条第二項第十五号に掲げるＩＰ―ＶＰＮサービスをいう。）に用いられる仮想専用線その他のこれと同等の安全性が確保されると認められる仮想専用線を含む。）を用いること。

1. using dedicated lines or the like (including virtual dedicated lines used by an IP-VPN service (meaning an IP-VPN service set forth in Article 1, paragraph (2), item (xv) of the Telecommunications Business Reporting Regulations (Order of the Ministry of Posts and Telecommunications No. 46 of 1988)) or any other virtual dedicated line whose safety is found to be equivalent thereto) as the telecommunications lines it uses for transmission and reception with the outside;

（２）　（１）に規定する電気通信回線に接続されるサーバ用の電子計算機のうち、医療情報取扱事業者からの医療情報の受信に用いるものについては、外部への送信機能を具備させないこと。

2. not equipping server computers that are connected to a telecommunications line as prescribed in 1. and that are used for receiving medical information from enterprises handling medical information with a function that allows them to transmit data to the outside;

（３）　（１）に規定する電気通信回線に接続されるサーバ用の電子計算機のうち、匿名加工医療情報取扱事業者への匿名加工医療情報の送信に用いるものについては、外部からの受信機能を具備させないこと。また、（２）又はホに規定する電子計算機以外のサーバ用の電子計算機を用いること。

3. not equipping server computers that are connected to a telecommunications line as prescribed in 1. and that are used for transmitting anonymized medical data to enterprises handling anonymized medical data with a function that allows them to receive data from the outside; also, using server computers that do not constitute computers as prescribed in 2. or (e); and

（４）　（１）から（３）までに掲げるもののほか、認定事業医療情報等を適切に移送し、又は移送を受けるために、暗号化等必要な措置を講ずること。

4. beyond what is set forth in 1. through 3., encrypting data and taking other necessary measures to appropriately transfer or receive medical and related information and anonymized medical data associated with certified business;

ホ　匿名加工医療情報の作成の用に供する医療情報の管理は、ニ（２）及び（３）の電子計算機以外のサーバ用の電子計算機を用いることとし、ニ（２）及び（３）に規定する電子計算機を経由する以外の方法による外部へのネットワーク接続を行わないこと。また、ニ（２）及び（３）に規定する電子計算機との接続においては、専用線を用いること。

(e) it uses server computers that do not constitute computers as referred to in (d), 2. and 3. for managing the medical information it uses to produce anonymized medical data, and it does not connect its network to the outside by a means other than through computers as prescribed in (d), 2. and 3.; also, it uses dedicated lines for connecting with computers as prescribed in (d), 2. and 3.

五　その他の措置

(v) other measures:

イ　認定事業医療情報等の漏えいその他の事故が生じた場合における被害の補償のための措置を講じていること。

(a) it has taken measures meant to compensate for damage in the event that medical and related information and anonymized medical data associated with certified business is leaked or any other such incident occurs;

ロ　認定事業医療情報等を取り扱う施設設備の障害の発生の防止に努めるとともに、これらの障害の発生を検知し、及びこれらの障害が発生した場合の対策を行うため、事業継続計画の策定、その機能を代替することができる予備の機器の設置その他の適切な措置を講じていること。

(b) it endeavors to prevent damage to the facilities and equipment used to handle medical and related information and anonymized medical data associated with certified business, as well as taking appropriate measures to detect damage in them and to respond if damage is found, including the formulation of a business continuity plan and the installation of spare devices that can function in their stead;

ハ　医療情報の提供を受ける際に、医療情報取扱事業者による当該医療情報の提供の方法及びこれに係る安全管理のための措置が適正である旨を確認していること。

(c) when receiving medical information, it verifies that the means by which the enterprise handling the medical information provides the medical information and its security control measures for this are proper; and

ニ　匿名加工医療情報の提供の契約において、匿名加工医療情報取扱事業者による当該匿名加工医療情報の利用の態様及びこれに係る安全管理のための措置が匿名加工の程度に応じて適正であることを確保していること。

(d) in an agreement on the provision of anonymized medical data, it has ensured that the mode of use of the anonymized medical data by the enterprise handling that anonymized medical data and its security control measures for this are proper for the degree of anonymous processing.

（認定証の交付）

(Issuance of Certificates)

第七条　主務大臣は、法第八条第一項の認定をしたときは、申請者に対し、その旨を通知するとともに、様式第二による認定証を交付するものとする。

Article 7 Having granted a certification referred to in Article 8, paragraph (1) of the Act, the competent ministers are to notify the applicant of this and issue a certificate based on Form No. 2 thereto.

（変更の認定の申請等）

(Application for Amended Certification; Related Matters)

第八条　認定匿名加工医療情報作成事業者は、法第八条第二項第二号から第五号までに掲げる事項を変更しようとするときは、様式第三による申請書に次に掲げる書類を添えて、主務大臣に提出し、変更の認定を受けなければならない。

Article 8 (1) If a certified producer of anonymized medical data seeks to change any of the particulars set forth in Article 8, paragraph (2), items (ii) through (v) of the Act, it must submit a written application based on Form No. 3 to the competent ministers, along with the following documents, and obtain an amended certification:

一　法第八条第三項各号に掲げる認定の基準に適合していることを証する書類及び第三条第二項各号に掲げる書類のうち、当該変更事項に係る書類

(i) those of the documents evidencing that the certification standards set forth in the items of Article 8, paragraph (3) of the Act have been met and those of the documents set forth in the items of Article 3, paragraph (2) which relate to the particular that is to change; and

二　前条の認定証の写し

(ii) a copy of the certificate referred to in the preceding Article.

２　法第九条第一項ただし書の主務省令で定める軽微な変更は、次のいずれかに該当する場合とする。

(2) The minor changes specified by Order of the competent ministries that are referred to in the proviso of Article 9, paragraph (1) of the Act are changes falling under any of the following:

一　匿名加工医療情報作成事業を行う役員又は使用人の氏名の変更であって、役員又は使用人の変更を伴わないもの

(i) a change in the name of an officer or employee carrying on the business of producing anonymized medical data that does not involve a change of officers or employees; and

二　前号に掲げるもののほか、法第八条第二項第二号から第五号までに掲げる事項の実質的な変更を伴わないもの

(ii) beyond what is set forth in the preceding item, a change not involving any substantial change to a particular forth in Article 8, paragraph (2), items (ii) through (v) of the Act.

３　認定匿名加工医療情報作成事業者は、法第九条第二項の規定による届出をしようとするときは、様式第四による届出書に、変更事項に係る書類及び前条の認定証の写しを添えて、主務大臣に提出しなければならない。

(3) If a certified producer of anonymized medical data seeks to file a notification under Article 9, paragraph (2) of the Act, it must submit a written notification based on Form No. 4 to the competent ministers, along with documents relating to the particular that will change and a copy of the certificate referred to in the preceding Article.

（承継の認可の申請等）

(Application for Approval for Succession)

第九条　法第十条第三項の規定による届出をしようとする者は、様式第五による届出書に、次に掲げる書類及び被承継者に係る第七条の認定証を添えて、主務大臣に提出しなければならない。

Article 9 (1) A person seeking to file a notification under Article 10, paragraph (3) of the Act must submit a written notification based on Form No. 5 to the competent ministers, along with the following documents and the certificate referred to in Article 7 for the transferor:

一　法第十条第一項の規定により認定事業の全部を譲り受けて認定匿名加工医療情報作成事業者の地位を承継した法人にあっては、様式第六による事業譲渡証明書及び認定事業の全部の譲渡が行われたことを証する書面並びに承継者に係る第七条の認定証の写し

(i) if it is a corporation that has succeeded to the status of a certified producer of anonymized medical data as a result of taking over all of another person's certified business pursuant to the provisions of Article 10, paragraph (1) of the Act, a business transfer certificate based on Form No. 6 and documents evidencing that all of the certified business was transferred, and a copy of the certificate referred to in Article 7 for the successor;

二　法第十条第二項の規定による合併後存続する法人であって、認定匿名加工医療情報作成事業者の地位を承継した法人にあっては、その法人の登記事項証明書及び第七条の認定証の写し

(ii) if it is a corporation surviving a merger under Article 10, paragraph (2) that has succeeded to the status of a certified producer of anonymized medical data, its certificate of registered information and a copy of the certificate referred to in Article 7 for that corporation; or

三　法第十条第二項の規定による合併により設立された法人であって、認定匿名加工医療情報作成事業者の地位を承継した法人にあっては、その法人の登記事項証明書

(iii) if it is a corporation incorporated in a merger as under Article 10, paragraph (2) of the Act that has succeeded to the status of a certified producer of anonymized medical data, its certificate of registered information.

２　法第十条第四項の認可を受けようとする者は、様式第七による申請書に、次に掲げる書類及び譲渡人に係る第七条の認定証を添えて、主務大臣に提出しなければならない。

(2) A person seeking the approval referred to in Article 10, paragraph (4) of the Act must submit a written application based on Form No. 7 to the competent ministers, along with the following documents and the certificate referred to in Article 7 for the transferor:

一　様式第八による事業譲渡証明書及び認定事業の全部の譲渡が行われることを証する書面

(i) a business transfer certificate based on Form No. 8 and documents evidencing that all of the certified business will be transferred;

二　譲受人が法第八条第三項各号に掲げる認定の基準に適合していることを証する書類

(ii) documents proving that the transferee meets the certification standards set forth in the items of Article 8, paragraph (3) of the Act; and

三　譲受人に係る第三条第二項各号に掲げる書類

(iii) documents set forth in the items of Article 3, paragraph (2) for the transferee.

３　法第十条第五項の認可を受けようとする者は、様式第九による申請書に、次に掲げる書類及び被承継者に係る第七条の認定証を添えて、主務大臣に提出しなければならない。

(3) A person seeking the approval referred to in Article 10, paragraph (5) of the Act must submit a written application based on Form No. 9 to the competent ministers, along with the following documents and the certificate referred to in Article 7 for the transferor:

一　合併が行われることを証する書面

(i) documents evidencing that a merger will be carried out;

二　合併後存続する法人又は合併により設立される法人が法第八条第三項各号に掲げる認定の基準に適合していることを証する書類

(ii) documents evidencing that the corporation that will survive the merger or that will be incorporated in the merger will meet the certification standards set forth in the items of Article 8, paragraph (3) of the Act; and

三　合併後存続する法人又は合併により設立される法人に係る第三条第二項各号に掲げる書類

(iii) the documents set forth in the items of Article 3, paragraph (2) for the corporation that will survive the merger or that will be incorporated in the merger.

４　法第十条第六項の認可を受けようとする者は、様式第十による申請書に、次に掲げる書類及び被承継者に係る第七条の認定証を添えて、主務大臣に提出しなければならない。

(4) A person seeking the approval referred to in Article 10, paragraph (6) of the Act must submit a written application based on Form No. 10 to the competent ministers, along with the following documents and the certificate referred to in Article 7 for the transferor:

一　様式第十一による事業承継証明書及び分割により認定事業の全部の承継が行われることを証する書面

(i) a business transfer certificate based on Form No. 11 and documents evidencing that all of the certified business will be succeeded to in a company split;

二　分割により認定事業の全部を承継する法人が法第八条第三項各号に掲げる認定の基準に適合していることを証する書類

(ii) documents evidencing that the corporation that will succeed to all of the certified business in the company split meets the certification standards set forth in the items of Article 8, paragraph (3) of the Act; and

三　分割により認定事業の全部を承継する法人に係る第三条第二項各号に掲げる書類

(iii) the documents set forth in the items of Article 3, paragraph (2) for the corporation that will succeed to all of the certified business in the company split.

５　法第十条第八項の規定による届出をしようとする者は、様式第十二による届出書に、被承継者に係る第七条の認定証を添えて、主務大臣に提出しなければならない。

(5) A person seeking to file a notification under Article 10, paragraph (8) of the Act must submit a written notification based on Form No. 12 to the competent ministries, along with the certificate referred to in Article 7 for the transferor.

（廃止の届出）

(Notification of Discontinuation)

第十条　認定匿名加工医療情報作成事業者は、法第十一条第一項の規定による届出をしようとするときは、様式第十三による届出書に第七条の認定証を添えて主務大臣に提出しなければならない。

Article 10 If a certified producer of anonymized medical data seeks to file a notification under Article 11, paragraph (1) of the Act, it must submit a written notification based on Form No. 13 to the competent ministers, along with the certificate referred to in Article 7.

（解散の届出）

(Notification of Dissolution)

第十一条　清算人若しくは破産管財人又は外国の法令上これらに相当する者は、法第十二条第一項の規定による届出をするときは、様式第十四による届出書に第七条の認定証を添えて主務大臣に提出しなければならない。

Article 11 If a liquidator or bankruptcy trustee or a person equivalent thereto under the laws and regulations of a foreign state files a notification under Article 12, paragraph (1) of the Act, that person must submit a written notification based on Form No. 14 to the competent ministers, along with the certificate referred to in Article 7.

（帳簿の記載事項等）

(Particulars Required to Be Entered in Books)

第十二条　法第十三条の主務省令で定める事項は、次に掲げるものとする。

Article 12 (1) The particulars specified by Order of the competent ministries that are referred to in Article 13 of the Act are the following:

一　認定匿名加工医療情報作成事業者が匿名加工医療情報取扱事業者に対する匿名加工医療情報の提供を行った場合における次に掲げる事項

(i) the following particulars, when a certified producer of anonymized medical data has provided an enterprise handling anonymized medical data with anonymized medical data:

イ　当該匿名加工医療情報取扱事業者の名称及び住所その他の当該匿名加工医療情報取扱事業者を特定するに足りる事項

(a) particulars sufficient to identify the enterprise handling anonymized medical data, including the name and address thereof;

ロ　当該匿名加工医療情報の提供を行った年月日

(b) the date on which it provided the anonymized medical data; and

ハ　当該匿名加工医療情報の項目

(c) the items of the anonymized medical data;

二　匿名加工医療情報取扱事業者が他の匿名加工医療情報取扱事業者に対する匿名加工医療情報の提供を行った場合における次に掲げる事項

(ii) the following particulars, when an enterprise handling anonymized medical data has provided another enterprise handling anonymized medical data with anonymized medical data:

イ　提供元の匿名加工医療情報取扱事業者の名称及び住所その他の当該匿名加工医療情報取扱事業者を特定するに足りる事項

(a) particulars sufficient to identify the enterprise handling anonymized medical data that is the providing source, including the name and address thereof;

ロ　提供先の匿名加工医療情報取扱事業者の名称及び住所その他の当該匿名加工医療情報取扱事業者を特定するに足りる事項

(b) particulars sufficient to identify the enterprise handling anonymized medical data that is the recipient, including the name and address thereof;

ハ　当該匿名加工医療情報の提供を行った年月日

(c) the date on which the anonymized medical data was provided; and

ニ　当該匿名加工医療情報の項目

(d) the items of the anonymized medical data;

三　法第十九条の規定により匿名加工医療情報の消去を行った場合における次に掲げる事項

(iii) the following particulars, when the relevant person has deleted anonymized medical data pursuant to the provisions of Article 19 of the Act:

イ　当該匿名加工医療情報の消去を行った年月日

(a) the date on which it deleted the anonymized medical data; and

ロ　当該匿名加工医療情報の項目

(b) the items of the anonymized medical data;

四　法第二十五条の規定により他の認定匿名加工医療情報作成事業者に対して医療情報の提供を行った場合における次に掲げる事項

(iv) the following particulars, if the relevant person has provided medical information to another certified producer of anonymized medical data pursuant to the provisions of Article 25 of the Act:

イ　当該他の認定匿名加工医療情報作成事業者の名称及び住所その他の当該他の認定匿名加工医療情報作成事業者を特定するに足りる事項

(a) particulars sufficient to identify the other certified producer of anonymized medical data, including the name and address thereof;

ロ　当該医療情報の提供を行った年月日

(b) the date on which it provided the medical information; and

ハ　当該医療情報の項目

(c) the items of the medical information;

五　法第二十五条の規定により他の認定匿名加工医療情報作成事業者から医療情報の提供を受けた場合における次に掲げる事項

(v) the following particulars, if the relevant person has received medical information from another certified producer of anonymized medical data pursuant to the provisions of Article 25 of the Act:

イ　当該他の認定匿名加工医療情報作成事業者の名称及び住所その他の当該他の認定匿名加工医療情報作成事業者を特定するに足りる事項

(a) particulars sufficient to identify the other certified producer of anonymized medical data, including the name and address thereof;

ロ　当該医療情報の提供を受けた年月日

(b) the date on which it received the medical information; and

ハ　当該医療情報の項目

(c) the items of the medical information;

２　法第十三条の帳簿は、文書、電磁的記録又はマイクロフィルムを用いて作成しなければならない。

(2) The books referred to in Article 13 of the Act must be prepared using written documents, electronic or magnetic records, or microfilm.

３　認定匿名加工医療情報作成事業者は、第一項各号に規定する場合には、その都度、遅滞なく、同項各号に掲げる事項を帳簿に記載し、その記載の日から三年間保存しなければならない。

(3) In a case as prescribed in the items of paragraph (1), a certified producer of anonymized medical data must enter the particulars set forth in the relevant item of that paragraph in its books without delay, and preserve them for a period of three years from the date of entry.

（事業計画書等）

(Business Plans)

第十三条　認定匿名加工医療情報作成事業者は、毎事業年度開始前に、認定事業に関し事業計画書及び収支予算書を作成し、主務大臣に提出するとともに、公表しなければならない。これを変更しようとするときも、同様とする。

Article 13 (1) Prior to the commencement of each business year, a certified producer of anonymized medical data must prepare and submit to the competent ministers a business plan and an income and expenditure budget for its certified business, and issue a public announcement of the same. The same applies if it seeks to change these.

２　認定匿名加工医療情報作成事業者は、毎事業年度終了後三月以内に、認定事業に関し事業報告書及び収支決算書を作成し、主務大臣に提出するとともに、公表しなければならない。

(2) Within three months from the end of each business year, a certified producer of anonymized medical data must prepare and submit to the competent ministries a business report and a statement of income and expenditure for the certified business, and issue a public announcement of the same.

（認定の取消しを行う場合の手続）

(Procedure for Rescission of Certification)

第十四条　主務大臣は、法第十五条第一項又は第十六条第一項の規定に基づき、法第八条第一項の認定を受けた者の認定を取り消したときは、その旨を書面により当該認定を受けていた者に通知するものとする。

Article 14 Having rescinded the certification of a person that has been certified as referred to in Article 8 paragraph (1) of the Act based on Article 15, paragraph (1) or Article 16, paragraph (1) of the Act, the competent ministers are to notify the person that had obtained that certification in writing thereof.

（旅費の額）

(Amount of Travel Expenses)

第十五条　令第五条の旅費の額に相当する額（次条及び第十七条において「旅費相当額」という。）は、国家公務員等の旅費に関する法律（昭和二十五年法律第百十四号。次条及び第十七条において「旅費法」という。）の規定により支給すべきこととなる旅費の額とする。この場合において、当該検査のためその地に出張する職員は、一般職の職員の給与に関する法律（昭和二十五年法律第九十五号）第六条第一項第一号イに規定する行政職俸給表（一）による職務の級が四級である者であるものとしてその旅費の額を計算するものとする。

Article 15 The amount constituting the amount of travel expenses that are referred to in Article 5 of the Order (referred to as the "amount constituting travel expenses" in the following Article and Article 17) is the amount of travel expenses that are to be paid out pursuant to the provisions of the Act on Travel Expenses of National Public Officers, etc. (Act No. 114 of 1950; referred to as the "Travel Expenses Act" in the following Article and Article 17). In such a case, the amount of travel expenses for any official making a business trip to the place of inspection for the purpose of the relevant inspection is to be calculated on the assumption that the official is at the fourth grade of service on the Administrative Service (I) Salary Schedule prescribed in Article 6, paragraph (1), item (i), (a) of the Act on Remuneration of Officials in Regular Service (Act No. 95 of 1950).

（在勤官署の所在地）

(Location of Office Where Official Works)

第十六条　旅費相当額を計算する場合において、当該検査のため、その地に出張する職員の旅費法第二条第一項第六号の在勤官署の所在地は、次の表に掲げるところによる。

Article 16 When the amount constituting travel expenses is calculated, the location of the office where the official works referred to in Article 2, paragraph (1), item (vi) of the Travel Expenses Act for each official making a business trip to the place of inspection for the purpose of the relevant inspection is set forth in the following table.

|  |  |
| --- | --- |
| 主務大臣の区分 Classification of competent ministers | 在勤官署の所在地 Location of office where official works |
| 内閣総理大臣 Prime Minister | 東京都千代田区永田町一丁目十一番三十九号 1-11-39 Nagata-cho, Chiyoda-ku, Tokyo, Japan |
| 文部科学大臣 Minister of Education, Culture, Sports, Science and Technology | 東京都千代田区霞が関三丁目二番二号 3-2-2 Kasumigaseki, Chiyoda-ku, Tokyo, Japan |
| 厚生労働大臣 Minister of Health, Labour and Welfare | 東京都千代田区霞が関一丁目二番二号 1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo, Japan |
| 経済産業大臣 Minister of Economy, Trade and Industry | 東京都千代田区霞が関一丁目三番一号 1-3-1 Kasumigaseki, Chiyoda-ku, Tokyo, Japan |

（旅費の額の計算に係る細目）

(Details Related to Calculation of Amount of Travel Expenses)

第十七条　旅費法第六条第一項の支度料は、旅費相当額に算入しない。

Article 17 (1) The preparation fee referred to in Article 6, paragraph (1) of the Travel Expenses Act is not included in the amount constituting travel expenses.

２　検査を実施する日数は、当該検査に係る事務所その他の事業所ごとに三日として旅費相当額を計算する。

(2) The number of days during which an inspection is conducted is deemed to be three days per office or place of business subject to the inspection when the amount equivalent to travel expenses is calculated.

３　旅費法第六条第一項の旅行雑費は、一万円として旅費相当額を計算する。

(3) The miscellaneous travel expenses referred to in Article 6, paragraph (1) of the Travel Expenses Act are deemed to be 10,000 yen when the amount constituting travel expenses is calculated.

４　主務大臣が、旅費法第四十六条第一項の規定により、実費を超えることとなる部分又は必要としない部分の旅費を支給しないときは、当該部分に相当する額は、旅費相当額に算入しない。

(4) If, pursuant to the provisions of Article 46, paragraph (1) of the Travel Expenses Act, the competent ministers do not pay out any part of travel expenses that exceed actual costs or that are unnecessary, the amount equivalent to that part is not included in the calculation of the amount constituting travel expenses.

（匿名加工医療情報の作成の方法に関する基準）

(Standards for Producing Anonymized Medical Data)

第十八条　法第十八条第一項の主務省令で定める基準は、次のとおりとする。

Article 18 The standards specified by Order of the competent ministers that are referred to in Article 18, paragraph (1) of the Act are as follows:

一　医療情報に含まれる特定の個人を識別することができる記述等の全部又は一部を削除すること（当該全部又は一部の記述等を復元することのできる規則性を有しない方法により他の記述等に置き換えることを含む。）。

(i) deleting all or part of any description or account contained in the medical information that can be used to identify a specific individual (this includes replacing all or part of it with another description or account, using an approach that does not have the regularity to enable someone to restore the full or partial description or account);

二　医療情報に含まれる個人識別符号の全部を削除すること（当該個人識別符号を復元することのできる規則性を有しない方法により他の記述等に置き換えることを含む。）。

(ii) deleting all individual identification codes contained in the medical information (this includes replacing them with other descriptions or accounts, using an approach that does not have the regularity to enable someone to restore the individual identification codes);

三　医療情報と当該医療情報に措置を講じて得られる情報とを連結する符号（現に認定匿名加工医療情報作成事業者において取り扱う情報を相互に連結する符号に限る。）を削除すること（当該符号を復元することのできる規則性を有しない方法により当該医療情報と当該医療情報に措置を講じて得られる情報を連結することができない符号に置き換えることを含む。）。

(iii) deleting codes that link medical information to the information derived from measures taken involving that medical information (limited to codes cross-linking information that is being handled by a certified producer of anonymized medical data at the time in question) (this includes replacing such codes with other codes that cannot be used to link the medical information and information derived from measures taken involving that medical information, using an approach that does not have the regularity to enable someone to restore the codes);

四　特異な記述等を削除すること（当該特異な記述等を復元することのできる規則性を有しない方法により他の記述等に置き換えることを含む。）。

(iv) deleting idiosyncratic descriptions and accounts (including replacing the idiosyncratic descriptions and accounts with other descriptions and accounts by a method that does not have the regularity to enable someone to restore the idiosyncratic descriptions and accounts); and

五　前各号に掲げる措置のほか、医療情報に含まれる記述等と当該医療情報を含む医療情報データベース等を構成する他の医療情報に含まれる記述等との差異その他の当該医療情報データベース等の性質を勘案し、その結果を踏まえて適切な措置を講ずること。

(v) beyond the measures set forth in the preceding items, taking appropriate measures based on the results of a consideration of the attributes of a database or similar collection of medical information, including the differences between descriptions and accounts contained in medical information that is included in the database or similar collection of medical information and those contained in other medical information that makes up the same database or similar collection of medical information.

（医療情報等の消去の記録）

(Record of Deleting Medical and Related Information)

第十九条　認定匿名加工医療情報作成事業者は、法第十九条の規定による医療情報等の消去を行ったときは、次に掲げる事項の記録を作成し、その作成の日から三年間保存しなければならない。

Article 19 (1) Having deleted medical and related information under Article 19 of the Act, a certified producer of anonymized medical data must create a record of the following particulars and preserve the record for a period of three years from the date of creation:

一　当該医療情報等の消去を行った年月日

(i) the date on which it deleted the medical and related information; and

二　当該医療情報等の項目

(ii) the items of the medical and related information

２　前項の記録を作成する方法は、文書、電磁的記録又はマイクロフィルムを用いて作成する方法とする。

(2) The means of creating a record as referred to in the preceding paragraph is a means that involves creating that record using a written document, electronic or magnetic record, or microfilm.

（従業者の監督）

(Supervision of Workers)

第二十条　法第二十一条の規定により認定匿名加工医療情報作成事業者が行わなければならない従業者に対する監督は、第六条で定める安全管理措置に従って業務を行っていることの確認その他の措置を講ずることにより行うものとする。

Article 20 A certified producer of anonymized medical data is to exercise the supervision that it is required to exercise over its workers pursuant to the provisions of Article 21 of the Act by confirming that business is being carried out in accordance with the security control measures specified in Article 6 and by taking other measures.

（委託契約の締結）

(Conclusion of Entrustment Contracts)

第二十一条　認定匿名加工医療情報作成事業者は、法第二十三条第一項の規定による委託を行う場合には、次に掲げる事項を記載した文書により当該委託を受けた認定医療情報等取扱受託事業者との契約を締結しなければならない。

Article 21 (1) If entrusting a person with business as under Article 23, paragraph (1) of the Act, a certified producer of anonymized medical data must enter into a contract with the enterprise certified for entrustment with handling medical and related information and anonymized medical data that is entrusted with that business, through a document stating the following particulars:

一　当該委託に係る業務の範囲

(i) the scope of operations relating to the entrustment;

二　当該委託に係る業務の手順に関する事項

(ii) the particulars of procedures for operations subject to entrustment;

三　前号の手順に基づき当該委託に係る業務が適正かつ円滑に行われているかどうかを当該認定匿名加工医療情報作成事業者が確認することができる旨

(iii) that the certified producer of anonymized medical data can check on whether or not operations subject to entrustment are being performed properly and smoothly in accordance with the procedures referred to in the preceding item;

四　当該認定医療情報等取扱受託事業者に対する指示に関する事項

(iv) the particulars of giving instructions to the enterprise certified for entrustment with handling medical and related information and anonymized medical data;

五　前号の指示を行った場合において当該指示に基づく措置が講じられたかどうかを当該認定匿名加工医療情報作成事業者が確認することができる旨

(v) that having given instructions as referred to in the preceding item, the certified producer of anonymized medical data can check on whether or not measures have been taken based on those instructions;

六　当該認定医療情報等取扱受託事業者が当該認定匿名加工医療情報作成事業者に対して行う報告に関する事項

(vi) the particulars of reports that the enterprise certified for entrustment with handling medical and related information and anonymized medical data makes to the certified producer of anonymized medical data; and

七　その他当該委託に係る業務について必要な事項

(vii) other particulars necessary for operations subject to entrustment.

２　前項の規定は、法第二十三条第二項の規定による再委託について準用する。この場合において、「認定匿名加工医療情報作成事業者」とあるのは、「法第二十三条第一項の規定により医療情報等又は匿名加工医療情報の取扱いの全部又は一部の委託を受けた認定医療情報等取扱受託事業者」と読み替えるものとする。

(2) The provisions of the preceding paragraph apply mutatis mutandis to re-entrustment under Article 23, paragraph (2) of the Act. In such a case, the term "certified producer of anonymized medical data" is deemed to be replaced with "enterprise certified for entrustment with handling medical and related information and anonymized medical data that is entrusted with all or part of the handling of medical and related information or anonymized medical data pursuant to the provisions of Article 23, paragraph (1) of the Act".

３　第一項の規定は、法第二十三条第三項の規定により適用される同条第二項の規定による再委託について準用する。この場合において、「認定匿名加工医療情報作成事業者」とあるのは、「法第二十三条第二項の規定により医療情報等又は匿名加工医療情報の取扱いの全部又は一部の再委託を受けた認定医療情報等取扱受託事業者」と読み替えるものとする。

(3) The provisions of paragraph (1) apply mutatis mutandis to re-entrustment under Article 23, paragraph (2) of the Act which is applied pursuant to the provisions of paragraph (3) of that Article. In such a case, the term "certified producer of anonymized medical data" is to be deemed to be replaced with "an enterprise certified for entrustment with handling medical and related information and anonymized medical data who is further entrusted with all or part of the handling of medical and related information or anonymized medical data pursuant to the provisions of Article 23, paragraph (2) of the Act."

（委託先の監督）

(Supervision of Entrusted Persons)

第二十二条　法第二十四条の規定により認定匿名加工医療情報作成事業者が行わなければならない委託を受けた者に対する監督は、医療情報等又は匿名加工医療情報の安全管理が適正に図られるよう、安全管理の業務に関する監査その他必要な措置を講ずることにより行うものとする。

Article 22 A certified producer of anonymized medical data is to exercise the supervision over an entrusted person that it is required to exercise pursuant to the provisions of Article 24 of the Act by carrying out audits of security control operations and taking other measures to achieve the proper security controls for medical and related information and anonymized medical data.

（他の認定匿名加工医療情報作成事業者に対する医療情報の提供）

(Provision of Medical Information to Other Certified Producers of Anonymized Medical Data)

第二十三条　認定匿名加工医療情報作成事業者は、法第二十五条第一項の規定による医療情報の授受においては、次に掲げる事項を記載した文書により授受に係る他の認定匿名加工医療情報作成事業者との契約を締結し、その契約書を保存しなければならない。

Article 23 In giving and receiving medical information under Article 25, paragraph (1) of the Act, a certified producer of anonymized medical data must enter into a contract with another certified producer of anonymized medical data relating to the giving and receiving of that information through a document stating the following particulars, and must preserve the written contract:

一　法第二十五条第一項の規定により医療情報の提供を行う認定匿名加工医療情報作成事業者の名称、住所及び代表者の氏名

(i) the name and address of the certified producer of anonymized medical data providing the medical information pursuant to the provisions of Article 25, paragraph (1) of the Act, and the name of its representative;

二　前号の提供を受ける認定匿名加工医療情報作成事業者の名称、住所及び代表者の氏名

(ii) the name and address of the certified producer of anonymized medical data receiving what is provided as referred to in the preceding paragraph, and the name of its representative;

三　第一号の医療情報の項目

(iii) the items of the medical information referred to in item (i); and

四　第一号の医療情報の提供の方法

(iv) the means of providing the medical information referred to in item (i).

（苦情の処理）

(Complaint Processing)

第二十四条　認定匿名加工医療情報作成事業者は、認定事業に関し管理する医療情報等又は匿名加工医療情報の取扱いに関する苦情については、次の各号に定めるところにより、これを処理しなければならない。

Article 24 A certified producer of anonymized medical data must process complaints about the handling of medical and related information or anonymized medical data that it manages in connection with its certified business pursuant to the provisions of the following items:

一　苦情を受け付けたときは、遅滞なく、当該苦情に係る事項の原因を究明すること。

(i) when receiving a complaint, investigating the cause of the matter to which the complaint pertains without delay;

二　前号の規定による原因究明の結果に基づき、認定事業に関し管理する医療情報等又は匿名加工医療情報の取扱いに関し改善が必要な場合には、所要の措置を講ずること。

(ii) taking the required measures if, based on the results of an investigation into the cause of a matter as referred to in the preceding item, it is necessary to improve the handling of medical and related information or anonymized medical data that it manages in connection with its certified business; and

三　苦情の内容、原因究明の結果及び改善措置を記載した苦情処理記録を作成し、その作成の日から三年間保存すること。

(iii) producing a record of its complaint processing that states the details of the complaint, the results of its investigation into the cause, and improvement measures, and preserving the record for a period of three years from the date of its creation.

第二十五条　認定匿名加工医療情報作成事業者は、苦情を受け付けるための窓口の設置、苦情の対応の手順の策定その他の措置を講ずることにより、法第二十七条第一項の目的を達成するために必要な体制を整備しなければならない。

Article 25 A certified producer of anonymized medical data must set in place the necessary framework to achieve the purpose referred to in Article 27, paragraph (1) of the Act by taking measures such as establishing a point of contact for receiving complaints and formulating procedures for dealing with them.

（準用）

(Mutatis Mutandis Application of Provisions)

第二十六条　第三条、第四条、第六条（第五号ハ及びニを除く。）、第七条の規定は法第二十八条の認定について、第八条から第十一条まで、第十二条第一項第三号、第二項及び第三項、第十三条、第十八条、第十九条、第二十条、第二十二条、第二十四条並びに第二十五条の規定は認定医療情報等取扱受託事業者について、第十四条の規定は認定医療情報等取扱受託事業者に係る認定の取消しについて、それぞれ準用する。この場合において、次の表の上欄に掲げる規定中同表の中欄に掲げる字句は、それぞれ同表の下欄に掲げる字句に読み替えるものとする。

Article 26 The provisions of Article 3, Article 4, Article 6 (excluding item (v), (c) and (d)), and Article 7 apply mutatis mutandis to the certification referred to in Article 28 of the Act; the provisions of Articles 8 through 11, Article 12, paragraph (1), item (iii), paragraphs (2) and (3), Article 13, Article 18, Article 19, Article 20, Article 22, Article 24, and Article 25 apply mutatis mutandis to an enterprise certified for entrustment with handling medical and related information and anonymized medical data; and the provisions of Article 14 apply mutatis mutandis to the rescission of the certification of an enterprise certified for entrustment with handling medical and related information and anonymized medical data. In such a case, the terms and phrases set forth in the middle column of the table below that appear in the provisions set forth in the left-hand column of that table are deemed to be replaced with the corresponding terms and phrases set forth in the right-hand column of that table.

|  |  |  |
| --- | --- | --- |
| 第三条第一項 Article 3, paragraph (1) | 第八条第一項 Article 8, paragraph (1) | 第二十八条 Article 28 |
| 様式第一 Form No. 1 | 様式第十五 Form No. 15 |
| 第四条 Article 4 | 匿名加工医療情報作成事業 the business of producing anonymized medical data | 法第二十八条に規定する事業 the business prescribed in Article 28 of the Act |
| 第七条 Article 7 | 第八条第一項 Article 8, paragraph (1) | 第二十八条 Article 28 |
| 様式第二 Form No. 2 | 様式第十六 Form No. 16 |
| 第八条第一項柱書 the main sentence of Article 8, paragraph (1) | 第八条第二項第二号から第五号まで Article 8, paragraph (2), items (ii) through (v) | 第八条第二項第四号又は第五号 Article 8, paragraph (2), item (iv) or (v) |
| 様式第三 Form No. 3 | 様式第十七 Form No. 17 |
| 第八条第一項第一号 Article 8, paragraph (1), item (i) | 第八条第三項各号 the items of Article 8, paragraph (3) | 第八条第三項第一号、第三号及び第四号 Article 8, paragraph (3), items (i), (iii), and (iv) |
| 第八条第二項第一号 Article 8, paragraph (2), item (i) | 匿名加工医療情報作成事業 the business of producing anonymized medical data | 法第二十八条に規定する事業 the business prescribed in Article 28 of the Act |
| 第八条第二項第二号 Article 8, paragraph (2), item (ii) | 第八条第二項第二号から第五号まで Article 8, paragraph (2), items (ii) through (v) | 第八条第二項第四号又は第五号 Article 8, paragraph (2), item (iv) or (v) |
| 第八条第三項 Article 8, paragraph (3) | 様式第四 Form No. 4 | 様式第十八 Form No. 18 |
| 第九条第一項柱書 the main sentence of Article 9, paragraph (1) | 様式第五 Form No. 5 | 様式第十九 Form No. 19 |
| 第九条第一項第一号 Article 9, paragraph (1), item (i) | 様式第六 Form No. 6 | 様式第二十 Form No. 20 |
| 第九条第二項柱書 the main sentence of Article 9, paragraph (2) | 様式第七 Form No. 7 | 様式第二十一 Form No. 21 |
| 第九条第二項第一号 Article 9, paragraph (2), item (i) | 様式第八 Form No. 8 | 様式第二十二 Form No. 22 |
| 第九条第二項第二号 Article 9, paragraph (2), item (ii) | 第八条第三項各号 the items of Article 8, paragraph (3) | 第八条第三項第一号、第三号及び第四号 Article 8, paragraph (3), items (i), (iii), and (iv) |
| 第九条第三項柱書 the main sentence of Article 9, paragraph (3) | 様式第九 Form No. 9 | 様式第二十三 Form No. 23 |
| 第九条第三項第二号 Article 9, paragraph (3), item (ii) | 第八条第三項各号 the items of Article 8, paragraph (3) | 第八条第三項第一号、第三号及び第四号 Article 8, paragraph (3), items (i), (iii), and (iv) |
| 第九条第四項柱書 the main sentence of Article 9, paragraph (4) | 様式第十 Form No. 10 | 様式第二十四 Form No. 24 |
| 第九条第四項第一号 Article 9, paragraph (4), item (i) | 様式第十一 Form No, 11 | 様式第二十五 Form No. 25 |
| 第九条第四項第二号 Article 9, paragraph (4), item (ii) | 第八条第三項各号 the items of Article 8, paragraph (3) | 第八条第三項第一号、第三号及び第四号 Article 8, paragraph (3), items (i), (iii), and (iv) |
| 第九条第五項 Article 9, paragraph (5) | 様式第十二 Form No. 12 | 様式第二十六 Form No. 26 |
| 第十条 Article 10 | 様式第十三 Form No. 13 | 様式第二十七 Form No. 27 |
| 第十一条 Article 11 | 様式第十四 Form No. 14 | 様式第二十八 Form No. 28 |
| 第十二条第三項 Article 12, paragraph (3) | 第一項各号 the items of paragraph (1) | 第一項第三号 paragraph (1), item (iii) |
| 同項各号 the relevant item of that paragraph | 同号 that item |
| 第十四条 Article 14 | 第八条第一項 Article 8, paragraph (1) | 第二十八条 Article 28 |

（医療情報の提供停止の求めの方法）

(Means of Requesting a Person to Stop Providing Medical Information)

第二十七条　法第三十条第一項の規定による提供の停止の求めは、医療情報取扱事業者に対し、書面又は口頭その他の方法で行うものとする。

Article 27 A person is to make a request to an enterprise handling medical information to stop providing information under Article 30, paragraph (1) of the Act in writing, orally, or by other means.

（医療情報の提供に係る事前の通知等）

(Prior Notice Concerning the Provision of Medical Information)

第二十八条　法第三十条第一項又は第二項の規定による通知は、次に掲げるところにより、行うものとする。

Article 28 (1) The relevant person is to notify the principal as under Article 30, paragraph (1) or (2) of the Act as follows:

一　認定匿名加工医療情報作成事業者に提供される医療情報によって識別される本人又はその遺族が当該提供の停止を求めるために必要な期間を定めて通知すること。

(i) notifying the principal after specifying the necessary period for the principal who is identified in medical information that is to be provided to a certified producer of anonymized medical data, or for a surviving family member of the principal, to request the it to stop providing that information; and

二　本人が法第三十条第一項各号に掲げる事項を認識することができる適切かつ合理的な方法によること。

(ii) using an appropriate and reasonable means that allows the principal to become cognizant of the particulars set forth in the items of Article 30, paragraph (1) of the Act.

２　医療情報取扱事業者が、法第三十条第一項又は第二項の規定による届出をするときは、次に掲げるいずれかの方法により行わなければならない。

(2) If an enterprise handling medical information files a notification under Article 30, paragraph (1) or (2) of the Act, it must do so in one of the following ways:

一　主務大臣が定めるところにより、電子情報処理組織（主務大臣の使用に係る電子計算機と届出を行う者の使用に係る電子計算機とを電気通信回線で接続した電子情報処理組織をいう。）を使用する方法

(i) a means that involves using an electronic data processing system (meaning an electronic data processing system that connects computers used by the competent ministers with a computer used by a person making a notification over telecommunications lines) as specified by the competent ministers; or

二　様式第二十九による届出書及び当該届出書に記載すべき事項を記録した光ディスク等を提出する方法

(ii) a means that involves the submission of a written notification based on Form No. 29 and something such as an optical disk onto which the particulars required to be stated in the written notification have been recorded.

３　医療情報取扱事業者が、代理人によって法第三十条第一項又は第二項の規定による届出をする場合には、様式第三十によるその権限を証する書面（電磁的記録を含む。以下同じ。）を主務大臣に提出しなければならない。

(3) If an enterprise handling medical information has an agent file a notification under Article 30, paragraph (1) or (2) of the Act, it must submit to the competent ministers a document (inclusive of an electronic or magnetic record; the same applies hereinafter) evidencing the authority of the agent based on Form No. 30.

（医療情報の提供に係る主務大臣による公表）

(Public Announcement by Competent Ministers Regarding Provision of Medical Information)

第二十九条　法第三十条第三項の規定による公表は、同条第一項又は第二項の規定による届出があった後、遅滞なく、インターネットの利用その他の適切な方法により行うものとする。

Article 29 The public announcement under Article 30, paragraph (3) of the Act is to be issued using the Internet or by other appropriate means without delay after a notification under paragraph (1) or (2) of that Article has been filed.

（医療情報の提供に係る医療情報取扱事業者による公表）

(Public Announcement by an Enterprise Handling Medical Information Regarding Provision of Medical Information)

第三十条　医療情報取扱事業者は、法第三十条第三項の規定による公表がされたときは、速やかに、インターネットの利用その他の適切な方法により、同条第一項に掲げる事項（同項第二号、第三号又は第五号に掲げる事項に変更があったときは、変更後の当該各号に掲げる事項）を公表するものとする。

Article 30 When a public announcement under Article 30, paragraph (3) of the Act has been issued, an enterprise handling medical information is to promptly issue a public announcement of the particulars set forth in paragraph (1) of that Article (or the particulars set forth in item (ii), (iii), or (v) of that paragraph after any change that has been made) using the Internet or by other appropriate means.

（書面の交付）

(Delivery of Documents)

第三十一条　法第三十一条第一項の主務省令で定める事項は、次に掲げる事項とする。

Article 31 The particulars specified by Order of the competent ministries referred to in Article 31, paragraph (1) of the Act are the following particulars:

一　法第三十条第一項に規定する求めがあった旨

(i) an indication that a request prescribed in Article 30, paragraph (1) of the Act has been made;

二　前号の求めを行った者の氏名及びその他の当該者を特定するに足りる事項

(ii) particulars sufficient to identify the person that has made the request referred to in the preceding item, including the name and address thereof;

三　第一号の求めを受けた年月日

(iii) the date on which it received the request referred to in item (i);

四　法第三十一条第一項に規定する主務省令で定める書面を交付する旨

(iv) an indication that the document specified by Order of the competent ministries prescribed in Article 31, paragraph (1) of the Act will be delivered;

五　医療情報の提供の停止の年月日

(v) the date on which it will stop providing the medical information; and

六　第一号の求めにより交付する書面の交付年月日

(vi) the date of delivery of the document to be delivered upon the request referred to in item (i).

（書面の写し等の保存義務）

(Obligation to Preserve a Copy of Documents)

第三十二条　法第三十一条第三項の規定による書面の写し又は電磁的記録の保存は、同条第一項の規定により書面を交付し、又は同条第二項の規定により電磁的記録を提供した日から三年間行わなければならない。

Article 32 The relevant person must preserve a copy of a document or an electronic or magnetic record as under Article 31, paragraph (3) of the Act for three years after the date when the document is delivered pursuant to the provisions of paragraph (1) of that Article or the electronic or magnetic record is provided pursuant to the provisions of paragraph (2) of that Article.

（医療情報の提供に係る記録の作成）

(Creating Records of the Provision of Medical Information)

第三十三条　法第三十二条第一項の規定による記録の作成は、次に掲げるところにより、行うものとする。

Article 33 The relevant person is to create a record under Article 32, paragraph (1) of the Act as follows:

一　文書、電磁的記録又はマイクロフィルムを用いて作成するものとする。

(i) it is to create the record using a written document, electronic or magnetic record, or microfilm; and

二　医療情報を認定匿名加工医療情報作成事業者に提供したときは、その都度、速やかに作成しなければならない。ただし、当該認定匿名加工医療情報作成事業者に対し医療情報を継続的に若しくは反復して提供したとき、又は当該認定匿名加工医療情報作成事業者に対し医療情報を継続的に若しくは反復して提供することが確実であると見込まれるときは、一括して作成することができる。

(ii) it must create a record promptly once it has provided medical information to a certified producer of anonymized medical data; provided, however, that if it has provided or expects to provide medical information to the certified producer of anonymized medical data continuously or repeatedly, it may create the record in an integrated manner.

（医療情報の提供に係る記録事項）

(Particulars to Be Recorded Regarding the Provision of Medical Information)

第三十四条　法第三十二条第一項の主務省令で定める事項は、次に掲げる事項とする。

Article 34 (1) The particulars specified by Order of the competent ministries that are referred to in Article 32, paragraph (1) of the Act are the following particulars:

一　法第三十条第一項の規定により医療情報を認定匿名加工医療情報作成事業者に提供した年月日

(i) the date on which the relevant person provided the medical information to the certified producer of anonymized medical data pursuant to the provisions of Article 30, paragraph (1) of the Act;

二　前号の認定匿名加工医療情報作成事業者の名称及び住所その他の当該認定匿名加工医療情報作成事業者を特定するに足りる事項

(ii) particulars sufficient to identify the certified producer of anonymized medical data referred to in the preceding item, including the name and address thereof;

三　第一号の医療情報によって識別される本人の氏名その他の当該本人を特定するに足りる事項

(iii) particulars sufficient to identify the principal who is identified by the medical information referred to in item (i), including the name and address thereof; and

四　当該医療情報の項目

(iv) the items of the medical information.

２　前項各号に掲げる事項のうち、既に前条に規定する方法により作成した法第三十二条第一項の記録（当該記録を保存している場合におけるものに限る。）に記録されている事項と内容が同一であるものについては、当該事項の記録の作成を省略することができる。

(2) It is permissible not to create a record of a particular set forth in any of the items of the preceding paragraph that is identical in substance to a particular contained in a record as referred to in Article 32, paragraph (1) of the Act that has already been produced by the means prescribed in the preceding Article (but only if that record has been preserved).

（医療情報の提供に係る記録の保存期間）

(Period for the Preservation of Records Regarding the Provision of Medical Information)

第三十五条　法第三十二条第二項の主務省令で定める期間は、次の各号に掲げる場合の区分に応じて、当該各号に定める期間とする。

Article 35 The period specified by Order of the competent ministries that is referred to in Article 32, paragraph (2) of the Act is the period specified in the relevant of the following items for the classification set forth in that item:

一　第三十三条第二号ただし書に規定する方法により記録を作成した場合　最後に当該記録に係る医療情報の提供を行った日から起算して三年を経過する日までの間

(i) if a record has been created by the means prescribed in the proviso of Article 33, item (ii): the period that runs until the last day in the three-year period calculated as beginning on the last day on which the relevant person provided the medical information to which the record pertains; or

二　前号以外の場合　三年間

(ii) cases other than the preceding item: for three years.

（医療情報の提供を受ける際の確認）

(Confirmation When Receiving Medical Information)

第三十六条　法第三十三条第一項の規定による確認は、次の各号に掲げる事項の区分に応じて、当該各号に定めるところによるものとする。

Article 36 (1) The relevant person is to make the confirmation under Article 33, paragraph (1) of the Act pursuant to the provisions of the relevant of the following items for the classification set forth in that item:

一　法第三十三条第一項第一号の事項　医療情報を提供する医療情報取扱事業者から申告を受ける方法その他の適切な方法

(i) the particulars referred to in Article 33, paragraph (1), item (i) of the Act: by a means that involves receiving a report from the enterprise handling medical information that is providing the medical information or any other such appropriate means; or

二　法第三十三条第一項第二号の事項　法第三十条第三項の規定により主務大臣の公表が行われた旨及び医療情報取扱事業者からの医療情報の取得の経緯を示す記録の提示を受ける方法その他の適切な方法

(ii) the particulars referred to in Article 33, paragraph (1), item (ii) of the Act: being presented with a record confirming that a public announcement has been issued by the competent ministers pursuant to the provisions of Article 30, paragraph (3) of the Act and being presented with a record indicating circumstances under which medical information was acquired from an enterprise handling medical information, or any other such appropriate means.

２　前項の規定にかかわらず、医療情報取扱事業者から他の医療情報の提供を受けるに際して既に前項に規定する方法による確認（当該確認について次条に規定する方法による記録の作成及び保存をしている場合におけるものに限る。）をした事項については、当該事項の内容と当該提供に係る法第三十三条第一項各号に掲げる事項の内容が同一であることの確認を行う方法とする。

(2) Notwithstanding the provisions of the preceding paragraph, the means of confirming particulars that the relevant person has already confirmed by a means prescribed in the preceding paragraph (but only if a record of the confirmation has been produced and preserved by the means prescribed in the following Article) when being provided with other medical information by an enterprise handling medical information, is to confirm that the substance of the particulars is identical to that of the particulars set forth in the items of Article 33, paragraph (1) concerning the other medical information with which it was provided.

（医療情報の提供を受ける際の記録事項）

(Particulars to Be Recorded When Medical Information Is Received)

第三十七条　法第三十三条第三項の主務省令で定める事項は、次に掲げる事項とする。

Article 37 (1) The particulars specified by Order of the competent ministries referred to in Article 33, paragraph (3) of the Act are the following particulars:

一　法第三十条第一項の規定により医療情報の提供を受けた年月日

(i) the date on which the relevant person receives the medical information pursuant to the provisions of Article 30, paragraph (1) of the Act;

二　法第三十三条第一項各号に掲げる事項

(ii) the particulars set forth in the items of Article 33, paragraph (1) of the Act;

三　第一号の医療情報によって識別される本人の氏名その他の当該本人を特定するに足りる事項

(iii) particulars sufficient to identify the principal who is identified by the medical information referred to in item (i), including the name and address thereof;

四　第一号の医療情報の項目

(iv) the items of medical information referred to in item (i); and

五　法第三十条第三項の規定により公表されている旨

(v) an indication that a public announcement has been issued pursuant to the provisions of Article 30, paragraph (3) of the Act.

２　前項に掲げる事項のうち、既に前条に規定する方法により作成した法第三十三条第三項の記録（当該記録を保存している場合におけるものに限る。）に記録されている事項と内容が同一であるものについては、当該事項の記録の作成を省略することができる。

(2) It is permissible not to create a record of a particular set forth in the preceding paragraph which is identical in substance to a particular contained in the record referred to in Article 33, paragraph (3) of the Act that has already been produced by the means prescribed in the preceding Article (but only if that record has been preserved).

（準用）

(Mutatis Mutandis Application of Provisions)

第三十八条　第三十三条及び第三十五条の規定は、認定匿名加工医療情報作成事業者について準用する。この場合において、次の表の上欄に掲げる規定中同表の中欄に掲げる字句は、それぞれ同表の下欄に掲げる字句に読み替えるものとする。

Article 38 The provisions of Article 33 and Article 35 apply mutatis mutandis to a certified producer of anonymized medical data. In such a case, the terms and phrases set forth in the middle column of the following table that appear in the provisions set forth in the left-hand column of that table are deemed to be replaced with the corresponding terms and phrases set forth in the right-hand column of that table.

|  |  |  |
| --- | --- | --- |
| 第三十三条 Article 33 | 第三十二条第一項 Article 32, paragraph (1) | 第三十三条第三項 Article 33, paragraph (3) |
| 医療情報を認定匿名加工医療情報作成事業者に提供した provided medical information to a certified producer of anonymized medical data | 医療情報取扱事業者から医療情報の提供を受けた been provided with medical information by an enterprise handling medical information |
| 認定匿名加工医療情報作成事業者に対し医療情報を medical information to the certified producer of anonymized medical data | 医療情報取扱事業者から by an enterprise handling medical information |
| 提供したとき、 has provided | 医療情報の提供を受けたとき、 has been provided with medical information |
| 提供する expects to provide | 医療情報の提供を受ける expects to be provided with medical information |
| 第三十五条 Article 35 | 第三十二条第二項 Article 32, paragraph (2) | 第三十三条第四項 Article 33, paragraph (4) |
| 行った provided | 受けた was provided with |

（立入検査をする者の身分証明書）

(Identification of Persons Carrying Out On-site Inspections)

第三十九条　法第三十五条第二項の職員の身分を示す証明書は、様式第三十一によるものとする。

Article 39 The identification of an official referred to in Article 35, paragraph (2) of the Act is to be based on Form No. 31.