

**Recent legislative efforts to balance
the use of large-scale personal
genomic data and the protection of
privacy in Japan**

Natsuko Yamamoto

*Department of Biomedical Ethics and
Public Policy, Graduate School of
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Overview

1. PPI Acts and other legislation in Japan

✂ PPI Act: Act on Protection of Personal Information

(個人情報保護法)

2. Contents of the amended of PPI Acts

3. Influence of amended PPI Acts on human genomics and medical research

Overview

1. PPI Acts and other legislations in Japan

✕ PPI Act: Act on Protection of Personal Information

(個人情報保護法)

2. Contents of amendments of PPI Acts

3. Influence of amended PPI Acts on human genomics and medical research

Legislative efforts after 2013

| | |
|------|--|
| 2013 | Japan Revitalization Strategy (日本再興戦略), Cabinet decision |
| 2013 | Act for the Promotion of Regenerative Medicine |
| 2013 | Act to Ensure Safety in Regeneration |
| 2013 | Revised Japanese Pharmaceutical |
| 2014 | Act on the Use of Numbers to Identify Individual in Administrative Procedure |
| 2014 | Act on Promotion of Healthcare Policy |
| 2014 | Act on the Independent Administrative Agency of Japan's Agency for Medical Research and Development (AMED) |

Development and improvement of Biobanks, Databases

Legislative efforts after 2013

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Development and
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Biobanks,
Databases

Legislative efforts after 2013

Promotion of the
utilization and
protection of various
kinds of personal
information

Japan Revitalization Strategy(日本再興戦略),

World's Most Advanced IT
国家創造宣言), Cabinet

investigative committee to
consider protection and utilization of personal data

2015 Dec **Amendment of PPI Act (個人情報保護法改正)**

2016 May **Amendment of PPI-HAO and PPI-HIAA Acts**

Promulgation of Cabinet Order and rules of the
2016 Oct Personal Information Protection Commission for
PPI Act

Legislative efforts after 2013

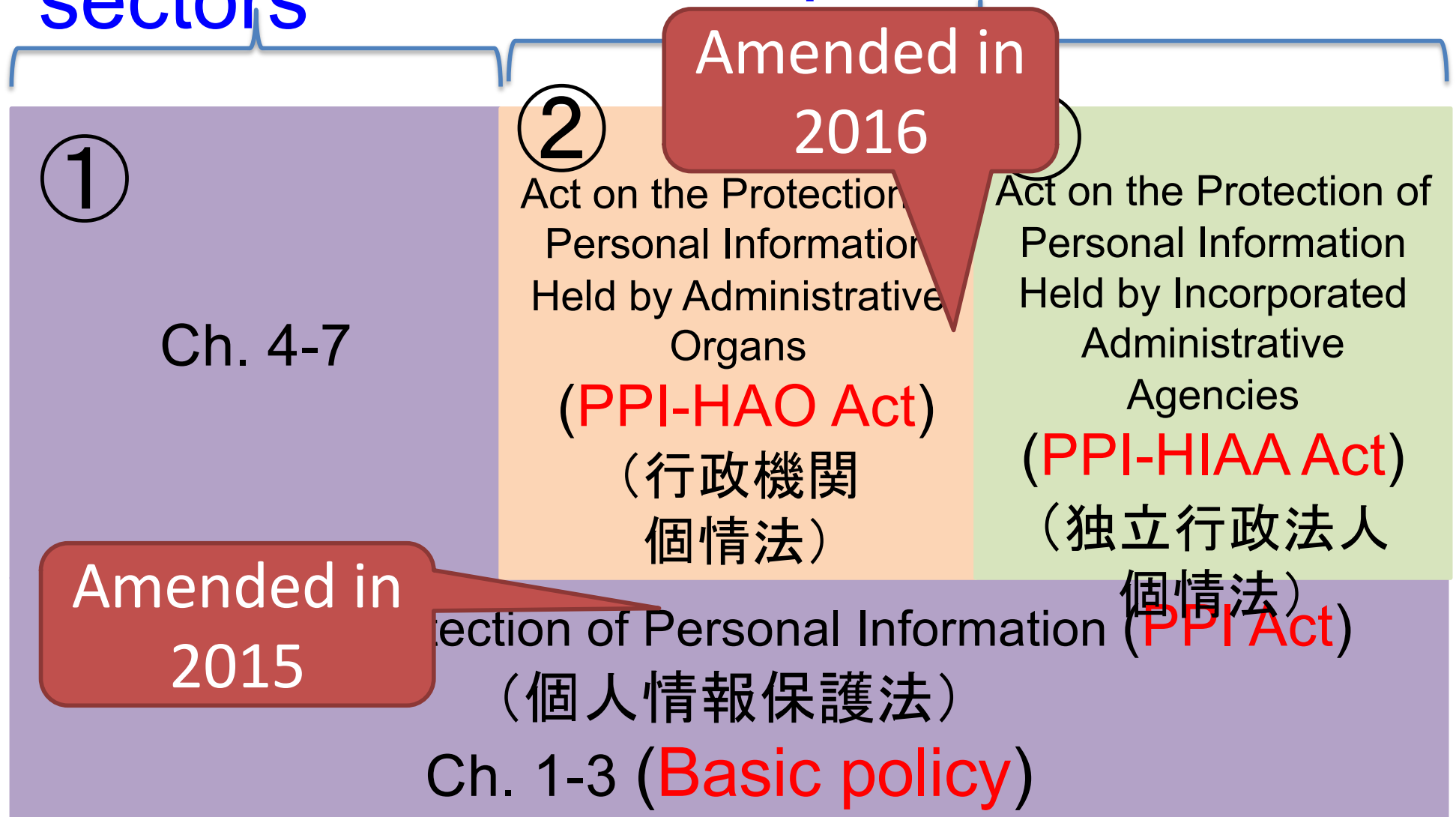
| | | |
|------|-----|---|
| 2013 | | Japan Revitalization Strategy(日本再興戰略), |
| 2013 | | World's Most Advanced IT (國家創造宣言), Cabinet |
| 2013 | | Advisory committee to consider protection and utilization of personal data |
| 2015 | Dec | Amendment of PPI Act (個人情報保護法改正) |
| 2016 | May | Amendment of PPI-HAO and PPI-HIAA Acts |
| 2016 | Oct | Promulgation of Cabinet Order and rules of the Personal Information Protection Commission for PPI Act |

Promotion of utilization and protection of various personal informations

Framework of PPI Acts

for private
sectors

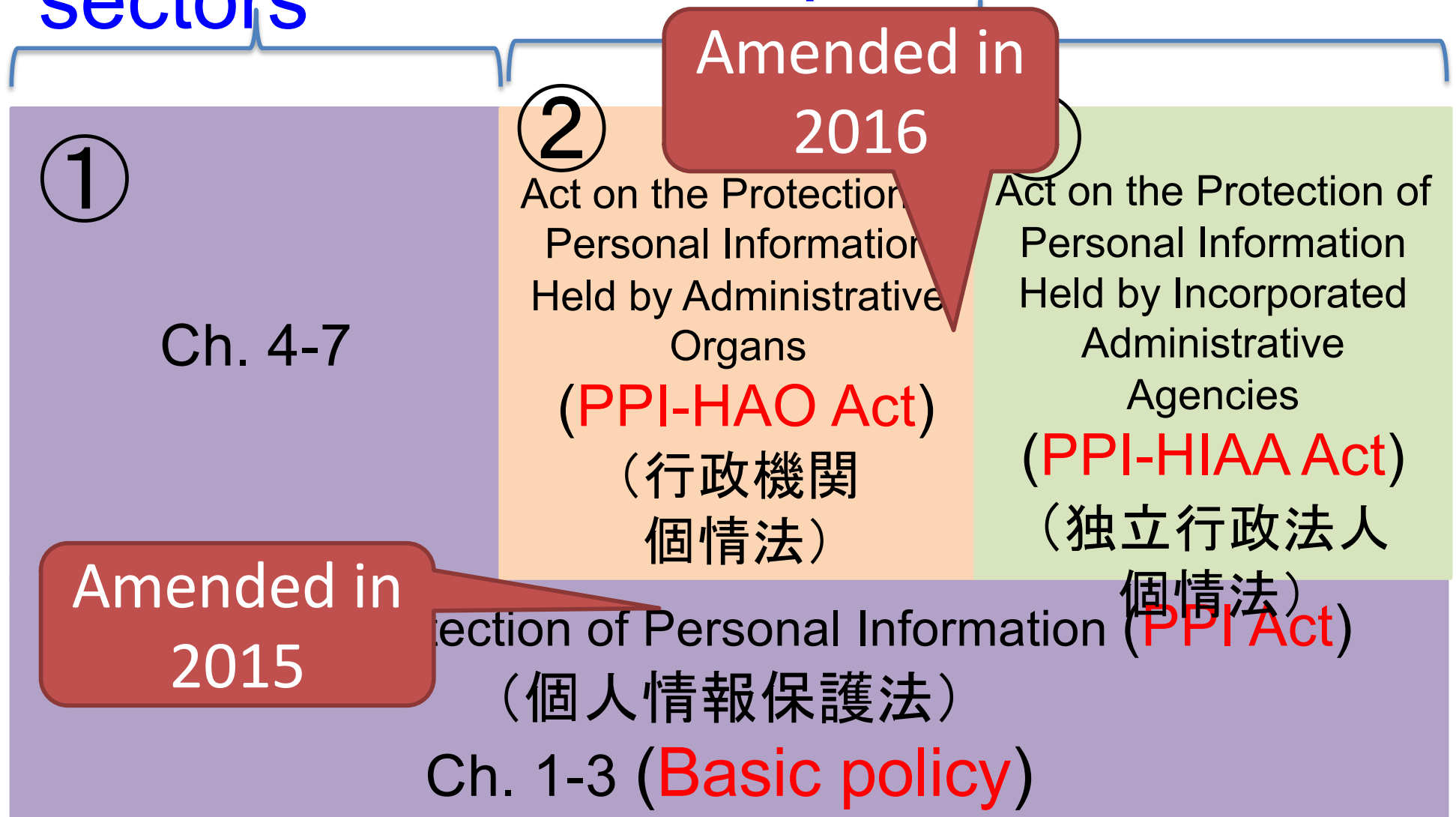
for public sectors



Framework of PPI Acts

for private
sectors

for public sectors



Backgrounds of the amendments

- ✓ Cabinet decisions in 2013

- ✓ Foreign pressure;

EU General data protection regulation
(**GDPR**) (※EU一般データ保護規則という法律)

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Key points of the amended PPI Act

1. Clearer definition of “Personal Information”
2. Rules for utilizing Personal Data
3. Establishment of Personal Information Protection Commission(PPC)
4. Globalization
5. Others

Points of the amended PPI Act

1. Clearer definition of “Personal Information”
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Key points concerning genomics

Genomic information was included in these new categories of personal information;

“Personal Identification code”

(「個人識別符号」)

“Sensitive personal information”

(「要配慮個人情報」)

Most important point in genomics

Genomic information was included in the
new categories of personal information;

“Personal Identification code”

(「個人識別符号」)

“Sensitive personal information”

(「要配慮個人情報」)

Genomic information

Personal Information



- name
- address
- date of birth



Fingerprint data



Facial-recognition data



Passport number



Driver's license number



MY NUMBER
(Individual numbers)

= newly defined* =

Original definition of personal information

Personal Identification code

ned as pe

Genomic information

Personal Information



- name
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Fingerprint data



Facial-recognition data



Passport number



Driver's license number



MY NUMBER
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Original personal information

Personal Identification code

個人識別符号

Personal identification code (Individual identification code)

個人情報保護法 第2条

2 この法律において「個人識別符号」とは、次の各号のいずれかに該当する文字、番号、記号その他の符号のうち、政令で定めるものをいう。

Amended Act on the Protection of Personal Information

(Tentative Translation, Ver.1, Dec 2016) Article 2

(2) An “individual identification code” in this Act means any character, letter, number, symbol or other codes prescribed by cabinet order which fall under any of the following categories.

個人識別符号

Personal identification code (Individual identification code)

個人情報保護法 第2条

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(2) An “individual identification code” in this Act means those prescribed by cabinet order which are any character, letter, number, symbol or other codes falling under any of each following item.



政令 第1条

一 次に掲げる身体の特徴のいずれかを電子計算機の用に供するために変換した文字、番号、記号その他の符号であって、特定の個人を識別するに足りるものとして個人情報保護委員会規則で定める基準に適合するもの

イ 細胞から採取されたデオキシリボ核酸(別名DNA)を構成する塩基の配列

Amendment to the Cabinet Order to Enforce the Act on the Protection of Personal Information

(Tentative Translation, Ver.1, Dec 2016) Article 1

(i) Those character, letter, number, symbol or other codes produced for digital use in confirmation to standards prescribed by rules of the Personal Information Protection Commission which stand for information related to any of the following physical characteristics which are sufficient to identify a specific individual.

(a) base sequence constituting Deoxyribonucleic Acid (DNA) taken from a cell;



政令 第1条

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Amendment to the Cabinet Order to Enforce the Act on the Protection of Personal Information

(Tentative Translation, Ver.1, Dec 2016) Article 1

(i) Those character, letter, number, symbol or other codes produced by having converted any of the following bodily features thereinto so as to be provided for use in computers which conform to standards prescribed by rules of the Personal Information Protection Commission as sufficient to identify a specific individual.

(a) base sequence constituting Deoxyribonucleic Acid (alias DNA) taken from a cell;



委員会規則 第2条

個人情報に関する法律施行令(以下「令」という。)第一条
第一号の個人情報保護委員会規則で定める基準は、特定の個人
を識別することができる水準が確保されるよう、適切な範囲を適切
な手法により電子計算機の用に供するために変換することとする。

Enforcement Rules for the Act on the Protection of Personal
Information

(Tentative translation, Ver.1, Dec 2016) Article 2

Standards prescribed by rules of the Personal Information
Protection Commission under Article 1, item (i) of the Order to
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(hereinafter referred to as the “Order”) shall be to convert for digital
use in an appropriate context by using appropriate methods so as to
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委員会ガイドライン(通則編)

イ 細胞から採取されたデオキシリボ核酸(別名DNA)を構成する塩基の配列

ゲノムデータ(細胞から採取されたデオキシリボ核酸(別名DNA)を構成する塩基の配列を文字列で表記したもの)のうち、全核ゲノムシーケンスデータ、全エクソームデータ、全ゲノム一塩基多型(single nucleotide polymorphism:SNP)データ、互いに独立な40箇所以上のSNPから構成されるシーケンスデータ、9座位以上の4塩基単位の繰り返し配列(short tandem repeat:STR)等の遺伝型情報により本人を認証することができるようにしたもの

Commission's Guideline
(English version is not available)



委員会ガイドライン(通則編)

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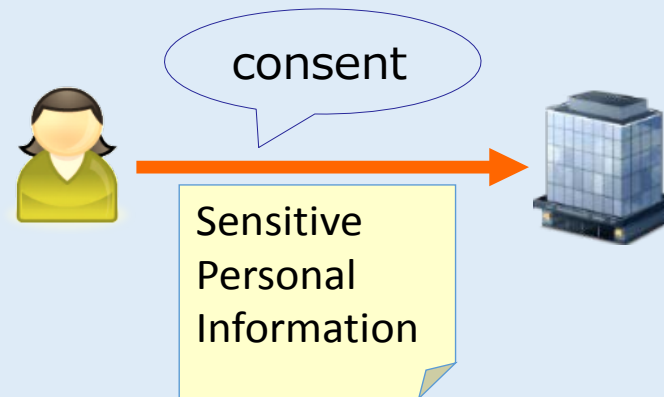
Sensitive personal information

Sensitive Information is

- race,
- religion,
- medical history
- personal information which has potential to bring about unjustifiable discrimination or prejudice

Genomic
information

**Require prior consent in
obtaining Sensitive Personal
Information**



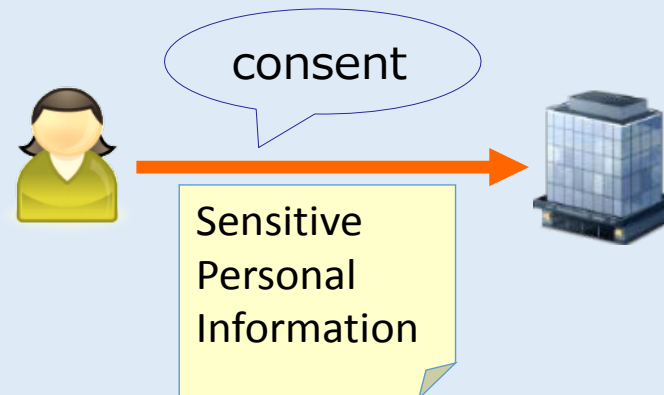
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要配慮個人情報 Sensitive personal information (Special care-required personal information)

政令 第2条

二 本人に対して医師その他医療に関連する職務に従事する者（次号において「医師等」という。）により行われた疾病の予防及び早期発見のための健康診断その他の検査（同号において「健康診断等」という。）の結果

三 健康診断等の結果に基づき、又は疾病、負傷その他の心身の変化を理由として、本人に対して医師等により心身の状態の改善のための指導又は診療若しくは調剤が行われたこと。

(ii) the results of a medical check-up or other examination (hereafter referred to as a “medical check-up etc.”) for the prevention and/or early detection of a disease conducted on an individual by a medical doctor or other persons engaged in duties related to medicine (hereafter referred to as a “doctor etc.”);

(iii) the fact that guidance for the improvement of the mental and physical conditions, or medical care or prescription has been given to an individual by a doctor etc. based on the results of a medical check-up etc. for reason of disease, injury or other mental and physical changes;

要配慮個人情報 Sensitive personal information (Special care-required personal information)

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consent

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**Require prior consent in
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consent

Sensitive
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Information



Benefits of the amended PPI Acts

- Harmonization with other countries for safer data sharing
- Positive cycle of genomic medical science

Advantage of amended PPI Acts

- Harmonization with other countries for safer data sharing
- Positive cycle of genomic medical science

Summary

- Personal genomic information is now clearly protected under the PPI Acts.
- PPI Act has three categories of personal information; original, personal identification code, sensitive information. Genomic information belongs to all three categories.
- The amendments should create a positive cycle of genomic medical science.

Summary

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- The amendments should create the positive cycle of genomic medical science.

Contact form
(English
version coming
soon!)

<https://www.genomics-society.jp>

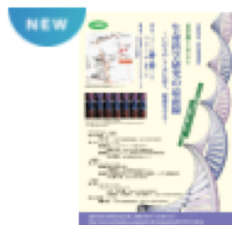
最新情報・お知らせ

すべて

お知らせ ▼

各種資料・情報 ▼

セミナー・イベント情報 ▼



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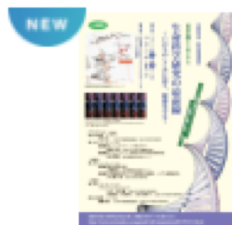
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Thank you for your attention.

This work is supported by

Advanced Genome Science,

MEXT KAKENHI Grant Number 16H06279

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Articles of exceptions, exceptional clause

個人情報取得・利用・提供に係る例外規定等一覧

| 主な対象機関 | 適用 | 分類 | 法律の例外規定 | 関係条項 |
|----------|---|---------------------------|---|------------------------------|
| 私立大学・学会等 | 個人情報 【適用除外】 | 取得・提供 自機関利用 | ●私立大学、学会等の学術研究機関が学術研究を行う場合 | 個人情報第76条第1項第3号 |
| 民間病院・企業等 | 個人情報 | 取得 (要配慮のみ) | ●法令、緊急、 公衆衛生 、法令事務、公開、政令 | 個人情報第17条第2項各号 |
| | | 自機関利用 | ●変更前の目的と 関連性 がある場合 ●法令、緊急、 公衆衛生 、法令事務 | 個人情報第15条第2項 個人情報第16条第3項各号 |
| | | 提供【国内】 | ●法令、緊急、 公衆衛生 、法令事務 | 個人情報第23条第1項各号 |
| | | | ●オプトアウト（要配慮個人情報を除く） ●委託、事業承継、共同利用 | 個人情報第23条第2項 個人情報第23条第5項各号 |
| 提供【外国】 | ●法令、緊急、 公衆衛生 、法令事務 ●第24条に規定する基準に適合する場合 | 個人情報第23条第1項各号 個人情報第24条 | | |
| 国 | 行個法 | 自機関利用 | ●変更前の目的と 相当の関連性 がある場合 ●自機関利用 + 相当な理由 | 行個法第3条第3項 行個法第8条第2項第2号 |
| | | 提供 | ●他の行政機関等へ提供 + 相当な理由 ●他の民間企業等へ提供 + 専ら学術研究 / 特別の理由 | 行個法第8条第2項第3号 行個法第8条第2項第4号 |
| 独法・国立大学等 | 独個法 | 自機関利用 | ●変更前の目的と 相当の関連性 がある場合 ●自機関利用 + 相当な理由 | 独個法第3条第3項 独個法第9条第2項第2号 |
| | | 提供 | ●他の行政機関等へ提供 + 相当な理由 ●他の民間企業等へ提供 + 専ら学術研究 / 特別の理由 | 独個法第9条第2項第3号 独個法第9条第2項第4号 |
| 地方公共団体 | 条例 | 取得・利用・提供 | ●各条例が適用される | 条例 |

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Consent Codes

Primary Categories (I^Y)

| NRES | GRU(CC) | HMB(CC) | DS-[XX](CC) | POA |
|------------------------------|--|--|---|--|
| no restrictions | general research use and clinical care | health/medical/bio-medical research and clinical care | disease-specific research and clinical care | population origins/ancestry research |
| No restrictions on data use. | For health/medical/biomedical purposes and other biological research, including the study of population origins or ancestry. | Use of the data is limited to health/medical/bio-medical purposes, does not include the study of population origins or ancestry. | Use of the data must be related to [disease]. | Use of the data is limited to the study of population origins or ancestry. |

Secondary Categories (II^Y) (can be one or more extra conditions, in addition to I^Y category)

| | | |
|---------|--------------------------------------|---|
| RS-[XX] | other research-specific restrictions | Use of the data is limited to studies of [research type] (e.g., pediatric research). |
| RUO | research use only | Use of data is limited to research purposes (e.g., does not include its use in clinical care). |
| NMDS | no "general methods" research | Use of the data includes methods development research (e.g., development of software or algorithms) ONLY within the bounds of other data use limitations. |
| GSO | genetic studies only | Use of the data is limited to genetic studies only (i.e., no research using only the phenotype data). |

Requirements

| | | |
|----------|-----------------------------------|--|
| NPU | not-for-profit use only | Use of the data is limited to not-for-profit organizations. |
| PUB | publication required | Requestor agrees to make results of studies using the data available to the larger scientific community. |
| COL-[XX] | collaboration required | Requestor must agree to collaboration with the primary study investigator(s). |
| RTN | return data to database/resource | Requestor must return derived/enriched data to the database/resource. |
| IRB | ethics approval required | Requestor must provide documentation of local IRB/REC approval. |
| GS-[XX] | geographical restrictions | Use of the data is limited to within [geographic region]. |
| MOR-[XX] | publication moratorium/embargo | Requestor agrees not to publish results of studies until [date]. |
| TS-[XX] | time limits on use | Use of data is approved for [x months]. |
| US | user-specific restrictions | Use of data is limited to use by approved users. |
| PS | project-specific restrictions | Use of data is approved for [x months]. |
| IS | institution-specific restrictions | Use of data is limited to use within an approved institution. |

SOM Dyke, *et al.* Consent Codes: Upholding Standard Data Use Conditions. *PLoS Genetics* 12(1): e1005772.

Consent Codes

Primary Categories (I^Y)

| NRES | GRU(CC) | HMB(CC) | DS-[XX](CC) | POA |
|------------------------------|--|--|---|--|
| no restrictions | general research use and clinical care | health/medical/bio-medical research and clinical care | disease-specific research and clinical care | population origins/ancestry research |
| No restrictions on data use. | For health/medical/biomedical purposes and other biological research, including the study of population origins or ancestry. | Use of the data is limited to health/medical/bio-medical purposes, does not include the study of population origins or ancestry. | Use of the data must be related to [disease]. | Use of the data is limited to the study of population origins or ancestry. |

Secondary Categories (II^Y) (can be one or more extra conditions, in addition to I^Y category)

| | | |
|---------|--------------------------------------|---|
| RS-[XX] | other research-specific restrictions | Use of the data is limited to studies of [research type] (e.g., pediatric research). |
| RUO | research use only | Use of data is limited to research purposes (e.g., does not include its use in clinical care). |
| NMDS | no "general methods" research | Use of the data includes methods development research (e.g., development of software or algorithms) ONLY within the bounds of other data use limitations. |
| GSO | genetic studies only | Use of the data is limited to genetic studies only (i.e., no research using only the phenotype data). |

Requirements

| | | |
|----------|-----------------------------------|--|
| NPU | not-for-profit use only | Use of the data is limited to not-for-profit organizations. |
| PUB | publication required | Requestor agrees to make results of studies using the data available to the larger scientific community. |
| COL-[XX] | collaboration required | Requestor must agree to collaboration with the primary study investigator(s). |
| RTN | return data to database/resource | Requestor must return derived/enriched data to the database/resource. |
| IRB | ethics approval required | Requestor must provide documentation of local IRB/REC approval. |
| GS-[XX] | geographical restrictions | Use of the data is limited to within [geographic region]. |
| MOR-[XX] | publication moratorium/embargo | Requestor agrees not to publish results of studies until [date]. |
| TS-[XX] | time limits on use | Use of data is approved for [x months]. |
| US | user-specific restrictions | Use of data is limited to use by approved users. |
| PS | project-specific restrictions | Use of data is approved for [x months]. |
| IS | institution-specific restrictions | Use of data is limited to use within an approved institution. |

SOM Dyke, *et al.* Consent Codes: Upholding Standard Data Use Conditions. *PLoS Genetics* 12(1): e1005772.