GDPR / PIPL	SOP 5.1.03

1. Purpose

The purpose of this SOP is to provide guidance to researchers collecting human subjects' data subject to the General Data Protection Regulation (GDPR) of the European Union (EU), the European Economic Area (EEA),[1] and the United Kingdom (UK) and the Personal Information Protection Law (PIPL) of the People's Republic of China.

2. General Information

The General Data Protection Regulation (GDPR) applies to users of our websites or mobile applications who are located in the EEA (consisting of the European Union, Iceland, Lichtenstein, and Norway) and/or the UK to the extent Caltech collects personal data in the course of (i) offering a good or service to such individuals, or (ii) monitoring the behavior of such individuals. The Personal Information Protection Law (PIPL) may apply to users of our websites or mobile applications who are located in China. These laws set forth a framework for the processing of personal data, the cross-border transfer of personal data, and the safeguarding of personal data. These laws also afford individuals rights with respect to their personal data. Caltech is committed to take reasonably necessary steps to ensure that personal data is protected consistent with GDPR and PIPL requirements.

Caltech has a general information website for GDPR found at: https://www.caltech.edu/general-data-protection-regulation-notice.

The regulatory requirements for GDPR are found at: https://gdpr-info.eu/

The regulatory requirements for PIPL are found at: https://www.china-briefing.com/news/the-prc-personal-information-protection-law-final-a-full-translation/

3. Principal Investigator (PI) Training Requirements

There are no specific training requirements associated with use of data subject to the GDPR or PIPL; however, PIs should follow this guidance.

4. Procedures

A. Determine whether personal data will be collected from subjects located in the European Economic Area (i.e., European Union, Iceland, Lichtenstein, and Norway), UK ***or*** China.

B. If so, review and complete the Notice and Consent Form template below for the GDPR and/or PIPL (China).

C. The Notice and Consent Form template asks researchers to identify the purpose(s) of processing the Personal Data. If it is not possible to fully identify the purpose(s) of processing the Personal Data for scientific research at the outset of the project, a researcher should endeavor to identify the general areas of scientific research. Additionally, when additional purpose(s) become clear at

[1] *See* Appendix A for a list of EEA member states.

a subsequent point during the research project, the researcher should re-contact and obtain additional consent for each additional identified purpose(s) of processing the Personal Data.

5. Notice and Consent Form Language

NOTE: Please delete the gray-highlighted instructions and yellow-highlighted placeholders before submitting the form to the IRB for review and providing to research subjects.

A. GDPR (EU/EEA)

GDPR NOTICE & CONSENT FORM
FOR RESEARCH PARTICIPANTS LOCATED IN THE
EUROPEAN UNION (EU) / EUROPEAN ECONOMIC AREA-BASED (EEA) /UNITED KINGDOM (UK)

You are receiving this General Data Protection Regulation (GDPR) notice and consent form in connection with your participation in the following research project:

TITLE OF RESEARCH PROJECT: [*title of research project*]

PRINCIPAL INVESTIGATOR: [*name of principal investigator & Caltech division*]

DATA CONTROLLER: The California Institute of Technology (Caltech)

The GDPR requires researchers to provide this notice to research participants who are physically located within the European Union (EU), the European Economic Area (EEA), or the United Kingdom (UK) when we collect personal data about these participants. This notice outlines what personal data we will collect, how we intend to use this information, and your rights with respect to your personal data for purposes of the GDPR. The GDPR does not apply to your personal data that is rendered anonymous such that you are not identifiable or can no longer be identified. Following your review, please sign at the bottom to indicate that you have read and understood how your personal data will be processed, your related rights, and that you consent to this processing as described below.

PERSONAL DATA WE WILL COLLECT

Fill out the categories of data you will use for the research project, aiming to be as detailed as possible (e.g., genetic date (in particular, ...); health data (in particular, . . .); behavior data (in particular, . . .); social media data (in particular, . . .)]

As part of this research project, we will collect and use personal data you provide to us or that we may obtain from other sources about you, including the following categories:

- [*specify all categories of data collected from or about the research participants*]

If this is the practice, include the following sentence. Otherwise, delete this sentence:

As a safeguard to protect your privacy, we pseudonymize (key-code) your personal data.

HOW WE WILL USE YOUR PERSONAL DATA

Note: The bullet points in blue text are examples. Please add as necessary and delete those that are not applicable. The last two bullet points in black text should remain.

Your collected personal data will be used for the following purposes:

- To determine eligibility criteria for the study
- To share with members of the research team so they properly conduct research and perform procedures required by this research
- To fulfill the research project's objectives as described in the *Research Study Informed Consent* form
- To provide study compensation and complying with compensation-related reporting requirements
- For future research studies or additional research by other researchers [(*describe if applicable*)]
- [*List any additional categories of individuals or entities who may receive access to personal data, including service providers who are contracted for handling data (e.g., cloud service providers) on your behalf, and describe the reason for disclosure*]
- To comply with legal, regulatory, or institution policy requirements, including requirements to share data with regulatory agencies overseeing the research
- To confirm proper conduct of the study and research integrity

Your personal data will be transferred to the United States. The European Commission has found that the United States does not maintain adequate data protection laws. However, we are committed to protecting the confidentiality of the personal data you give us. Transfer and use of your personal data is on the basis of your consent.

RETENTION OF YOUR PERSONAL DATA

Include the retention period (how long will you keep the data for after the end of the project). If the retention period depends on other factors, you don't have to mention an exact period of time, but you will have to mention the factors that influence the establishment of the period. Choose one of the two options and delete the other.

We retain your personal data for [*insert retention time*] after the project is completed, unless required by law or to protect our legal rights.

OR

The period of time for which we retain your personal data depends on [*include the specific factors that will influence this period of time (e.g., to fulfill the objectives of the research; to ensure the integrity of the research, to use for future research [describe]*]. We may also keep your information for longer periods if required by law or to protect our legal rights.

YOUR RIGHTS

If you participate in this study within the EU/EEA, the GDPR affords you certain rights with respect to your personal data, including the right to:

- Access, correct, or delete your personal data; however, these rights may be limited in certain circumstances, such as if the research team needs to keep your personal data to preserve the integrity of the research or to satisfy regulatory requirements;

- Restrict the types of activities the research team can do with your personal data;
- Object to using your personal data for specific types of activities; or
- Withdraw your consent to use your personal data for the purposes outlined in the *Research Study Informed Consent form* and in this document. If you withdraw your consent to participate in this study, this will not affect the lawfulness of our collection, use and disclosure of your personal information that occurs up to the point in time that you withdraw your consent. Even if you withdraw your consent, we may still use your data that has been anonymized. We may also maintain and use your personal data to the extent required for compliance with applicable law or institution policy.
- Complain to a supervisory authority.

To exercise your rights, please use the contact information below to submit a request. When you submit a request, please indicate your name, the name of this project, your reasons for making the request, if necessary, and other details you think will be useful for us to comply with your request. You may be asked to provide identification to establish and confirm your identity.

CONTACT INFORMATION IF YOU HAVE QUESTIONS OR CONCERNS

If you want to make a request relating to the rights listed above or if you have any questions about how your personal data is being handled, please contact:

Committee for the Protection of Human Subjects – Institutional Review Board
California Institute of Technology
1200 East California Blvd.
Pasadena, California 91125
Phone: 626-395-8448
Email: irb@caltech.edu

CONSENT SIGNATURE and DATE

Your consent is entirely voluntary, but declining to provide consent may impede your ability to participate in this research project.

Choose one of the following consent language as applicable

Consent via signature, use the following verbiage:

In signing this document, you indicate that you have read and understood how your personal data will be processed, your related rights, and that you consent to the processing of your data as provided in this document, which may include health and other sensitive personal data. In addition, you agree this information was explained to you, your questions have been answered to your satisfaction, and that you wish to continue participating in the study. If any new questions arise, you can contact the research team using the information provided above.

Participant's Name (printed) _____

_____ _____

Participant's Signature Date

Consent via online button, use the following verbiage:

By clicking below, you indicate that you have read and understood how your personal data will be processed, your related rights, and that you consent to the processing of your data as provided in this document, which may include health and other sensitive personal data. In addition, you acknowledge that this information was explained to you, your questions have been answered, and that you wish to continue participating in the study. If any new questions arise, you can contact the research team using the information provided above.

You may print a copy of this form for your files.

☐ I acknowledge that this information was explained to me, my questions have been answered to my satisfaction, and I voluntarily consent to participate in this study and permit my information to be collected and used as described in this Notice.

B. PIPL (CHINA)

PIPL NOTICE & CONSENT FORM
FOR RESEARCH PARTICIPANTS LOCATED IN
THE PEOPLE'S REPUBLIC OF CHINA

You are receiving this Personal Information Protection Law (PIPL) notice and consent form in connection with your participation in the following research project:

TITLE OF RESEARCH PROJECT: [*title of research project*]

PRINCIPAL INVESTIGATOR: [*name of principal investigator & Caltech division*]

DATA CONTROLLER: The California Institute of Technology (Caltech)

The PIPL requires researchers to provide this notice to research participants who are physically located within The People's Republic of China when we collect personal data about these participants. This notice outlines what personal data we will collect, how we intend to use this information, and your rights with respect to your personal data for purposes of the PIPL. The PIPL does not apply to your personal data that is rendered anonymous such that you are not identifiable or can no longer be identified. Following your review, please sign at the bottom to indicate that you have read and understood how your personal data will be processed, your related rights, and that you consent to this processing as described below.

PERSONAL DATA WE WILL COLLECT

Fill out the categories of data you will use for the research project, aiming to be as detailed as possible (e.g., genetic date (in particular, ...); health data (in particular, . . .); behavior data (in particular, . . .); social media data (in particular, . . .)]

As part of this research project, we will collect and use information you provide to us or that we may obtain from other sources about you, including the following categories:

- [*specify all categories of data collected from or about the research participants*]

If this is the practice, include the following sentence. Otherwise, delete this sentence:

As a safeguard to protect your privacy, we pseudonymize (key-code) your personal data.

HOW WE WILL USE YOUR PERSONAL DATA

Note: The bullet points in blue text are examples. Please add as necessary and delete those that are not applicable. The last two bullet points in black text should remain.

Your collected personal data will be used for the following purposes:

- To determine eligibility criteria for the study
- To share with members of the research team so they properly conduct research and perform procedures required by this research
- To fulfill the research project's objectives as described in the *Research Study Informed Consent* form
- To provide study compensation and complying with compensation-related reporting requirements
- For future research studies or additional research by other researchers [(*describe if applicable*)]
- [*List any additional categories of individuals or entities who may receive access to personal data, including service providers who are contracted for handling data (e.g., cloud service providers) on your behalf, and describe the reason for disclosure*]
- To comply with legal, regulatory, or institution policy requirements, including requirements to share data with regulatory agencies overseeing the research
- To confirm proper conduct of the study and research integrity

Your personal data will be transferred to the United States upon satisfaction of certain statutory requirements under the PIPL. We are committed to protecting the confidentiality of the personal data you give us, and have taken necessary organizational and technical measures to prevent unauthorized access, disclosure, leakage or loss of your personal data. Transfer and use of your personal data is on the basis of your consent.

RETENTION OF YOUR PERSONAL DATA

Include the retention period (how long will you keep the data for after the end of the project). If the retention period depends on other factors, you don't have to mention an exact period of time, but you will have to mention the factors that influence the establishment of the period. Choose one of the two options and delete the other.

We retain your personal data for [*insert retention time*] after the project is completed, unless required by law or to protect our legal rights.

OR

The period of time for which we retain your personal data depends on [*include the specific factors that will influence this period of time (e.g., to fulfill the objectives of the research; to ensure the integrity of the research, to use for future research [describe]*]. We may also keep your information for longer periods if required by law or to protect our legal rights.

YOUR RIGHTS

If you participate in this study within the People's Republic of China, the PIPL affords you certain rights with respect to your personal data, including the right to:

- Access, correct, or delete your personal data; however, the research team may need to keep your personal data as long as it is necessary to achieve the purpose of this research or to perform certain statutory or regulatory obligations;
- Restrict the types of activities the research team can do with your personal data;
- Object to using your personal data for specific types of activities; or
- Withdraw your consent to use your personal data for the purposes outlined in the *Research Study Informed Consent form* and in this document. If you withdraw your consent to participate in this study, this will not affect the lawfulness of our collection, use and disclosure of your personal data that occurs up to the point in time that you withdraw your consent. Even if you withdraw your consent, we may still use your personal data that has been anonymized. We may also maintain and use your personal data to the extent required for compliance with applicable law or institution policy.

To exercise your rights, please use the contact information below to submit a request. When you submit a request, please indicate your name, the name of this project, your reasons for making the request, if necessary, and other details you think will be useful for us to comply with your request. You may be asked to provide identification to establish and confirm your identity.

CONTACT INFORMATION IF YOU HAVE QUESTIONS OR CONCERNS

If you want to make a request relating to the rights listed above or if you have any questions about how your personal data is being handled, please contact:

Committee for the Protection of Human Subjects – Institutional Review Board
California Institute of Technology
1200 East California Blvd.
Pasadena, California 91125
Phone: 626-395-8448
Email: irb@caltech.edu

CONSENT SIGNATURE and DATE

Your consent is entirely voluntary, but declining to provide consent may impede your ability to participate in this research project.

Choose one of the following consent language as applicable:

Consent via signature, use the following verbiage:

In signing this document, you indicate that you have read and understood how your personal data will be processed, your related rights, and that you consent to the processing of your data as provided in this document, which may include health and other sensitive personal data. In addition, you agree this information was explained to you, your questions have been answered to your satisfaction, and that you wish to continue participating in the study. If any new questions arise, you can contact the research team using the information provided above.

Participant's Name (printed) _____

_____ _____

Participant's Signature Date

Consent via online button, use the following verbiage:

By clicking below, you indicate that you have read and understood how your personal data will be processed, your related rights, and that you consent to the processing of your data as provided in this document, which may include health and other sensitive personal data. In addition, you acknowledge that this information was explained to you, your questions have been answered, and that you wish to continue participating in the study. If any new questions arise, you can contact the research team using the information provided above.

You may print a copy of this form for your files.

☐ I acknowledge that this information was explained to me, my questions have been answered to my satisfaction, and I voluntarily consent to participate in this study and permit my information to be collected and used as described in this Notice.

Appendix A

European Economic Area (EEA) Member States[2]

1. Austria
2. Belgium
3. Bulgaria
4. Croatia
5. Republic of Cyprus
6. Czech Republic
7. Denmark
8. Estonia
9. Finland
10. France
11. Germany
12. Greece
13. Hungary
14. Iceland
15. Ireland
16. Italy
17. Latvia
18. Liechtenstein
19. Lithuania
20. Luxembourg
21. Malta
22. Netherlands
23. Norway
24. Poland
25. Portugal
26. Romania
27. Slovakia
28. Slovenia
29. Spain
30. Sweden

[2] The EEA consists of European Union (EU) Member States and Iceland, Liechtenstein and Norway.