Investigator Sponsored Research (ISR)
General Research (GR)
申請ガイド

Ver1.3

本申請システムは、以下のページで構成されています。

- Welcome page
- Introduction
- Content Information
- Organization Information
- Project Lead/Principal Investigator(PI)
- Study Details
- Budget Details
- Payee Information/Contracting organization
- Certifications

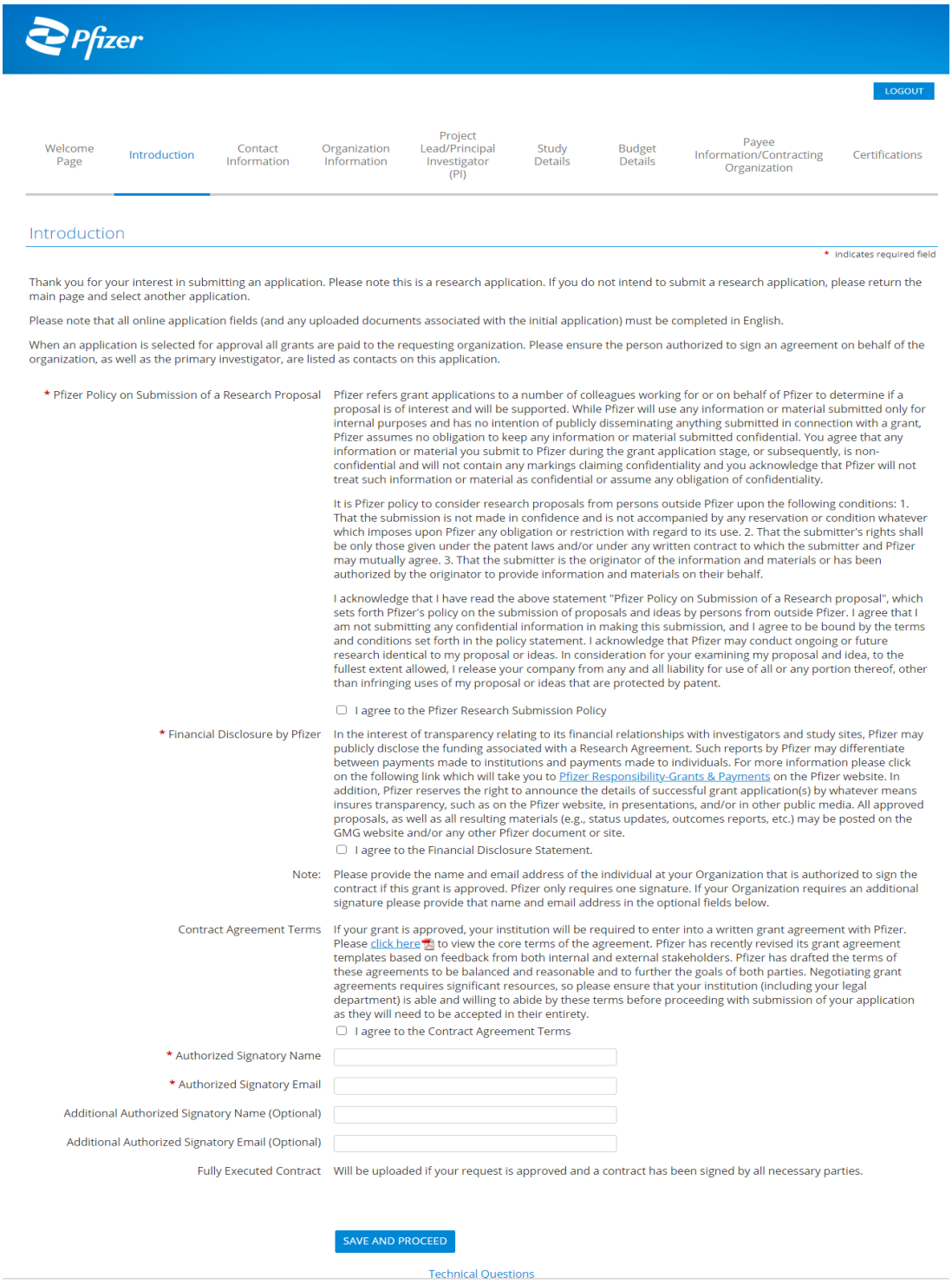
注:テキスト入力箇所は、全て英語で記入をお願いします。

Welcome page

- 申請や申請者情報を編集するページです

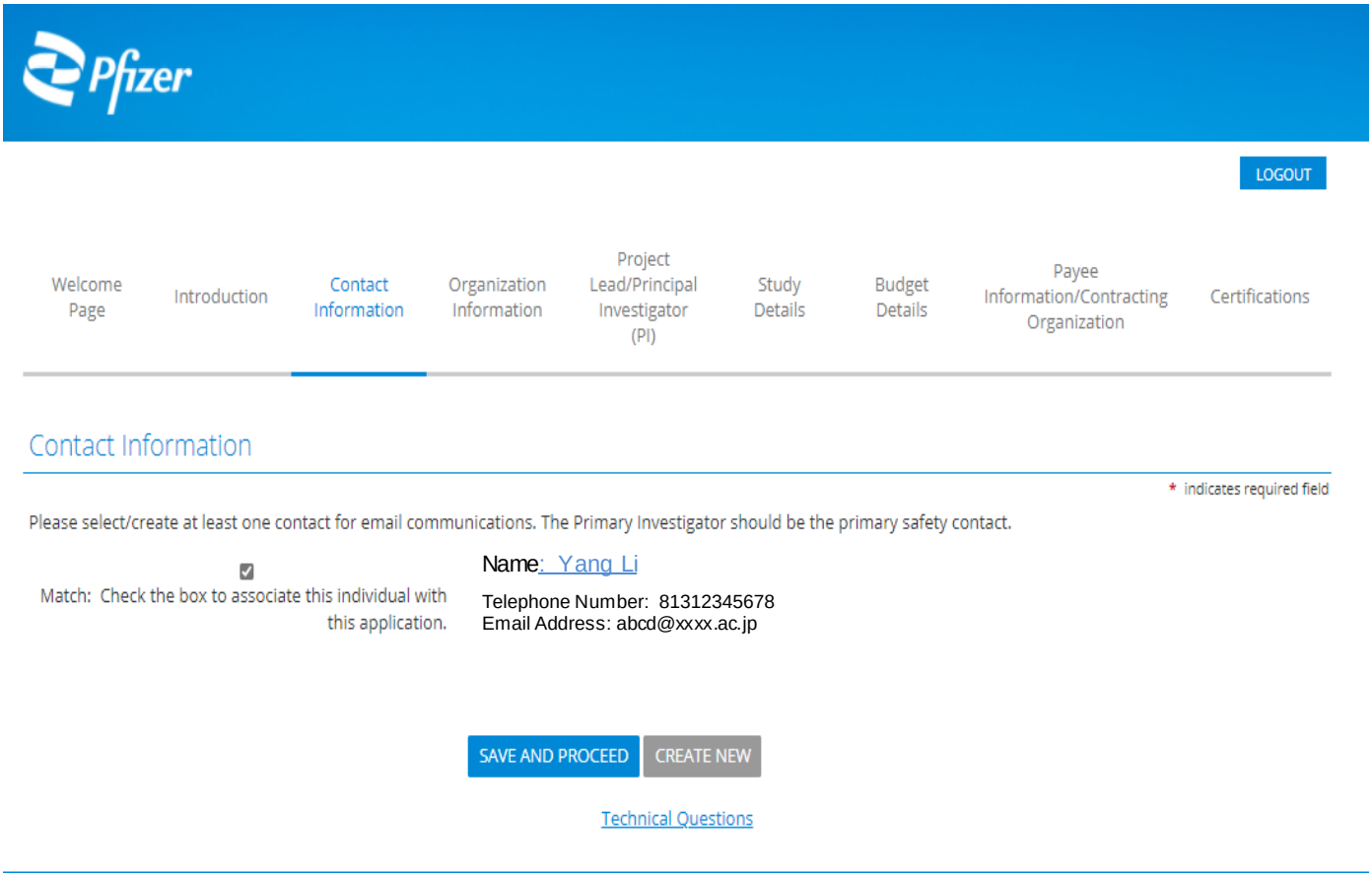
Introduction

- 申請する研究に対する、弊社のポリシーに合意いただく事を確認するページです



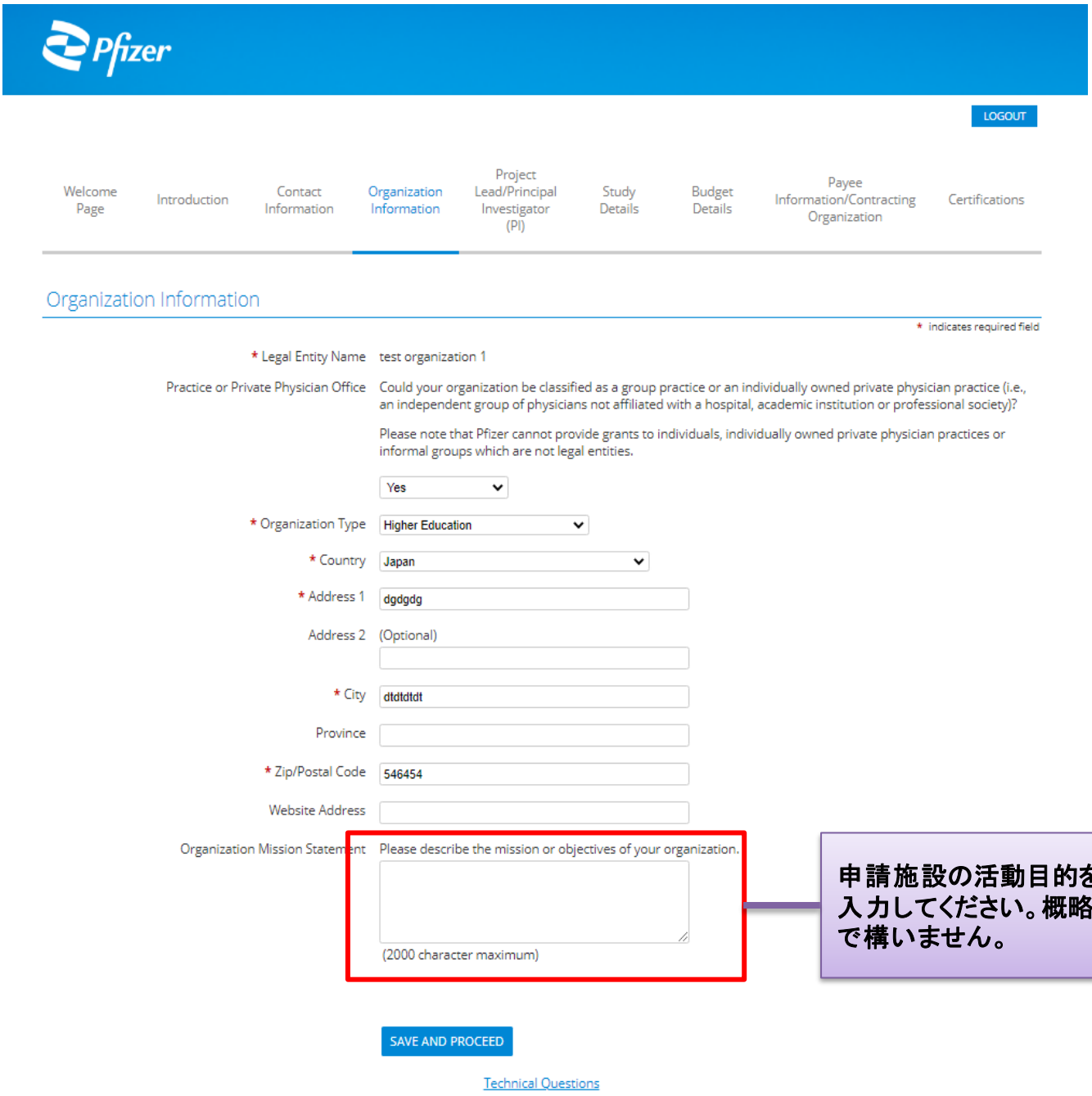
Contact Information

- Contact Informationを確認するページです



Organization Information

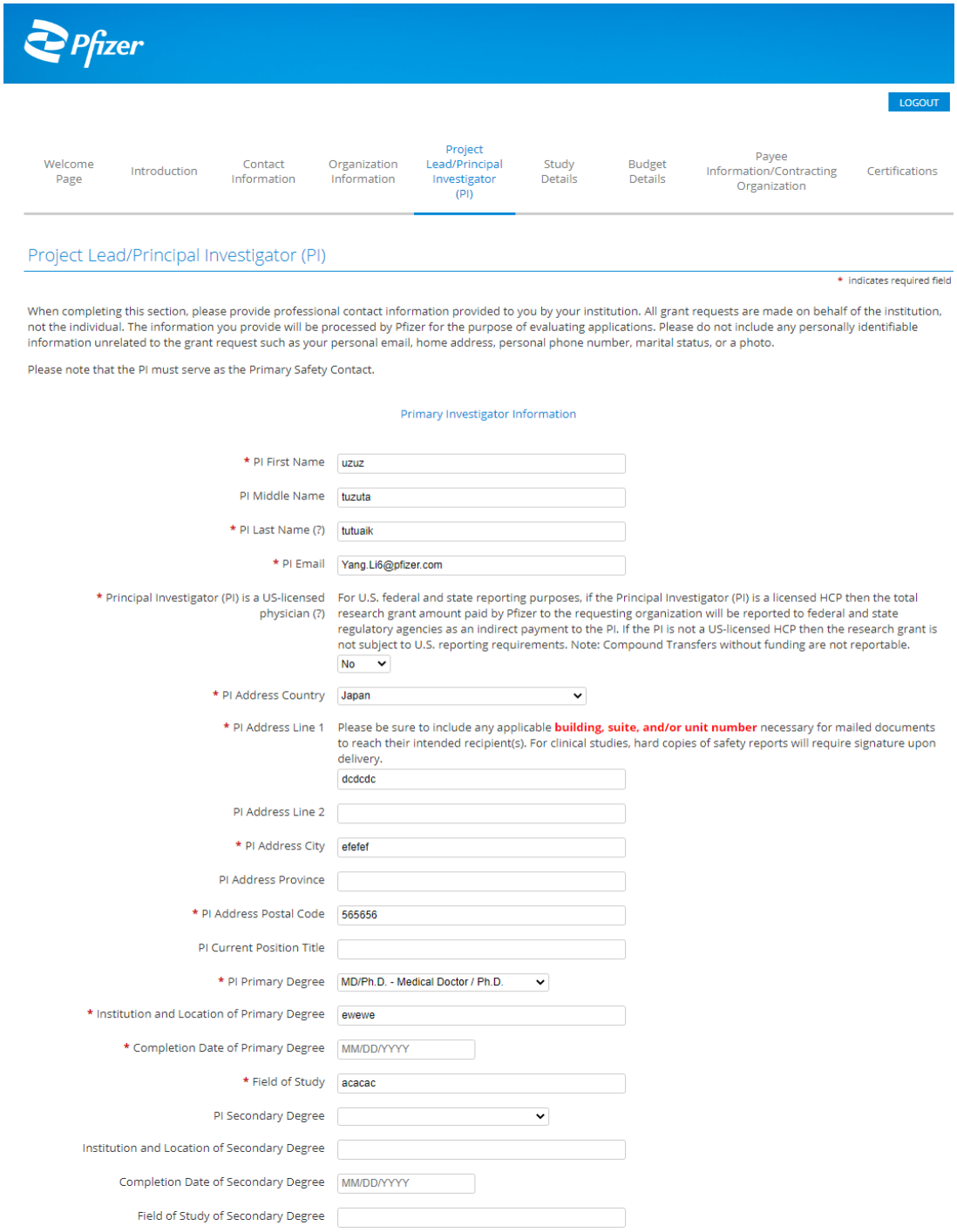
- 申請施設の情報を入力するページです



申請施設の活動目的を入力してください。概略で構いません。

Project Lead/ Principal Investigator (PI)-1

- Principal Investigatorの情報を入力するページです
- (?)をクリックすると、その項目の説明が表示されます



Project Lead/ Principal Investigator (PI)-2

PI Positions and Honors

(4000 character maximum)

PI Contributions to Science

(4000 character maximum)

Additional PI Information

Research Support and/or Scholastic Performance

(4000 character maximum)

Co-Investigator Information

Co-PI First Name (?)

Co-PI Middle Name

Co-PI Last Name

Co-PI Primary Degree

Co-PI Email

* PI Certification

I certify the information provided is accurate and complete.

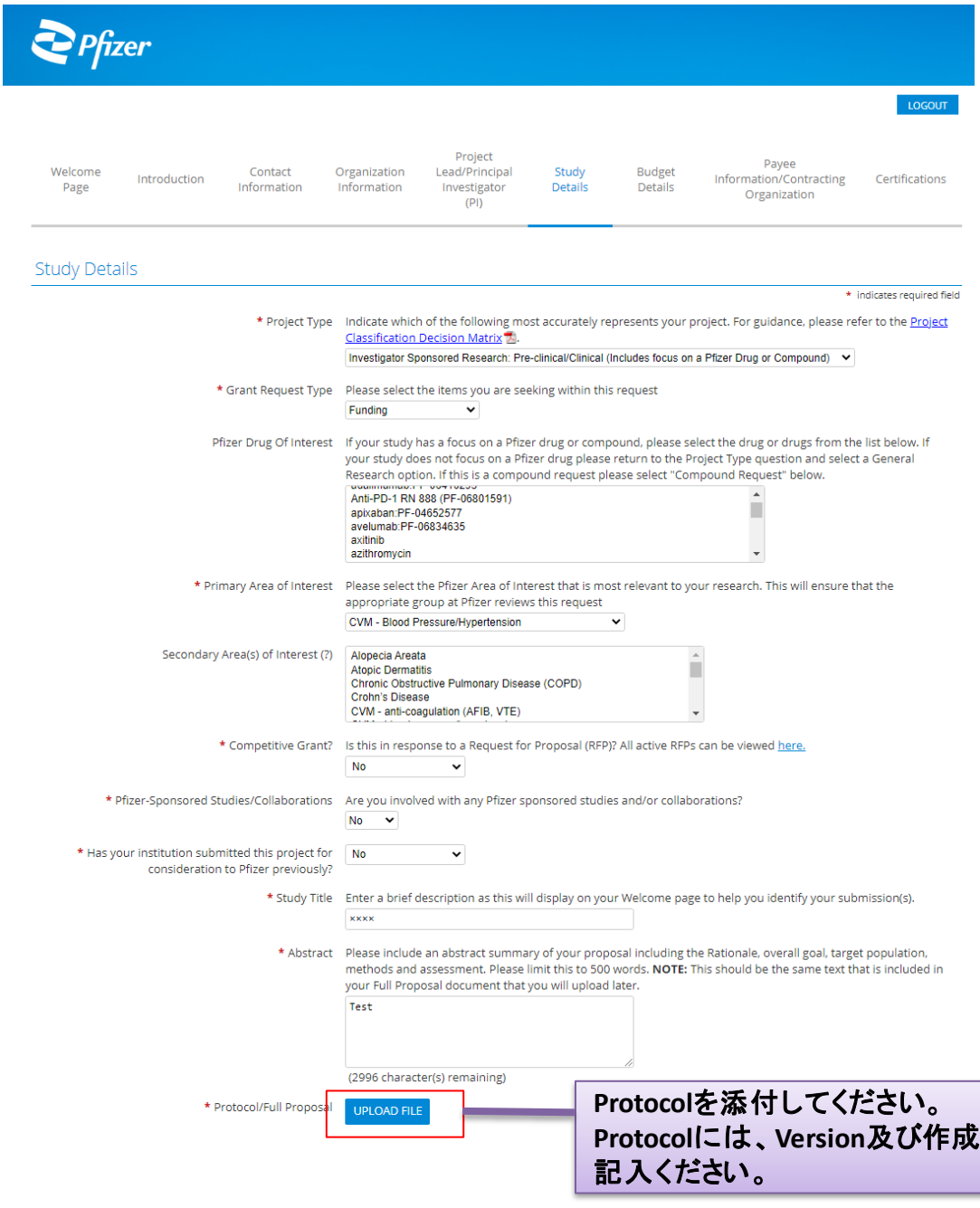
I certify

SAVE AND PROCEED

Technical Questions

Study Details-1

- 申請施設の情報を入力するページです
- (?)をクリックすると、その項目の説明が表示されます
- 後述（P.13）の「Budget details」のページの前に本ページの入力を完了する必要があります



Study Details-2

External Identification Number
Please note any External Identification Number assigned to the study by your institution

* Estimated Study Start Date
Please note that the start date must be at least 90 days post submission.
MM/DD/YYYY

* Estimated Study End Date
MM/DD/YYYY

* Project/activity related to pain or opioids
Please indicate whether or not the project/activity for which you are seeking support from Pfizer is related to or includes discussions about pain or opioids.

NOTE: To be eligible for funding, project/activity related to opioids must include components: 1) Aimed at increasing awareness of the risks of opioid addiction, abuse, and misuse; and 2) Detecting and preventing abuse, misuse, and diversion of opioids.

* Will any component of your activity/intervention offer continuing education credit?
No

* Research Setting
Please indicate if your study is a single-site or multi-site study.
Multiple-Site

* Primary Country Site
If Multi Site, please specify the Country of Primary Site from the list of countries.
Japan

Number of Sites
3

Additional Country Site(s)
Please select indicate the additional study sites from the list of countries

Afghanistan
ALand Islands
Albania
Algeria
American Samoa

Study Type
Please indicate if your study is clinical or pre-clinical. Your answer to this question will impact the questions asked later in the application.
Clinical

Clinical Study Type
What type of clinical study?
Interventional

Blinded Study?
Is your study blinded?
No

Age Group(s) of Study Population
Indicate the age group(s) of the populations studied
Adult

Ethnicity of Study Population
Indicate the ethnicity of the populations studied.

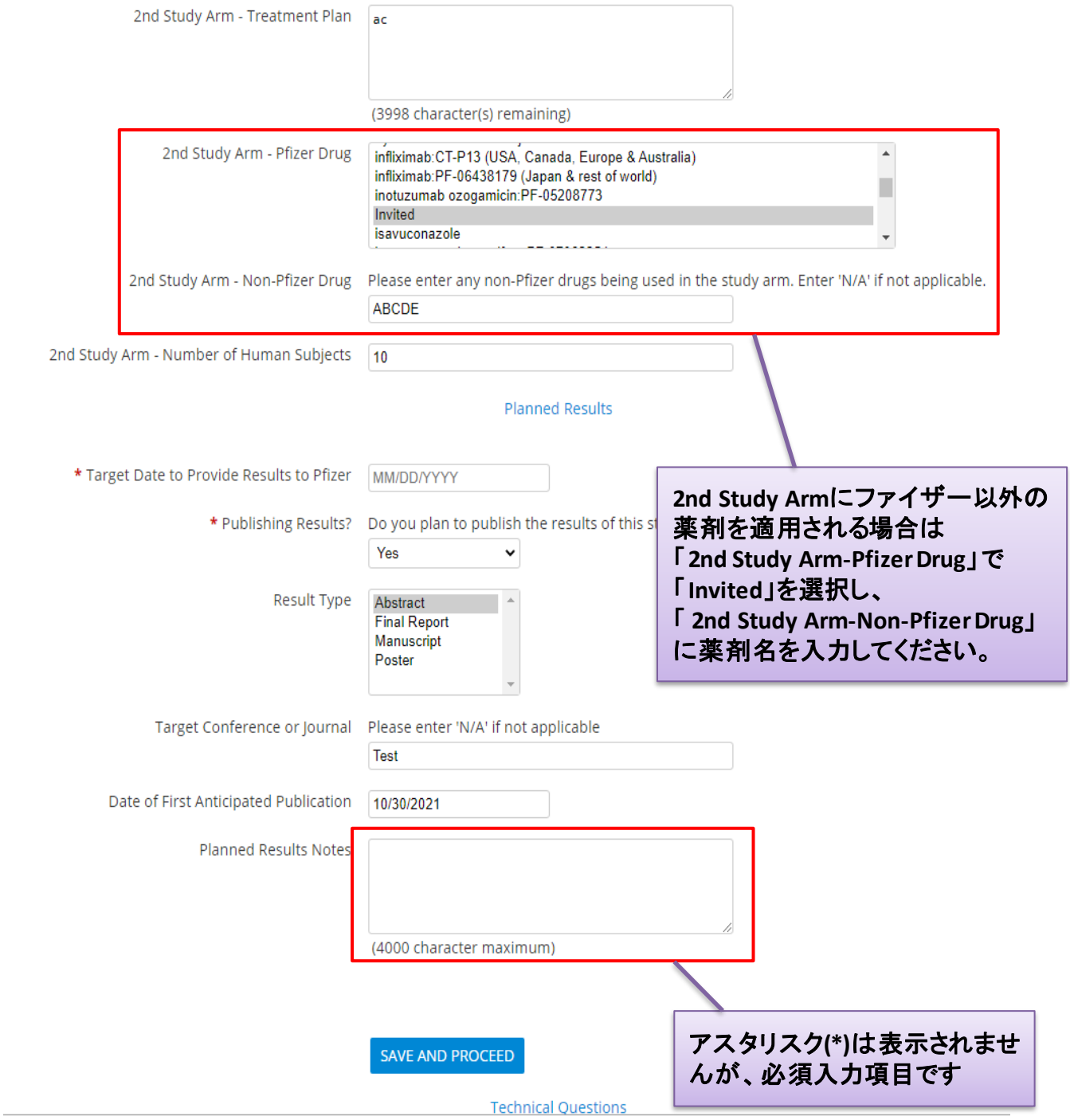
African
Asian
Caucasian
Hispanic
Open to All

日本国内のみの試験の場合も、システム設定の関係上、ここで「Japan」を選択いただく必要があります。

Study Details-3

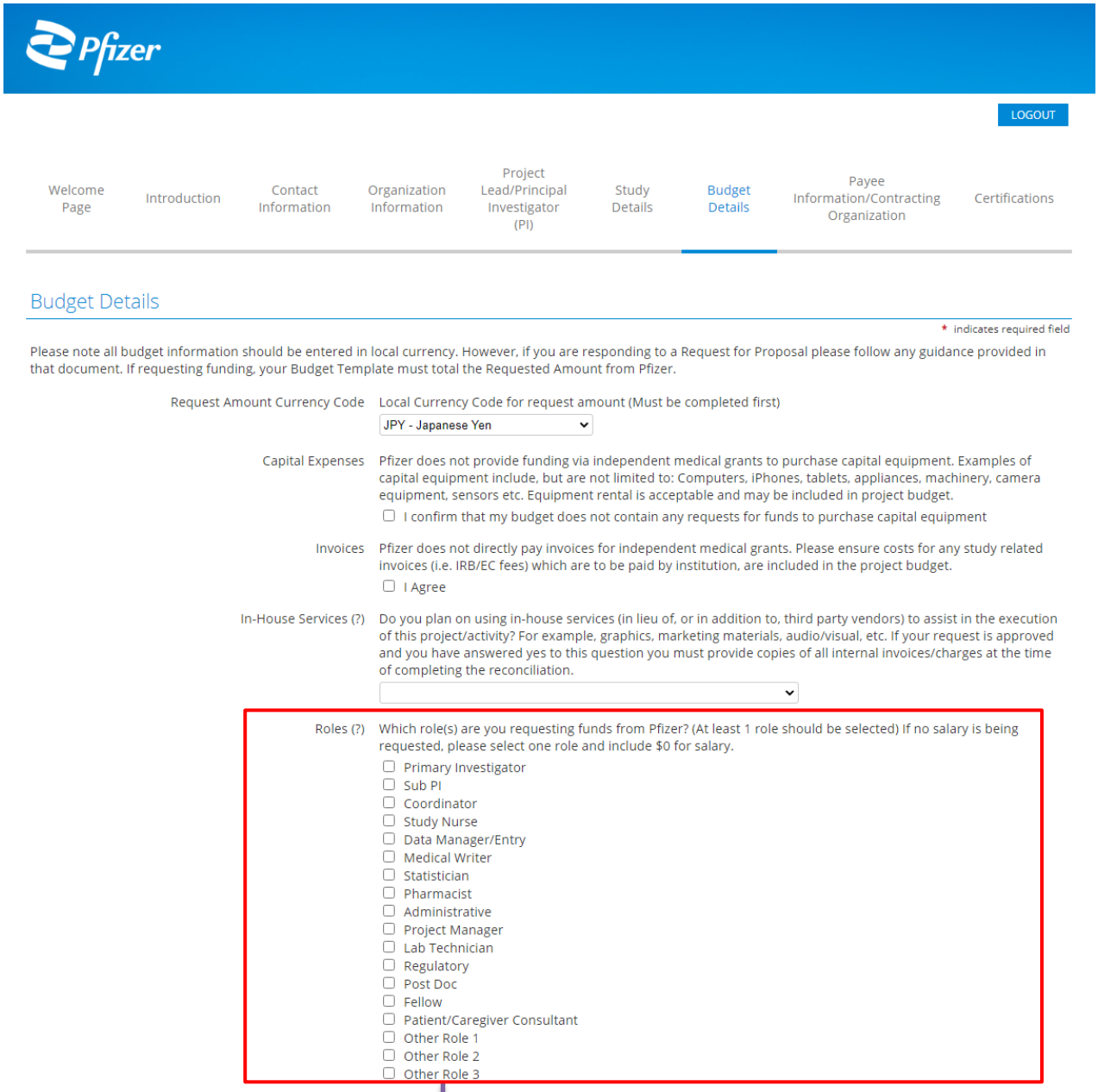
Length of Enrollment	Please indicate the anticipated Length of enrollment. Enter number of months. 24
Date of Estimated First Patient Enrollment	MM/DD/YYYY
* Does your study involve genetics or genomics?	No
Primary End Points: (i.e., what are you measuring?)	Test (3996 character(s) remaining)
Study Phases	Phase IV
Study Design	Open Label
Is the Study Randomized?	No
Total Subject Enrollment	100
Number of Arms	2
1st Study Arm - Treatment Plan	Test (3996 character(s) remaining)
1st Study Arm - Pfizer Drug	adalimumab:PF-06410293 Anti-PD-1 RN 888 (PF-06801591) apixaban:PF-04652577 avelumab:PF-06834635 axitinib
1st Study Arm - Non-Pfizer Drug	Please enter any non-Pfizer drugs being used in the study arm. Enter 'N/A' if not applicable. a
1st Study Arm - Number of Human Subjects	10

Study Details-4



Budget Details-1

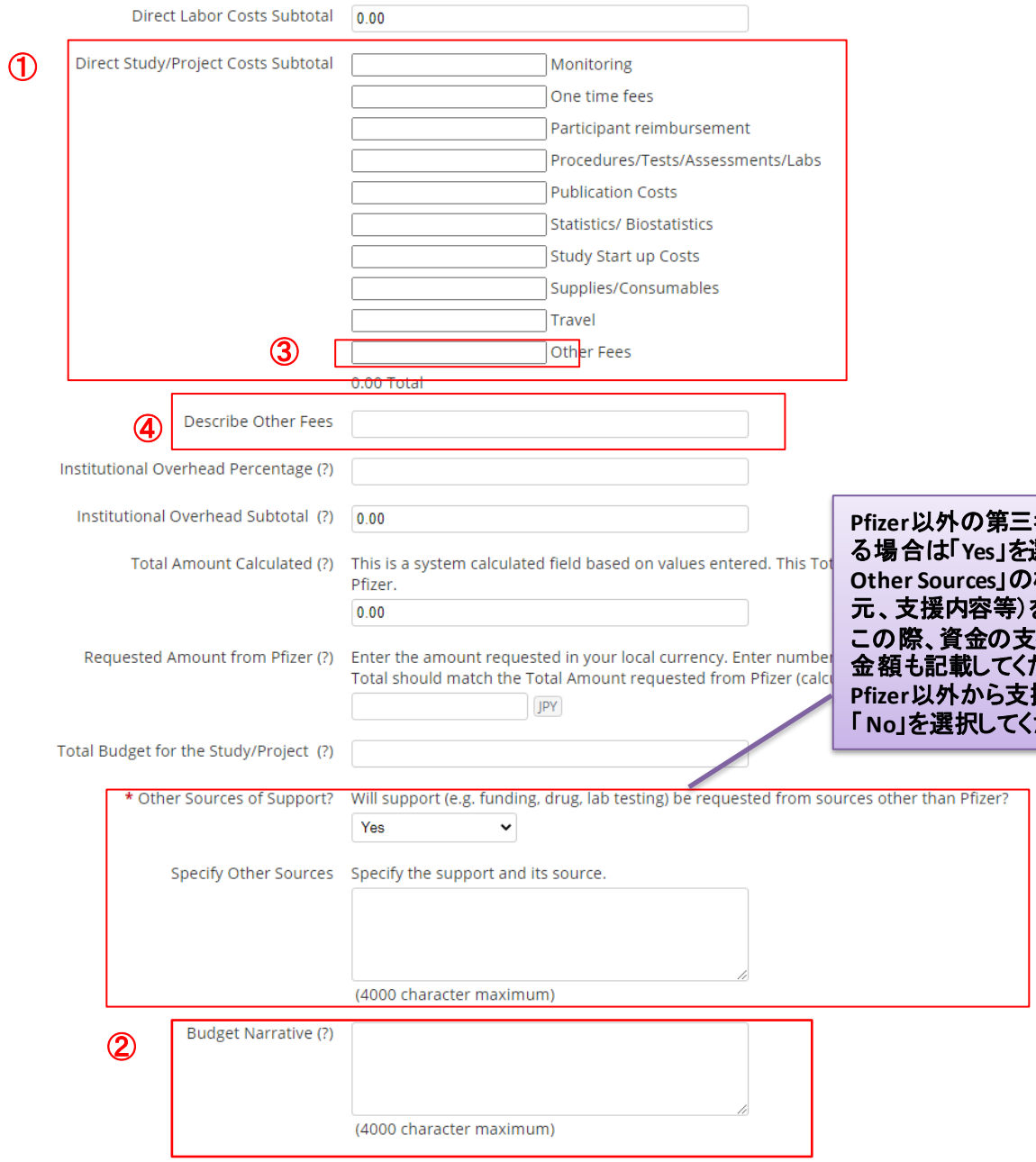
- 申請費用の情報を入力するページです
- (?)をクリックすると、その項目の説明が表示されます



- **費用をリクエストするRole項目にチェックを入れてください**
- **各項目に関する詳細(単価、必要な期間等)を要求する欄が表示されますので、それらの情報も入力ください**

注:システム上Primary Investigator, Sub PI, Post Doc及びFellowの予算入力が可能となっていますが、日本においては「医療用医薬品製造販売業公正競争規約」の観点より、医療担当者には報酬・謝礼を支払うことが出来ません。

Budget Details-2



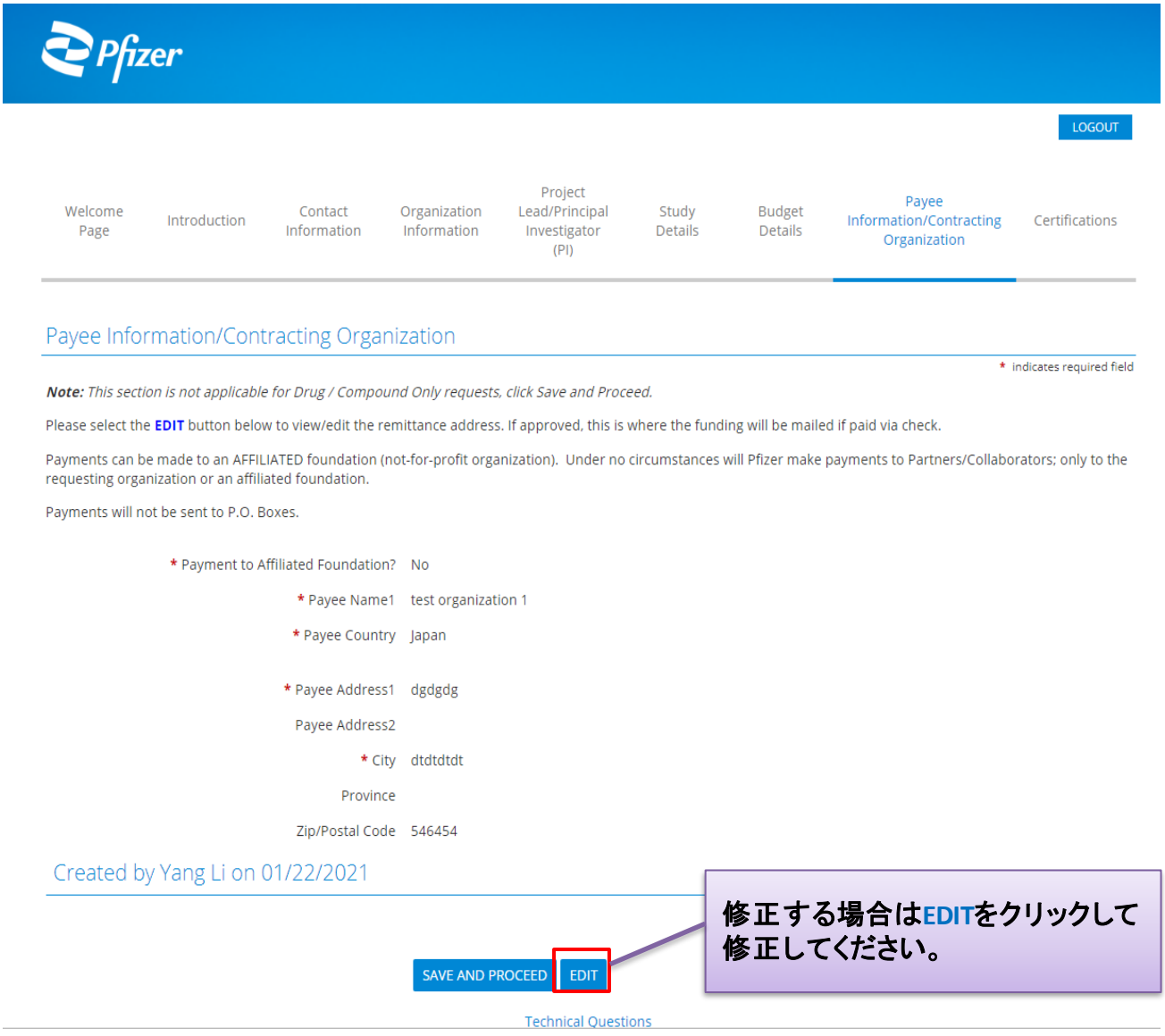
Pfizer以外の第三者からも支援を受ける場合は「Yes」を選択し、「Specify Other Sources」の欄にその概要（支援元、支援内容等）を記載してください。
この際、資金の支援を受ける場合は金額も記載してください。
Pfizer以外から支援を受けない場合は「No」を選択してください。

- 「Direct Study/Project Costs Subtotal」下の各項目（①）について、ご申請金額の適切性判断の為に必要となりますので、各内訳を「Budget Narrative」（②）に具体的に記載ください。
- 「Direct Study/Project Costs Subtotal」（①）に関するFAQはこちら：FAQ
- 当てはまる予算が不明の場合は、「Other fees」（③）に金額をご記入の上、「Describe other fees」（④）に使途をご記入ください。

注：消費税法上、助成金は消費税の課税対象外とされていることより、ご申請いただいた金額に消費税を上乗せしての支払いはできませんことにご留意ください。
消費税の課税対象となる物品購入や業務委託契約に対して、消費税を含めた支援を希望される場合は、消費税を加味した金額にて申請ください。

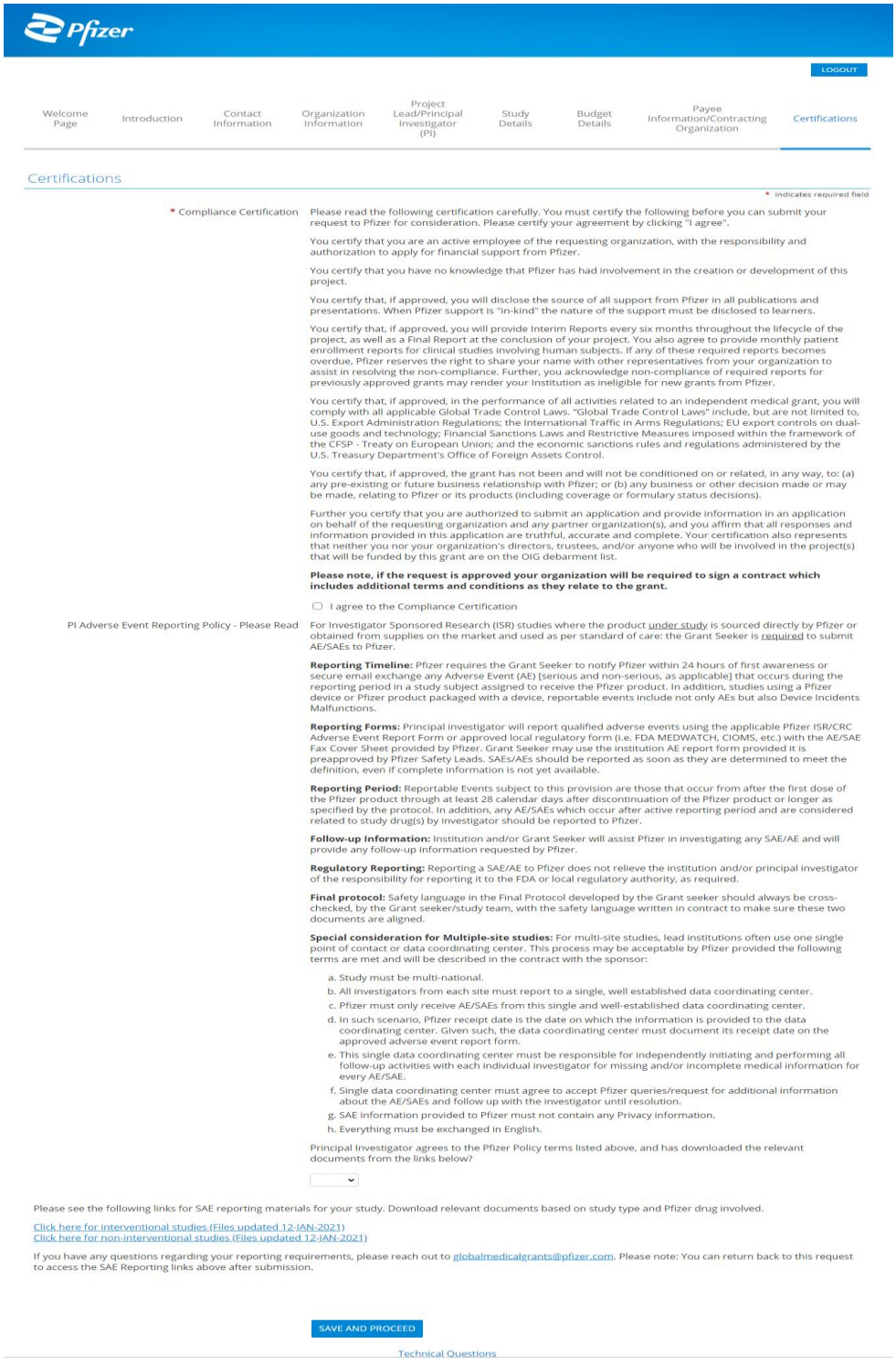
Payee Information/ Contracting Organization

- 支払および契約施設の情報を確認するページです



Certifications

- ISRに関するTerms and Conditionや有害事象報告について requirementの確認と承認をするページです



Pfizer

LOGOUT

Welcome Page | Introduction | Contact Information | Organization Information | Project Lead/Principal Investigator (PI) | Study Details | Budget Details | Payee Information/Contracting Organization | Certifications

Certifications

* Indicates required field

*** Compliance Certification**

Please read the following certification carefully. You must certify the following before you can submit your request to Pfizer for consideration. Please certify your agreement by clicking "I agree".

You certify that you are an active employee of the requesting organization, with the responsibility and authorization to apply for financial support from Pfizer.

You certify that you have no knowledge that Pfizer has had involvement in the creation or development of this project.

You certify that, if approved, you will disclose the source of all support from Pfizer in all publications and presentations. When Pfizer support is "in-kind" the nature of the support must be disclosed to learners.

You certify that, if approved, you will provide Interim Reports every six months throughout the lifecycle of the project, as well as a Final Report at the conclusion of your project. You also agree to provide monthly patient enrollment reports for clinical studies involving human subjects. If any of these required reports becomes overdue, Pfizer reserves the right to share your name with other representatives from your organization to assist in resolving the non-compliance. Further, you acknowledge non-compliance of required reports for previously approved grants may render your Institution as ineligible for new grants from Pfizer.

You certify that, if approved, in the performance of all activities related to an independent medical grant, you will comply with all applicable Global Trade Control Laws. "Global Trade Control Laws" include, but are not limited to, U.S. Export Administration Regulations; the International Traffic in Arms Regulations; EU export controls on dual-use goods and technology; Financial Sanctions Laws and Restrictive Measures imposed within the framework of the CFSP - Treaty on European Union; and the economic sanctions rules and regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control.

You certify that, if approved, the grant has not been and will not be conditioned on or related, in any way, to: (a) any pre-existing or future business relationship with Pfizer; or (b) any business or other decision made or may be made, relating to Pfizer or its products (including coverage or formulary status decisions).

Further you certify that you are authorized to submit an application and provide information in an application on behalf of the requesting organization and any partner organization(s), and you affirm that all responses and information provided in this application are truthful, accurate and complete. Your certification also represents that neither you nor your organization's directors, trustees, and/or anyone who will be involved in the project(s) that will be funded by this grant are on the OIG debarment list.

Please note, if the request is approved your organization will be required to sign a contract which includes additional terms and conditions as they relate to the grant.

☐ I agree to the Compliance Certification

PI Adverse Event Reporting Policy - Please Read

For Investigator Sponsored Research (ISR) studies where the product under study is sourced directly by Pfizer or obtained from supplies on the market and used as per standard of care: the Grant Seeker is required to submit AE/SAEs to Pfizer.

Reporting Timeline: Pfizer requires the Grant Seeker to notify Pfizer within 24 hours of first awareness or secure email exchange any Adverse Event (AE) [serious and non-serious, as applicable] that occurs during the reporting period in a study subject assigned to receive the Pfizer product. In addition, studies using a Pfizer device or Pfizer product packaged with a device, reportable events include not only AEs but also Device Incidents Malfunctions.

Reporting Forms: Principal investigator will report qualified adverse events using the applicable Pfizer ISR/CRC Adverse Event Report Form or approved local regulatory form (i.e. FDA MEDWATCH, CIOMS, etc.) with the AE/SAE Fax Cover Sheet provided by Pfizer. Grant Seeker may use the institution AE report form provided it is preapproved by Pfizer Safety Leads. SAEs/AEs should be reported as soon as they are determined to meet the definition, even if complete information is not yet available.

Reporting Period: Reportable Events subject to this provision are those that occur from after the first dose of the Pfizer product through at least 28 calendar days after discontinuation of the Pfizer product or longer as specified by the protocol. In addition, any AE/SAEs which occur after active reporting period and are considered related to study drug(s) by investigator should be reported to Pfizer.

Follow-up Information: Institution and/or Grant Seeker will assist Pfizer in investigating any SAE/AE and will provide any follow-up information requested by Pfizer.

Regulatory Reporting: Reporting a SAE/AE to Pfizer does not relieve the institution and/or principal investigator of the responsibility for reporting it to the FDA or local regulatory authority, as required.

Final protocol: Safety language in the Final Protocol developed by the Grant seeker should always be cross-checked, by the Grant seeker/study team, with the safety language written in contract to make sure these two documents are aligned.

Special consideration for Multiple-site studies: For multi-site studies, lead institutions often use one single point of contact or data coordinating center. This process may be acceptable by Pfizer provided the following terms are met and will be described in the contract with the sponsor:

a. Study must be multi-national.
b. All investigators from each site must report to a single, well established data coordinating center.
c. Pfizer must only receive AE/SAEs from this single and well-established data coordinating center.
d. In such scenario, Pfizer receipt date is the date on which the information is provided to the data coordinating center. Given such, the data coordinating center must document its receipt date on the approved adverse event report form.
e. This single data coordinating center must be responsible for independently initiating and performing all follow-up activities with each individual investigator for missing and/or incomplete medical information for every AE/SAE.
f. Single data coordinating center must agree to accept Pfizer queries/request for additional information about the AE/SAEs and follow up with the investigator until resolution.
g. SAE information provided to Pfizer must not contain any Privacy information.
h. Everything must be exchanged in English.

Principal Investigator agrees to the Pfizer Policy terms listed above, and has downloaded the relevant documents from the links below?

Please see the following links for SAE reporting materials for your study. Download relevant documents based on study type and Pfizer drug involved.

Click here for interventional studies (Files updated 12-JAN-2021)
Click here for non-interventional studies (Files updated 12-JAN-2021)

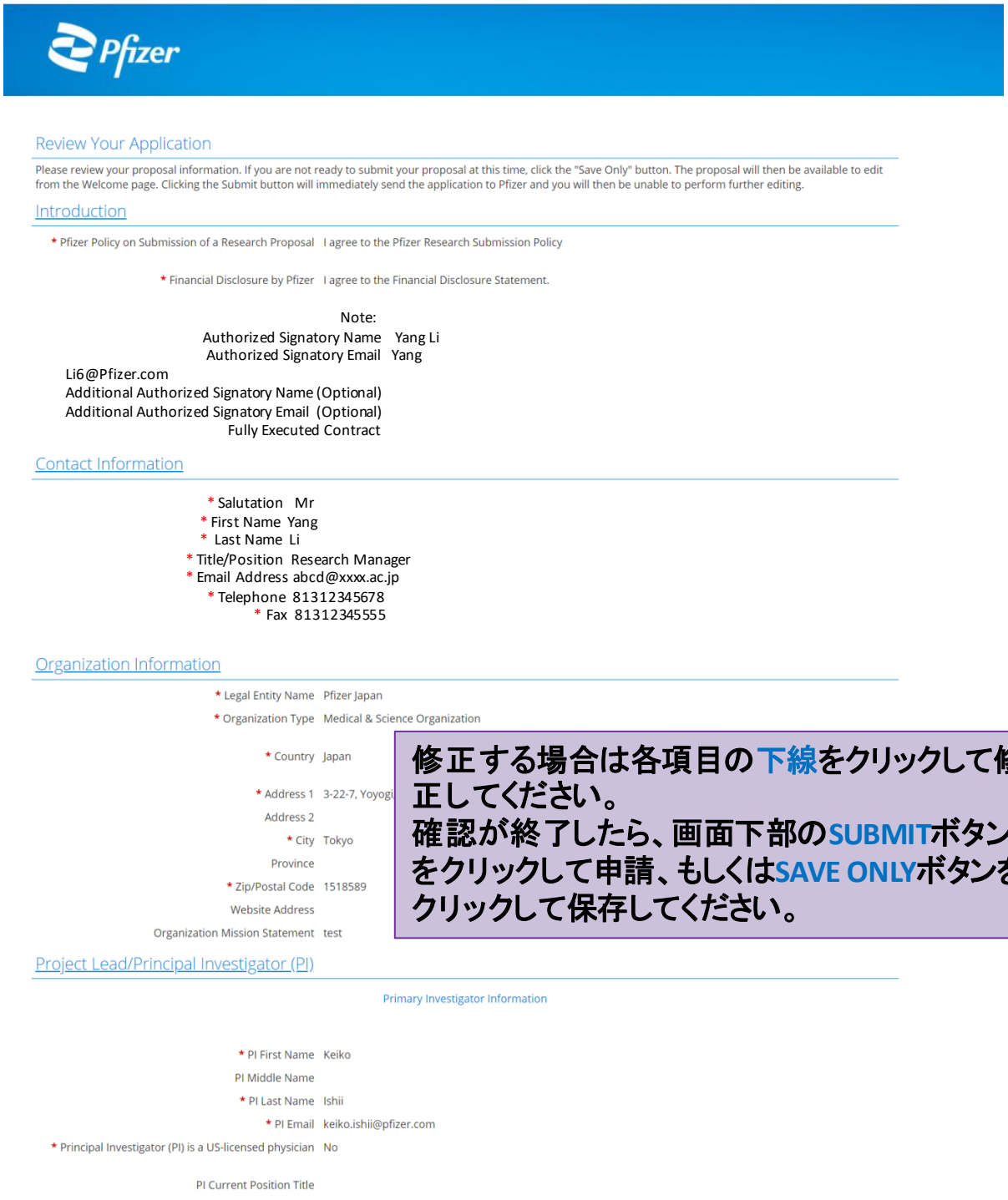
If you have any questions regarding your reporting requirements, please reach out to globalmedicalgrants@pfizer.com. Please note: You can return back to this request to access the SAE Reporting links above after submission.

SAVE AND PROCEED

Technical Questions

Certifications

- 今まで入力した申請情報を確認、申請/保存するページです



Review Your Application

Please review your proposal information. If you are not ready to submit your proposal at this time, click the "Save Only" button. The proposal will then be available to edit from the Welcome page. Clicking the Submit button will immediately send the application to Pfizer and you will then be unable to perform further editing.

Introduction

* Pfizer Policy on Submission of a Research Proposal I agree to the Pfizer Research Submission Policy

* Financial Disclosure by Pfizer I agree to the Financial Disclosure Statement.

Note:
Authorized Signatory Name Yang Li
Authorized Signatory Email Yang Li6@Pfizer.com
Additional Authorized Signatory Name (Optional)
Additional Authorized Signatory Email (Optional)
Fully Executed Contract

Contact Information

* Salutation Mr
* First Name Yang
* Last Name Li
* Title/Position Research Manager
* Email Address abcd@xxxx.ac.jp
* Telephone 81312345678
* Fax 81312345555

Organization Information

* Legal Entity Name Pfizer Japan
* Organization Type Medical & Science Organization
* Country Japan
* Address 1 3-22-7, Yoyogi
Address 2
* City Tokyo
Province
* Zip/Postal Code 1518589
Website Address
Organization Mission Statement test

修正する場合は各項目の下線をクリックして修正してください。
確認が終了したら、画面下部のSUBMITボタンをクリックして申請、もしくはSAVE ONLYボタンをクリックして保存してください。

Project Lead/Principal Investigator (PI)

Primary Investigator Information

* PI First Name Keiko
PI Middle Name
* PI Last Name Ishii
* PI Email keiko.ishii@pfizer.com
* Principal Investigator (PI) is a US-licensed physician No
PI Current Position Title