COLUMBIA UNIVERSITY
GDPR & HUMAN SUBJECTS RESEARCH

GDPR QUESTIONNAIRE

1. Background and Instructions

Please answer the following questions to enable Columbia University, Office of the General Counsel ("OGC") to assist you with determining whether the EU General Data Protection Regulation ("GDPR") applies to your human subjects research study. The GDPR is a European privacy and data protection law that went into effect on May 25, 2018. For your reference, please find a list of EEA countries at Appendix A. Please feel free to provide OGC with additional written responses or documentation to supplement your answers.

2. Description of Proposed Study

Name: _____

Location of Proposed Study:

_____

Brief Summary of Proposed Study:

_____
_____
_____

Name and Location of Study Sponsor:

_____

Name and Location of Principal Investigator (office contact information):

_____

3. Location of Research

a. Is Columbia the study sponsor?

Yes ☐ **No** ☐

b. If Columbia is the study sponsor, then:

1) Does Columbia have offices in the EEA involved in the research study (*e.g.*, a central data management organization, or a system managed from an EEA-based establishment)? **Yes** ☐ **No** ☒
2) Will Columbia carry out a clinical trial intended to support a marketing authorization filing in the EEA? **Yes** ☐ **No** ☐

3) Has Columbia hired a full service contract research organization ("CRO") established in the EEA to support the study and/or design the purpose of the study?

Yes ☐ **No** ☐

If "yes," then describe the CRO's role: _____

_____

c. If Columbia is not the study sponsor, then please provide contact information of the study sponsor, including the study sponsor's name, office address, email address and phone number:

Sponsor Name: _____

Address: _____

E-mail Address: _____

Phone: _____

4. <u>Status of Research Subject</u>

a. Will Columbia collect or use the personal data of research subjects who are *located in the EEA at any time of data collection* (regardless of research subject's country of residence or citizenship)?

Yes ☐ **No** ☐

b. Will Columbia collect or use the personal data of research subjects who are located in the United States or another country outside of the EEA?

Yes ☐ **No** ☐

If "yes," then indicate the country: _____

5. Offering a Good or Service

a. Does Columbia actively recruit or target research subjects who are located in an EEA country in connection with the research study?

Yes ☐ **No** ☐

b. Does Columbia offer or provide any of the following goods or services to research subjects who are located in an EEA country in connection with the research study?

1) Investigational product used in a clinical trial **Yes** ☐ **No** ☐
2) Diagnoses **Yes** ☐ **No** ☐
3) Medical advice **Yes** ☐ **No** ☐
4) Other health care treatment-related services **Yes** ☐ **No** ☐
5) Other **Yes** ☐ **No** ☐

If "other," then describe: _____

c. Does Columbia does have patient referral arrangements with health care providers located in the EEA?

Yes ☐ **No** ☐

d. Does Columbia intend to offer goods and services (such as those identified in Section 5(b) above) to research subjects located in the EEA at any point in the future?

Yes ☐ **No** ☐

e. Does Columbia advertise investigational products or the study to an EEA audience (including, but not limiting to, by paying a search engine to facilitate access in the EEA?)

Yes ☐ **No** ☐

f. Does Columbia's website for the study include any of the following?

1) Contact information for persons or locations in the EAA **Yes** ☐ **No** ☐
2) An EAA domain name (*e.g.* .eu, .de) **Yes** ☐ **No** ☐
3) Translations of website text to EAA languages **Yes** ☐ **No** ☐
4) Acceptance of payment in Euros or other EEA currency **Yes** ☐ **No** ☐

6. Monitoring of Research Subjects' Behavior

a. Will Columbia monitor the behavior of research subjects located in an EEA country through an app or any other use of wearable or smart devices (*e.g.*, cell phones, tablets, or other electronic devices)?

Yes ☐ **No** ☐

If "yes," then describe: _____

b. Will Columbia use cookies or other online tracking tools to monitor the online behavior of research subjects located in the EEA who may use a website related to the research study?

Yes ☐ **No** ☐

c. Will Columbia monitor the effects of a particular investigational medicinal product that has been used on research subjects located in the EEA during the course of the study by doing any of the following?

1) Speaking with the research subjects while they are located in the EEA **Yes** ☐ **No** ☐
2) Reviewing reports submitted by the research subjects while they are located in the EEA **Yes** ☐ **No** ☐
3) Reviewing reports submitted by research subjects' health care providers while the research subjects are located in the EEA **Yes** ☐ **No** ☐
4) Other **Yes** ☐ **No** ☐

If "other," then describe: _____

7. Additional Considerations

Are there additional facts or considerations you would like to bring to the attention of Columbia's OGC? If so, please describe them below.

_____
_____
_____
_____
_____
_____
_____
_____

8. Your Information

Please provide information that will allow Columbia's OGC to contact you regarding this form.

Name: _____

Title: _____

Department: _____

Phone: _____

Email: _____

***

Appendix A

European Economic Area (EEA) Member States[1]

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
31. United Kingdom

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