PERSONAL INFORMATION PRIVACY POLICY
(RESEARCH – PARTICIPANT CONSENT)

Information for those concerned,

Data collected from you will be processed according to the following principles: lawfulness, fairness and transparency; purpose limitation; data minimisation; accuracy; storage limitation; integrity and confidentiality.

UNIVERSITA' COMMERCIALE "LUIGI BOCCONI" (hereinafter referred to as "Bocconi University"), having its registered office in Milano at via Sarfatti 25, hereby declares that it falls within the field of application General Data Protection Regulation n. 679/2016 dealing with the protection of personal data (hereinafter referred to as the "Law"), with reference to the use of the data subject's personal data (hereinafter referred to as "Data") that is specifically indicated below.

Introduction

The purpose of this documents is to provide you all information necessary in order to decide whether you want to participate in this very research project.

- **Research title:** Investigating attitudes to surrogate evidence in health technology assessment: a binary choice experiment pilot
- **Type of project:** This study is part of an European Union funded project called COMED (Pushing the boundaries of Cost and Outcome analysis of MEDical Technologies)
- **Project founders:** Dr Oriana Ciani (oriana.ciani@unibocconi.it), Prof Aleksandra Torbica (aleksandra.torbica@unibocconi.it) from Bocconi University, leader in the COMED project.
- **Project partners:** Prof Rod Taylor (Rod.Taylor@glasgow.ac.uk) from Glasgow University, Dr Bogdan Grigore (b.grigore@exeter.ac.uk) from Exeter University, both partner institutions in the COMED project.
- **Research coordinator:** Dr Oriana Ciani (oriana.ciani@unibocconi.it)
- **Purpose of Research:** As part of the COMED (Pushing the boundaries of Cost and Outcome analysis of MEDical Technologies) Project, we sought out to explore how the decision-making process in health technology assessment (HTA) is impacted by the use of surrogate endpoint evidence. Our previous work within COMED showed that, despite surrogate

endpoints having a varying significance for different stakeholder groups, there is a clear universal need for a more unified understanding of the role and methods of validation of surrogate endpoints by healthcare policy makers. In order to further explore and quantify this need, we propose to use a binary choice experiment methodology.

We intend to undertake a full definitive choice experiment study on the use of surrogate endpoints with various HTA stakeholder groups including regulators, payers, clinicians and researchers. Before undertaking such a full study, we seek to test the feasibility of our approach in a pilot study.

- **Reasons for Data collection and Data collected:** We seek to undertake a definitive choice experiment study in several groups of stakeholders, including clinical/healthcare professionals, regulators involved in licensing, healthcare commissioners, health technology manufacturers, and other HTA/payer decision makers, as well as researchers. In preparation for such a study, we first seek to undertake a pilot to test the feasibility of participant recruitment and logistics of designing and conducting a choice experiment on the use of surrogate endpoints.

  As a proxy for the main study, we intend to recruit for the pilot among postgraduate students and alumni from the Bocconi University Master Programme in International Healthcare Management, Economics and Policy (MIHMEP) studying health economics, because there is a good overlap of the programme curriculum with the expert profile sought.

- **Details of Participation:** The exercise involves you reading two hypothetical scenarios each of which requires you to give your view on the strength of evidence for the validity of a surrogate endpoint and whether you would fund a technology based on this evidence. Before completing these two scenarios, we will ask you some brief demographic questions about yourself, seven attitudinal questions about the use of healthcare evidence and, at the end of this exercise, we would like your views on how you found undertaking this exercise. We anticipate that the completion of the scenarios and questions will take you about 15 minutes in total.

  Your data from this project will be treated anonymously. This process will be subject to appropriate safeguards to protect the security and confidentiality of your data. Only aggregate results for the study will be reported. All data will be held securely for up to 5 years.

- **Modality of Data processing:** Data will be aggregated using statistical methods. Any information you provide as text will be read by the researchers.

- **Risks and Benefits of participation:** There are no foreseeable risks to you participating in the study.
- **Data Sharing:** Only the study research team (Dr Ciani, Prof Torbica, Prof Taylor and Dr Grigore) will have access to collected data.
- **Data transfers to third countries:** Data may be stored in Italy and the United Kingdom. Data about you collected for the purposes of this project and similar future projects may be transferred to and stored at a destination outside the European Economic Area ("EEA"), for example where it is processed by an organisation operating outside the EEA who works for us or for one of our suppliers, or where personal data is processed by one of our suppliers who is based outside the EEA or who uses storage facilities outside the EEA. This process will be subject to appropriate safeguards to protect the security and confidentiality of your Data.
- **Security measures:** Study data will be held securely on password-protected computers, only available to the research team.
- **Methods of pseudonymisation or anonymization:** No directly identifying information (such as name or contact details) will be kept with the rest of the collected data or shared within the research team. Participant identifying information will be held securely on a password-protected computer, backed up on a secure server located at the University of Exeter (United Kingdom).
- **Methods of publication**: Aggregate results will be shared with the study funder (the European Commission) and disseminated in Open Access publications. All Data published will be anonymized.

Data Subject's Rights

Data subjects shall have the following rights:

- to require correcting the personal data we hold about you if it is incorrect;
- to require erasing your personal data;
- to require restricting our data processing activities (and, where our processing is based on your consent, you may withdraw that consent, without affecting the lawfulness of our processing based on consent before its withdrawal);
- to receive from us the personal data we hold about you which you have provided to us, including for the purpose of you transmitting that personal data to another data controller;
- to object, on grounds relating to your particular situation, to any of our particular processing activities where you feel this has a disproportionate impact on your rights.

Please note that the above rights are not absolute, and we may be entitled to refuse requests where exceptions apply. Consider the following in particular:

- the right to erasure shall not apply when it is likely to render impossible the achievement of the research purposes;
- the right to object may not apply when research is carried out for reasons of public interest.

If you have given your consent and you wish to withdraw it, please contact the responsible of the relevant department using the contact details set out below. Please note that where our processing of your personal data relies on your consent and where you then withdraw that consent, its withdrawal shall not cause any effect in the lawfulness of the previously processed Data.

Copyright Statement

Within the context of the research project, you consent that Bocconi University and the researcher edits, copies, archives, disseminates and publishes your contribution to the project. Moreover, in accepting to participate in the project you expressly waive potential copyrights that could emerge from the result of the project, granting Bocconi University and the researchers involved a non-exclusive, free, irrevocable and worldwide license to use your contribution for the purposes indicated below.

If you wish to be aware of the results of the projects, the researcher will make all reasonable steps to inform you, when privacy or other legal concerns do not impede to do so.

Contact us

If you have any queries about this privacy notice or how we process your personal data, you can contact our Data Protection Officer at the following e-mail address: dpo@unibocconi.it

Research Participant Declaration

I confirm that I received the information that precedes, and I declare having read and understood its content. Taking note that my Data are processed in full compliance with the Law, I freely consent to my Data to be used in the manner and uses described previously. Additionally, I also waive whichever copyrights or other Intellectual Property Rights that may

emerge of the research project in the manner indicated below. I also declare having understood my rights and limitations, as well as the procedure to exercise them.

(Participant email address)

(Date)