Informed Consent, Team Datenschutz der TU Berlin, Version vom 5.1.2023

**Title of Research Project: PRUDENT - Prioritization, incentives and Resource use for sUstainable DENTistry**

**Principal Investigator:** Dr. Ruth Waitzberg, [ruthw@jdc.org](mailto:ruthw@jdc.org)

**Co Investigators:** Lukas Schöner, Beatrice Durvy

**Sponsor/Funding:** the European Union, HORIZON2020

**Project Duration:** Jan. 2023 – Dec. 2028

**1.Project Description:**

**Background & Purpose of Research:** PRUDENT is a research study conducted by Department of Health Care Management, TU Berlin in collaboration with international partners across the EU. PRUDENT aims to develop and implement an innovative and context-adaptive framework for public coverage and optimized financing of oral care. It brings together top investigators from prestigious universities, public authorities and policymakers, civil society and patient organizations, health insurers, and health professionals, to achieve a step change in collective problem solving. As part of the study, we are conducting focus group discussions with key informants.

**Invitation to participate:** You are being invited to participate in a focus group discussion as part of PRUDENT. This focus group discussion aims to learn the perspectives of different stakeholders such as the general population and oral health professionals on “essential oral health care”. The ultimate goal is to build consensus on public preferences on oral health care coverage.

**Procedures**: If you decide to enrol in this study, you will participate in a focus group discussion, semi-structed in person or virtual (i.e., Microsoft Teams or Zoom) conducted by members of the research team. The focus group discussions will last approximately 1.5 hours.

**Voluntary Participation & Early Withdrawal:** Your participation in this study is voluntary. You can choose not to participate or refuse to answer a question, or withdraw at any time without penalty or loss of benefits to you. **If you wish to withdrawal from the study, you’re data may still be used, unless you tell us otherwise.**

**Risks:** We do not foresee any risks.

**Benefits:**

You will be supporting an impactful EU project that aims to improve the coverage of oral health across European countries. Your participation helps to develop potentially broader coverage of and improved access to oral health services in the future. Participating in a large-scale EU project offers a unique opportunity to be part of macro-level decision-making, develop skills and gain exposure to EU initiatives. You can actively contribute your insights, experiences, and concerns related to oral health coverage and, with this, have a direct impact on policy decisions that affect your own oral health and that of your communities.

**2. Information on the Planned Data Processing / Rights of Participants**

The data generated as part of the project will be processed as follows:

* Conversations will be recorded using a dictation device.
* The audio recordings will be pseudonymized and stored on the secured servers of the Technische Universität Berlin.
* The audio recordings will be securely and irreversibly deleted from the dictation device.
* Access to the audio recordings will be restricted to project staff.
* The interview audio recordings will be transcribed in an anonymized form, and the transcripts will be pseudonymized. This means that all personally identifiable information will be anonymized to prevent any identification of individuals.
* The consent forms, contact information, translation key (pseudonymization), and the original audio recordings will be securely stored and kept separate from each other, ensuring that third parties cannot associate individuals with the audio recordings.
* The translation key will be deleted once the purpose of the research project allows it, which will be by December 31, 2028, thereby fully anonymizing the data. The consent forms with contact information will also be deleted at that time.
* The audio recordings and transcripts will be retained on the secured servers of the Technische Universität Berlin for ten years, in accordance with the guidelines for good scientific research, and then securely and irreversibly deleted.
* No data will be shared with third parties.
* The analysis and evaluation of the interviews will be based on the anonymized transcripts. The results may be used for scientific publications, including presentations at conferences and other scholarly publications. Only anonymized research findings that do not allow for identification of individuals will be published. Individual anonymized quotations may be included in publications.
* The anonymized transcripts may be archived and made available to other researchers.
* All project staff with access to personally identifiable data are bound by confidentiality and obligated to maintain data secrecy.
* Your consent to participate in the interview is voluntary. You will not face any disadvantages for choosing not to participate, and you may also refuse to answer specific questions.

According to the General Data Protection Regulation (DSGVO), you have the following rights:

* Confirmation of whether personal data concerning you is being processed (Article 15 DSGVO).
* Access to this data and information about the processing (Article 15 DSGVO).
* Correction of any inaccurate data (Article 16 DSGVO).
* Deletion of data if processing is no longer justified or required (Article 17 DSGVO).
* Restriction of processing in certain legally defined cases (Article 18 DSGVO).
* Transmission of your personal data, if provided by you, to yourself or a third party in a structured, commonly used, and machine-readable format (Article 20 DSGVO).
* Termination of processing and deletion of data that have already been generated after revocation of your consent (Article 21 DSGVO).

Please note that revocation can only occur until complete anonymization, as we will no longer be able to associate your data or delete it afterwards.

This project is in compliance with the data protection regulations of the Technische Universität Berlin. If you have any concerns regarding data protection in the project, please contact the project coordinators directly or:

Data Protection Officer of Technische Universität Berlin

Annette Hiller, K3-DS,

Straße des 17. Juni 135, 10623 Berlin,

E-Mail: [info@datenschutz.tu-berlin.de](mailto:info@datenschutz.tu-berlin.de)

If you have any reason for complaint, you can also contact the responsible supervisory authority:

Berlin Commissioner for Data Protection and Freedom of Information

Alt–Moabit 59–61,10555 Berlin

E-Mail: [mailbox@datenschutz-berlin.de](mailto:mailbox@datenschutz-berlin.de)

**Publication of Research Findings:** We will be preparing manuscripts for publication.

**Compensation:** In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities.

Participants will receive reasonable compensation for expenses and time.

**3. Consent to Data Processing**

Within the scope of the above-described project, we would like to process your personal data. Participation in the project is voluntary and is solely for scientific purposes. Therefore, we require your consent under Art. 6 Absatz 1 Nr. 1 der Europäischen Datenschutz-Grundverordnung (DSGVO).