

## TAND Toolkit App Privacy Policy

### TANDem-2: Closing the gap to interventions for TAND

#### 1. About the TANDem-2 Project

Thank you for participating in this research. In TANDem-2 we will use the TAND Toolkit App to collect data from research participants, and use this data to examine longitudinal trajectories of TAND severity and its predictors, and to study caregiver wellbeing factors as mediators of TAND severity and TAND severity trajectories. This project is collaborative research by the University of Cape Town (UCT), South Africa, and the Vrije Universiteit Brussel (VUB), Belgium, in participation with the TAND consortium, a group of professionals and lived experts in Tuberous Sclerosis Complex (TSC) from many institutions around the world. UCT and VUB have joint responsibility (referred to as “the joint controllers”) of all research data and will therefore be responsible for the privacy and confidentiality of your information.

As is the case with all academic research, the TANDem-2 project also involves the processing of your personal data. This Privacy Policy explains how we handle your personal data, the questions and services you can request from us, and provides further information regarding privacy and data protection at both universities. Both universities take your privacy rights very seriously and process your data according to the principles stipulated by the new European General Data Protection Regulation (GDPR) that entered into force on 25 May 2018, as well as the South African data protection legislation, the Protection of Personal Information (POPI) Act of 1 July 2021.

#### 2. About the TAND Toolkit App

TAND is the term for ‘Tuberous Sclerosis Complex Associated Neuropsychiatric Disorders’. The TAND Toolkit App is intended to be used by individuals with Tuberous Sclerosis Complex (TSC) and families/caregivers of individuals with TSC, to identify their TAND profile of needs and to access a toolkit of self-help information. To start, the app will allow users to register in a secure way and to add a number of members to their ‘TSC Family’. Once registered, users will be able to capture a ‘TSC Story’ (information about their TSC diagnosis) for each TSC Family member; complete a self-report, quantified version of the TAND Checklist, called the ‘TAND-SQ’ (to identify and quantify the severity of TAND difficulties experienced); view their ‘TAND Clusters’ profile (that illustrates how different TAND clusters are affected); capture their ‘TAND Interventions’ (information about their treatments, interventions and supports for TAND); capture their ‘Wellbeing’ (information about their general wellbeing, resilience, worries and feelings); and view the ‘TAND Toolkit’. The TAND Toolkit will provide evidence-informed information about each cluster, including an introduction to the cluster, what should they seek (e.g. assessment, diagnosis, and treatment by a professional), and what can they do (e.g. self-help, home-based actions, strategies and interventions). The final component of the TAND Toolkit App is the ability to do ‘Surveys’ (to collect additional information from users about various aspects of TAND). The app can be used on Android and iOS mobile devices, and on computers.

#### 3. Protection of Personal Data

Both UCT and VUB attach great importance to the protection of your personal privacy. The universities reserve the right to make changes to the Privacy Policy if needed, to address the needs and requirements of society, to resolve technical issues, as well as abide by the relevant laws and regulations. For any such amendment, we will ask for your renewed consent before continuing the processing of your data.

#### **4. Guarantees for Processing of Personal Data**

UCT (with registered offices at Bremner Building, Lovers' Walk, Rondebosch, Cape Town, Western Cape, 7701, South Africa) and VUB (with registered offices at Pleinlaan 2, 1050 Elsenne, Belgium, KBO 0449.012.406), are jointly responsible for processing personal data of study participants in the TANDem-2 research project, which includes all 'User-Generated Content' collected by the TAND Toolkit App. The term 'User-Generated Content' is defined in the TAND Toolkit App Terms of Use; it refers to all data entered by the user when using the TAND Toolkit App, such as when registering a user profile, adding members to your TSC Family, completing a TSC Story, completing a TAND-SQ Checklist, capturing your TAND Interventions, capturing your Wellbeing, and submitting TAND-related Surveys. We process this data for different reasons, which we explain in detail in article 5. Your personal data is always treated in accordance with the applicable privacy regulations. Processing of personal data is limited to the intended objective, outlined in article 5. Personal data collected may be shared with our research partners at the University of Cape Town (UCT), Stellenbosch University (SU) in South Africa, and Oxford University (OU), for further data processing, as well as Esperity BV (Blv Brand Whitlock 108/1, 1200 Brussels, Belgium) who acts as the technical developer of the app. All data will be pseudonymised before sharing. Personal data will not be disclosed to third parties outside of our TANDem-2 research team and will not be used for direct marketing. We take the best possible security measures to prevent third parties from misusing your personal data.

#### **5. Personal Data and the Reasons for Processing**

##### **5.1 Personal data and data protection regulations**

The app will collect the following personal identifiers, first name, last name, and email address. The app will also collect year of birth, sex, preferred personal pronouns, and country. The app will not collect date of birth, address, mobile contact numbers or device serial numbers. It is essential to collect first name, last name and email address in order to personalise app user experience, to validate registered accounts, to enable users to reset their passwords, and to receive email notifications when their next step of data entry in the app needs to be completed.

All data collection, data management and data storage will be handled in strict compliance with the General Data Protection Regulation (GDPR) of the European Union. All data captured via the app will be stored as pseudonymised data on the app server.

##### **5.2 Internet protocol address**

When the application connects to our hosting servers to transmit data, the internet protocol (IP) address of the connecting device is temporarily logged. These IP addresses are not stored within the data management admin panel or the mobile application itself and cannot be linked to individual users or personal user data.

Although the application does not collect or process user-specific IP addresses, we use the temporarily logged IP addresses — which are not associated with any identifiable user information — solely for purposes of server security, application stability, and performance monitoring. For these operational and security purposes, IP addresses may be retained for a maximum period of 90 days, after which they are automatically deleted or anonymised. This processing is conducted in accordance with applicable data protection laws, including the General Data Protection Regulation (GDPR), and serves our legitimate interests in maintaining the integrity, availability, and security of the application.

### 5.3 What data will be collected?

#### 5.3.1 When registering as an app user

Information about the TANDem-2 project will be advertised on the tandconsortium.org website. Interested participants can click on the link to be taken to a secure webpage where they can register to use the TAND Toolkit App. Interested research participants will be prompted to read and accept the Study Information and Consent Form, Privacy Policy, and Terms of Use, to enter their first name, last name and email address, and to create a password, before an app user account will be registered. A validation link will be sent to the user's email address. Registration of an app user account is only finalised once the link in the email has been clicked, this is to ensure the integrity of each account. The app will collect basic personal and demographic information about the app users. This information includes your first name, last name, year of birth, sex, preferred personal pronouns, email address and country.

#### 5.3.2 When adding TSC members to 'My TSC Family'

You will be asked to enter basic personal and demographic information (first name, year of birth, sex, preferred personal pronouns, and country) for each individual with TSC in your family. Further questions may include level of education, employment status, income, living situation, family structure, support from your medical care team and social network, etc. The display of questions will depend on whether an adult with TSC is completing the questionnaires about themselves, or whether a family caregiver is completing the questionnaire about a child/adult dependent. The app user will be able to download a PDF summary of their data captured.

#### 5.3.3 When completing 'My TSC Story'

You will be asked to complete a 'TSC Story' for each TSC Family member. Information such as age of diagnosis with TSC, first concern that lead to a TSC diagnosis, physical signs and symptoms of TSC, seizures or epilepsy, genetic testing for TSC, and treatment with mTOR inhibitors, cannabidiol, or other treatments for physical signs and symptoms of TSC will be captured. These data will be used to create a profile of their/your TSC, to see how it relates to their/your TAND profile. The app user will be able to download a PDF summary of their data captured.

### 5.3.4 When completing ‘My TAND Checklist’

For each TSC Family member, the TAND-SQ Checklist will capture information regarding developmental milestones, level of language, behavioural difficulties, psychiatric diagnoses, intellectual ability, scholastic skills, brain skills, psychosocial impact on the individual with TSC and the caregiver, helpful strategies to manage TAND, and strengths and skills of the individual with TSC. The collected information will be used to create and analyse their/your TAND profile. The app user will be able to download a PDF summary of their data captured.

### 5.3.5 When completing ‘My TAND Interventions’

For each TSC Family member, information on different types of treatments, interventions and supports for various aspects of TAND will be captured, such as medications, psychological/talking/behavioural therapies, educational supports, social supports, and caregiver/family training and support. The app user will be able to download a PDF summary of their data captured.

### 5.3.6 When completing ‘My Wellbeing’

Information about the wellbeing of the individual with TSC, as well as the caregiver, will be captured in this section. Questions will cover topics of general wellbeing, resilience, worries, feelings and care/caregiving. The app user will be able to download a PDF summary of their data captured.

### 5.3.7 When submitting ‘My Surveys’

TAND surveys will be made available every now and then, and are not compulsory to complete. These TAND surveys will ask questions that help us to learn more about the identification and treatment of TAND difficulties. The app user will be able to download a PDF summary of their data captured.

### 5.3.8 When the user decides to ‘Contact Us’

The app user is able to ‘Contact Us’ by submitting an app-related support request via the app if they are experiencing a problem with the app functionality. The data management team can view and respond to this problem from the admin panel. First name, last name and email address will be processed for support request reasons, in order to respond to queries.

## 5.4 App notifications

App users will receive periodic email and in-app notifications where users will be reminded to enter their next step of data collection. There will be five main data collection steps over the period of one year where users are required to complete all components mentioned in article 5.3. On mobile devices, the app will only be able to access notifications and sharing functionality; location and contacts will not be accessed. Email or in-app notification reminders will be used to notify the app user when, for instance, their new data entry step is required, or when a new survey is available to complete. The app user is able to download PDF summaries of their data captured in the app, and is able to share a PDF using the built-in share functionality of the device – this is external to the app, no information such as email addresses or mobile numbers will be stored by the app.

### 5.5 How long will your data be stored for?

All app data will be stored and encrypted on your device (in the absence of internet connection) and on our servers (as soon as the data is transferred to the servers when internet connectivity becomes available). Pseudonymised data (linked to a unique user code) and will be stored for a minimum of 20 years, after which the data may be anonymised (all personal identifiers will be removed) and stored indefinitely for archiving and scientific research purposes. You have the right to delete your app account and all data collected, this can be done using the app.

### 6. Prior Consent as Legal Basis

The legal basis for the processing of your data is consent, as defined in art. 4.11 and 6.1.a [GDPR](#). Prior to starting the processing of your data, we inform you thoroughly on the terms of processing and, based on such terms, we ask for your prior, explicit, free, unambiguous, active, informed and revocable consent. Once you have given your consent to the processing of your data, you may revoke your consent at any time, without affecting the legitimacy of our processing of your data before such revocation. You may execute your right to revoke your consent by contacting us on the details stated in article 8.

When reporting a problem, as described in art. 5.3.8, the legal ground for processing of your personal data is our legitimate interest. This legitimate interest is our commitment to support you when facing technical difficulties, to detect bugs and errors and to enhance security and the proper functioning of the TAND Toolkit App for all of our participants.

### 7. Storage of Your Personal Data

During registration, personal identifiable data will be captured (such as first name, last name and email address) and will be securely transmitted to a server where these data will be hashed or encrypted. Whenever data are uploaded to our servers, it is pseudonymised — meaning your name, email, and other directly identifying information are removed and replaced with a unique code — before being stored on our web servers. Pseudonymised data (linked to a unique user code) and will be stored for a minimum of 20 years, after which the data may be anonymised (all personal identifiers will be removed) and stored indefinitely for archiving and scientific research purposes. At any moment you can request a copy of the data that is stored, but once your data has been anonymised and aggregated for research purposes, it can no longer be linked back to you and cannot be deleted. The aggregated and anonymised results of your data may be used in scientific publications, conferences, or other public communications relating to TANDem-2 research. You will not be personally identifiable in any such outputs.

For storage, we apply the following protection and security measures:

- Data storage on your device is secured in accordance with your own personal security settings. The TAND Toolkit App itself is username and password protected, and multifactor authentication can be activated within the app.
- In the case where mobile apps are used, all data on the latest Apple devices and on most Android operated devices are encrypted.
- Data are sent from your device to our GDPR compliant web servers through encrypted and secured HTTPS API protocols.
- Data are treated confidentially.
- For analysis purposes, researchers may download the data to secure local storage environments. This data is provided in an aggregated and anonymised format, meaning the unique codes are removed, and it is no longer possible to trace the data back to any individual. For research purposes, the relationship between answers to the questions in the app will be kept to understand how data is linked to each other.
- Access to the data is limited to:
  - Yourself, when data are identifiable and stored on your device.
  - UCT, VUB, and Esperity bv (the app developer, on a need-to-access basis for technical support and with proper safeguards), in pseudonymised format when transferred to our GDPR compliant web servers.
  - UCT, VUB, SU, and OU when data are aggregated and anonymised, and transferred to our local secure storage solution.
- Security measures are revised and updated from time to time. Scientific research codes of conduct of UCT and VUB apply, including a duty to observe confidentiality of your data.

The technical implementation, hosting, and maintenance of the TAND Toolkit App is provided by Esperity bv. Esperity processes data strictly under instruction of the joint controllers and complies with GDPR Article 28 obligations. Esperity employs state-of-the-art encryption, multi-factor authentication, and regular security monitoring. All personal data is pseudonymised and stored in secure EU-based servers (OVH).

## 8. Your Rights

We would like to make sure that you are fully aware of all your data protection rights. Please be advised that you have full control of all your data stored on the servers of the TAND Toolkit App. You can withdraw from the study at any time by deleting your app user account by clicking on the 'Delete account' option in the app settings. Please note that if you wish to delete all your data, including data already collected, you must *contact us before deleting your account*. You can submit this request to the project principal investigators, Prof. Anna Jansen ([anna.jansen@vub.be](mailto:anna.jansen@vub.be)) and Prof. Petrus de Vries ([petrus.devries@uct.ac.za](mailto:petrus.devries@uct.ac.za)), and copy the Data Protection Officer at Vrije Universiteit Brussel ([dpo@vub.be](mailto:dpo@vub.be)). If you delete your account without notifying us in advance, your personal identifiers (such as your first name, last name, and email address) will be permanently deleted, but the data already collected through the app will be retained and used for research purposes. Once your account is deleted, you will no longer be able to log in or access the app.

Nevertheless, you are legally entitled to the following:

- **The right to information and access** – You have the right to request information on our processing of your personal data and to request copies of your personal data.
- **The right to rectification** – You have the right to request that we correct any information you believe is inaccurate. You also have the right to request us to complete the information you believe is incomplete.
- **The right to erasure** – You have the right to request that we delete your personal data under the conditions determined by law.
- **The right to restrict processing** – You have the right to request that we restrict the processing of your personal data, under certain conditions.
- **The right to object to processing** – When our processing is based on general or legitimate interest, you have the right to object to our processing of your personal data, under certain conditions.
- **The right to data portability** – You have the right to request that we transfer the data that we have collected to another organisation, or directly to you, under certain conditions and as far it is technically possible.

When our processing activity is based on your prior consent, withdrawal of such given consent is always possible without this affecting the lawfulness of the processing of personal data as this is on the basis of the permission previously granted.

VUB will be responsible for observing your privacy interests and to respond to your requests. To exercise your rights as a concerned party, you can email your question to the principal investigator Prof. Anna Jansen ([anna.jansen@vub.be](mailto:anna.jansen@vub.be)) and the co-principal investigator Prof. Petrus de Vries ([petrus.devries@uct.ac.za](mailto:petrus.devries@uct.ac.za)). In both cases, we need to ascertain your identity and the relevance of your request regarding your proper personal data. Please also provide us with your app username in order for us to properly respond to your subject's rights requests. If you make a request, we have one month to respond to you.

## 9. Accountability and Processing – Data Protection Officer

We greatly value your right to privacy. UCT and VUB are jointly responsible for the processing of your data (referred to as “joint controllers”). As a single point of contact, Vrije Universiteit Brussel, Pleinlaan 2, 1050 Brussels (Belgium) will respond to all of your inquiries. In case you have specific questions about your rights concerning the processing of your data, you can contact the university's data protection officer, by email on [dpo@vub.be](mailto:dpo@vub.be).

## 10. Complaints

Finally, should you wish to file a complaint about how your information is treated, you can contact your own data protection supervisor in your country and/or the Belgian Data Protection Authority who is the lead authority for VUB and responsible for upholding the law on data protection in Belgium: Data Protection Authority (GBA), Drukpersstraat 35, 1000 Brussel, +32 2 274 48 00, [contact@apd-gba.be](mailto:contact@apd-gba.be), [www.gegevensbeschermingsautoriteit.be](http://www.gegevensbeschermingsautoriteit.be).