



COVID-RED: Vroege vaststelling van een COVID-19-infectie

Wat doen we met uw gegevens?

Welke gegevens verzamelen wij?

In dit onderzoek verzamelen wij verschillende gegevens van u. Deze hebben wij nodig om de vragen van dit onderzoek te kunnen beantwoorden. En om de resultaten te kunnen publiceren. We kunnen de gegevens ook gebruiken voor andere onderzoeken naar corona.

De gegevens die we verzamelen zijn:

- Uw contactgegevens (email)
- Uw identiteitsgegevens (geboortemaand en -jaar, geslacht), en medische gegevens (algemene gezondheid, medische aandoeningen, ziektegeschiedenis, gebruik van medicijnen en verslavende middelen, of u een corona-besmetting heeft, en gegevens van een eventuele coronavaccinatie). Dit zijn de gegevens die u invult op deze site.

Hoe beschermen we uw privacy?

Aan dit onderzoek werken verschillende bedrijven mee:

- Het UMC Utrecht
- Julius Clinical, een Nederlands bedrijf dat het UMC Utrecht helpt met de uitvoering van dit onderzoek
- Ava, een Zwitsers bedrijf dat de app en armband heeft gemaakt

Om uw privacy te beschermen geven wij uw gegevens een code. Op al uw gegevens zetten we alleen deze code. Deze code wordt gegeven door de medewerkers van Julius Clinical bij wie de gegevens binnenkomen. Zij bewaren de sleutel van de code op een beveiligde plek binnen Julius Clinical. Als we uw gegevens verwerken, gebruiken we steeds alleen deze code. Ook in rapporten en publicaties over het onderzoek kan niemand terughalen dat het over u ging.

Wie kunnen uw gegevens zien?

Alle gegevens worden strikt vertrouwelijk behandeld. Alleen sommige medewerkers van Julius Clinical en het UMC Utrecht, en controleurs van het onderzoek kunnen al uw persoonlijke gegevens (dus ook uw email) zien. Die medewerkers zijn degenen bij wie de gegevens binnenkomen ('datamanagers'), de mensen van de helpdesk, en de mensen die contact met u opnemen als er extra vragen zijn. De controleurs kunnen mensen zijn uit de

commissie die de veiligheid van het onderzoek in de gaten houdt, controleurs die door het UMC Utrecht zijn ingehuurd, of nationale en internationale toezicht houdende autoriteiten.

Alle andere mensen die aan dit onderzoek meewerken, zien alleen de gecodeerde gegevens. Zij weten dus niet dat deze gegevens van u zijn.

In dit onderzoek sturen we uw gecodeerde gegevens ook naar landen buiten de Europese Unie. In die landen gelden niet de privacyregels van de Europese Unie. Maar uw privacy zal op een gelijkwaardig niveau worden beschermd.

Hoelang bewaren we uw gegevens?

Uw gegevens worden 20 jaar bewaard.

Kunt u uw toestemming voor het gebruik van uw gegevens weer intrekken?

U kunt uw toestemming voor het gebruik van uw gegevens op ieder moment intrekken. Maar let op: trekt u uw toestemming in, en hebben onderzoekers dan al gegevens verzameld voor een onderzoek? Dan mogen zij deze gegevens nog wel gebruiken.

Wilt u meer weten over uw privacy?

Wilt u meer weten over uw rechten bij de verwerking van persoonsgegevens? Kijk dan op www.autoriteitpersoonsgegevens.nl of op https://ec.europa.eu/info/law/law-topic/data-protection/data-protection-eu_en. Heeft u vragen over uw rechten? Neem dan contact op met COVID-RED@juliusclinical.com. Heeft u een klacht over de verwerking van uw persoonsgegevens? Neem dan contact op met de Functionaris Gegevensbescherming UMC Utrecht; privacy@umcutrecht.nl; 088 75 555 55.

Privacy Policy for Ava COVID-RED app

Last Updated: February 10, 2021 / V1.0

Welcome to the Ava COVID-RED App (the “**App**”), created by the COVID-19 Rapid Early Diagnostic (COVID-RED) consortium and as a result of funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 101005177. The Ava COVID-RED app was developed by Ava AG, a company formed under the laws of Switzerland with domicile in Zurich, Switzerland, and its subsidiary Ava Science, Inc., a Delaware corporation with principal business in San Francisco, California (collectively “**Ava**” or “**we**”). This Privacy Policy governs the use of Ava-branded bracelets (the “**Device**”) offered as a result of your participation in the COVID-RED clinical trial, including – unless otherwise stated – any software as embedded in such Device (collectively, the “**Products**”), as well as any services provided by Ava in connection with these products (the “**Services**”).

With this Privacy Policy we would like to inform you about how we process personal data within the scope of our business activities and inform you about your rights. We are aware of the importance of processing personal data for you as a data subject and the protection of your privacy is of the utmost importance to us.

As an internationally operating company, the EU General Data Protection Regulation (“**GDPR**”) is important to us in addition to the Swiss data protection regulations. We have aligned this Privacy Policy with the stricter standard of the GDPR.

This Privacy Policy does not apply to information collected offline or by third parties not affiliated with Ava that www.covid-red.eu (hereafter the “**Site**”) may link to (“Third Party Sites”). Please read this Privacy Policy and the Informed Consent Form carefully before using the App.

BY USING THE APP OR SERVICES, YOU AGREE TO THIS PRIVACY POLICY. IF YOU DO NOT AGREE, DO NOT USE THE SERVICES.

1. Name and address of the controller

We are one of the three controllers within the meaning of the GDPR, who determines the purposes and means of processing personal data. Our contact address can be found at

<https://www.avawomen.com/de/about/>. If you have any questions regarding data protection, please do not hesitate to contact us:

Ava AG

Gutstrasse 73

8055 Zürich

Switzerland (Company No. CHE-194.144.871)

Our data protection coordinator can also be reached via the following contact details:

E-mail address: dataprivacy@avawomen.com

Ava is supervised by the following regulatory authorities:

For Switzerland/EU/EFTA: Swissmedic, Hallerstrasse 7, CH-3000 Bern

For the United States of America: U.S. Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993.

The App was created specifically for the COVID-19 response and in fulfilment of funding terms specified under grant agreement No. 101005177 from the Innovative Medicines Initiative 2 JU. All data collected by the App is collected to support COVID-19-related efforts and/or epidemiological research. The Medical Ethical Assessment Committee Utrecht (known as **“The Committee”**), an independent ethics board recognized by the Central Committee on Research Involving Human Subjects (CCMO), has reviewed documents submitted by Ava and other COVID-RED beneficiaries to establish that the App collects only personal and/or sensitive data which is strictly necessary for supporting the public health emergency. The Committee has, in drawing up its advice, evaluated the App and the Device against the criteria and preconditions as laid down in the Medical Devices Decree, as well as Council Directive 93/42 / EEC of 14 June 1993 on medical devices and other relevant Dutch and / or European regulations. The Committee has considered the suitability of the protocol, with regard to the objective and reason of the research, the design of the research, the ethical aspects, the methods and the material will be used to obtain and document subject consent, including agreement with this Privacy Policy. The App and the Device have passed ethics committee review and are deemed acceptable for use in the COVID-RED clinical trial.

2. Information We Collect.

Ava's Products enable customers (the "**User**" or "**you**") to track their physiological parameters for the purposes of monitoring their general health and well-being. When providing these Products, Ava collects both personally identifiable information ("**PII**"), which can be used to identify an individual user, and non-personally identifiable information ("**non-PII**"), as set forth below.

a. Information you provide to us directly

i. Account and Device Activation: When you activate your Device, you will be asked to download the App and login with your study-assigned username and password. Upon first logging into the App, you will be asked to enter information about yourself, such as a personal e-mail address, gender, age, country of birth, height, weight, pre-existing conditions, recent vaccinations, menstrual cycle, birth control status, and other information generally related to COVID-19 and your health. We use this information to personalize your data and to be able to provide services. Your personal e-mail address will only be used to send an automated e-mail message in case you forget your password and choose to reset it. Your e-mail address cannot be accessed by study staff or clinical researchers at Ava. PII and non-PII data are stored in different databases, physically separated and each differently encrypted. Thus, all PII data will be linked only to your anonymized study id and username.

ii. Health Information: The Device is intended to be worn at night. When worn, the Device collects data on key physiological parameters such as skin temperature, resting pulse, breathing rate, etc. (collectively "**Health Information**" or "**HI**"). The Device synchronizes the collected HI recorded with the App on your mobile device using a wireless Bluetooth connection, and the HI is then stored on servers operated by a third party service provider on behalf of Ava. This HI is stored and used to provide the Services of our Products and is associated with your account. Each time a synchronization occurs, the Device logs data about the transmission. Some examples of the log data are the sync time and date, device battery level, and the IP address used when syncing.

iii. Communication: We collect communications between you and Ava, such as services related emails regarding account management, notices regarding technical issues or changes to the Products, some of which you cannot opt out. Personal correspondence, such as emails or letters, or third party correspondence about you may go into a file specific to you and will only be stored for as long as it is

necessary for the execution of the contractual relationship between you and us.

b. Other information collected

i. Traffic data: When you use the App, Ava collects information about that visit (known as “**Traffic Data**”). Traffic Data is stored as anonymous, aggregate and non-PII data. Traffic Data is not stored together with other PII of the user.

Such Traffic Data includes Device information, location information, and web navigational data, subject to the permissions you have granted. This information is compiled and analyzed to measure traffic and usage trends for the Products so we can enhance your experience during Product use.

3. How We Use Your Information and Legal Basis.

In addition to some of the specific uses of information we describe in this Privacy Policy, Ava may use your PII to provide the Products and Services, to communicate with you and for the purpose of concluding the contract with you. The processing of PII is also necessary for the fulfilment of legal obligations. Ava may use non-PII, such as anonymized sets of HI data, for academic and clinical research purposes. Anonymized research data cannot be linked to you as an individual or identify you in anyway. Analyses based on the aggregated data may be published in academic journals, presented at medical conferences, and/or be used to further our understanding of COVID-19 and epidemiology.

If you have given your consent to the processing of your PII for certain purposes, we will process your PII within the scope of and based on this consent, insofar as we have no other legal basis and we require such a basis. A given consent can be revoked for the future at any time.

4. Confidentiality and Sharing Your Information.

Except as noted in this Privacy Policy, including without limitations the sections below, we will keep your PII and HI private, and we will not rent or sell your information to third parties or nonaffiliated companies without your consent. Specifically, we will never share or make public any HI that you disclose to Ava during the course of using the Products.

As part of our business and/or research activities, we may disclose your PII to third parties (as listed below) in Switzerland, the EU or other countries for the purposes set out above and where appropriate. If we transfer data to a country without adequate legal data protection, we ensure an adequate level of protection by means of data transfer agreements (namely on the basis of the so-called standard contractual clauses of the European Commission) or rely on an alternative legal basis for processing such as contract and mandate processing, the establishment, exercise or enforcement of legal claims, overriding public interests, published personal data or because it is necessary to protect the integrity of data subjects.

a. Joint controllers and COVID-RED beneficiaries

As part of the analysis of the research results, Ava may share non-PII, such as anonymized sets of HI data, with our joint controllers and COVID-Red beneficiaries for academic and clinical research purposes.

b. Third party service providers

Ava may hire other companies to perform certain business-related functions, such as maintaining databases, sending email and direct-mail communications, offering and developing certain features of the Products, conducting research and analytics, and maintenance and security. When we employ another company to perform a function of this nature, we only provide them with the personal information that they need to perform their specific function. We may also share non-PII, aggregated or anonymized information without restriction.

c. Legal requirements

Ava may disclose any collected data if required to do so by law or in the good faith belief that such action is necessary to (i) comply with a legal obligation or assist government enforcement agencies, (ii) in case of legal proceedings protect and defend the rights or property of Ava or other Users, (iii) protect against legal liability; or (iv) protect the security or integrity of the Services. This may include responding to legal requests from other jurisdictions where we have a good faith belief that the response is required by law in that jurisdiction, affects users in that jurisdiction, and is consistent with internationally recognized standards.

d. Merger and acquisitions; bankruptcy

Your PII may be provided to a party if Ava files for bankruptcy, or there is a transfer of the assets or ownership of Ava in connection

with proposed or consummated corporate reorganizations, such as mergers, acquisitions or other change of control. We will ensure that the information-receiving party will be bound to the same level of confidentiality protection as Ava and will handle your personal information with the same level of care as Ava. You will continue to own your HI.

5. How We Process and Store Your Information.

a. Security

Ava has technical, organizational and physical safeguards in place to help protect against unauthorized access to use or disclose user data we maintain. Under our security practices and policies, access to personally identifiable information is authorized only for those who have a business need for such access.

We work hard to protect personal data that we collect and store. If you become aware of any unauthorized attempt to access, use or disclose personal data, please email us immediately. We will work relentlessly to address any problems. You are solely responsible for maintaining the confidentiality of any username or password used for accessing the Services, and you are solely and fully responsible for all activities that occur under your password or account. Ava has no control over the use of an account and expressly disclaims any liability derived therefrom. Should you become aware that any unauthorized party may be using your password or account, please notify us promptly.

b. Storing and processing your information / International Data Transfers

Your information is stored and processed on servers located in Europe, either by us or by a third party acting on behalf of Ava such as Amazon Web Services, or in any other country in which Ava or its service providers may operate. In those circumstances, we as a Data Controller ensure that we have the necessary safeguards in place for any international transfers outside the EU and Switzerland. Information may also be stored locally on the devices you use to access the Services.

6. Updating Your Information and Opting Out.

a. Changing or deleting your account information

You can access, review and change your profile and data that you have provided to Ava by logging into the App and entering in the new information yourself. If you no longer wish to participate in the COVID-RED clinical trial, you may contact the study coordinator to request your account's deletion. You must promptly update your personal information if it changes or is inaccurate. In the event of the death of an Ava User, please contact us. We will usually conduct our communication via email; should we require any other information, we will contact you at the email address you have provided in your request.

b. Opting out

You may opt out of receiving electronic communications from us or from our partners that you consented to receive communication from, by following the instructions in those emails, i.e., by clicking on the "unsubscribe link" provided in such communications. As noted above, you cannot opt out of certain communication, such the error free use of the Ava Product or Services. Our Service may also deliver notifications to your phone or mobile device. You can disable these notifications by changing the settings on your mobile device.

c. How long we keep your personal information

The PII collected by us will only be stored for as long as it is necessary for the execution of our Services or the other purposes pursued with the processing and/or a legal obligation to store and document or a predominant private or public interest exists. As soon as the PII collected by us are no longer required for the above-mentioned purposes, they will be deleted or anonymized as far as possible. Non-PII information gathered, compiled or analyzed by Ava in connection with its performance of the Services provided under Agreement, including without limitation any analyzes or reports of aggregated or anonymized data, can be used for any scientific purposes as determined by Ava in its reasonable discretion.

7. Children's Privacy.

Ava is for adults only. Ava does not intentionally collect personal information from anyone under the age of 18. If you are under the age of 18, please do not attempt to enroll in the COVID-RED clinical trial or provide any personal information about yourself to us. If we learn that we have collected personal information from a child according to article 8 GDPR, we will promptly delete that information. If you believe that we might have any information from a child according to article 8 GDPR, please contact us.

8. Other Websites.

The App may contain links and interactive functionality interacting with the websites of third parties that are not owned or controlled by Ava and/or other COVID-RED beneficiaries. The information practices of those websites linked to the App is not covered by this Privacy Policy. Your browsing and interaction with these third party sites, as well as the submissions of any personal information to those sites, is governed by their privacy policies. We recommend that you review the terms and privacy policies of each such website. You agree that we are not responsible and do not have control over any third parties that you authorize to access your personal information. If you are using a third party website or service and you allow them to access your personal information, you do so at your own risk.

9. Your Rights.

You have the right to information, correction, limitation of data processing, deletion of your PII, objection, revocation of the declaration of consent under data protection law for the future and data transferability within the framework of the data protection law applicable to you and to the extent provided for therein (such as in the case of the GDPR). In addition, you have the right to assert your claims in court or to file a complaint with the responsible data protection authority.

Switzerland's competent data protection authority is the Federal Data Protection and Information Commissioner.

10. Modifications.

We reserve the right to update this Privacy Policy from time to time without notice. The most current version will be posted on the Site. Any changes we make will be effective from the date we post them on the Site. It is your responsibility to check this Privacy Policy periodically for changes. Your continued use of the App following the posting of changes will mean that you accept and agree to the changes. Please refer to the Informed Consent Form posted on the Site to see additional terms and conditions that govern your use of the App.