





DATA USE AGREEMENT – EPIC Europe

FOR ACCESS TO DATA ON THE IARC SCIENTIFIC IT PLATFORM

DUA Reference Number: TO BE INSERTED BY IARC

This **Data Use Agreement** ("**Agreement**") enters into full force and effect as of the date of its final signature ("**Effective Date**")

BETWEEN:

The International Agency for Research on Cancer, World Health Organization, 25 avenue Tony Garnier, CS 90627, 69366 Lyon Cedex 07, France ("**IARC**"), represented for the purposes hereof by Charu Mehta, Director of Administration and Finance, with **IARC PI** as IARC/WHO's Principal Investigator hereunder; and

INSERT NAME OF RECEIVING INSTITUTE (the "**Receiving Institute**"), ADDRESS COLLABORATING INSTITUTE, represented for the purposes hereof by NAME and TITLE OF RECEIVING INSTITUTE's AUTHORIZED REPRESENTATIVE, with NAME OF RECEIVING INSTITUTE'S PI as Receiving Institute's Principal Investigator hereunder;

(each a "Party" and collectively the "Parties").

Definitions

In addition to the capitalized terms defined elsewhere in this Agreement, the following terms shall have the meaning as defined here below, whether used in singular or plural.

Access: remote access to the Data via the IARC Scientific IT Platform, as duly authorized and granted by IARC to the Users for the sole purpose of carrying out the Research Project. Access shall be provided to a User for as long as deemed necessary by IARC and at IARC's discretion, subject to a valid fully executed Agreement being in place.

Applicable Data Protection Laws: any (national/regional/EU/federal/state) data protection and privacy legislation and regulations, as applicable to the Receiving Institute, governing the type of research being performed and/or the Data being used under this Agreement. For the avoidance of doubt, in view of IARC's status as part of WHO and as an International Organization within the UN System, for IARC *Applicable Data Protection Laws* shall mean, in lieu of any of the foregoing: the Personal Data Protection and Privacy Principles for UN System Organizations, UN-HLCM 2018 (the "<u>UN Principles</u>"), the WHO regulatory framework and the <u>IARC Data Protection Policy</u>, which are aligned with internationally recognized standards.

Data: de-identified data from the EPIC-Europe data repository held by IARC, as briefly described in clause 2 of the Agreement and more substantially in Annex 1, including data that may qualify as personal data.

Governing Documents: the "EPIC-Europe Data and Biospecimen Access Policy" and the "Publication Guidelines for EPIC-Europe related studies", all together referred to as the *Governing Documents*. These Governing Documents govern the Access to and use of the Data under this Agreement.

Research Project: The research project mentioned in clause 2 of the Agreement and further described in Annex 1, as previously approved by the EPIC-Europe Steering Committee, the IARC Ethics Committee and any local ethics committee as may be required.

Research Results: all scientific results obtained/arising from the use of the Data within the Research Project under this Agreement, including any derived data and variables.

User: an individual employed by the Receiving Institute who (a) has a need to Access and use the Data for the purpose of carrying out the Research Project, (b) works under the responsibility and supervision of the Receiving Institute's Principal Investigator, and (c) is listed in and has signed Annex 2, acknowledging and agreeing to the terms set out in the Agreement.

User Authentication Information: the required confidential user identifiers, such as log-in credentials, issued by IARC to a User in order to Access the Data on the IARC Scientific IT Platform.

The Parties AGREE AS FOLLOWS:

- This Agreement will start on the Effective Date and, unless terminated earlier, will end on 28 February 1. 2026 ("End Date"). This date is not modifiable!
- The purpose of this Agreement is to allow Access to, and allow use of the following Data held by IARC: 2.

INSERT SHORT DESCRIPTION OF THE DATA TO BE MADE AVAILABLE VIA THE SCIENTIFIC IT PLATFORM

for the purpose of the project entitled:

INSERT PROJECT TITLE (the "Research Project")

The Data and the Research Project are further described in Annex 1.

Research Project approval: EPIC Steering Committee approval: PF1 REF(S), DATE(S) OF EPIC SC APPROVAL IARC Ethics Committee approval: IEC APPROVAL REF(S) If required local ethics committee approval APPROVAL REFERENCE(S), DATE(S), ETC. AS APPLICABLE To be deleted if not applicable.

- IARC/WHO will grant Access to the Data remotely via the IARC Scientific IT Platform, to the 3. authorized Users of the Receiving Institute as listed in Annex 2.
- 4. The Receiving Institute represents that all Users that are granted Access to the Data via the IARC Scientific IT Platform under this Agreement shall adhere to all terms and conditions set out in this Agreement.
- The Receiving Institute shall comply with any applicable ethical requirements, including review and 5. approval of the Research Project by the relevant local ethics committee and/or the IARC Ethics Committee.
- 6. This Agreement shall be read in conjunction with, and shall remain subject to the Governing Documents. The Receiving Institute and the Users represent they shall comply with the applicable Governing Documents.
- In case of any discrepancy between the Annexes and the terms and conditions of the core Agreement, 7. the latter shall prevail. In the event of any discrepancy between the Agreement and any applicable 2 DUA/IARC/2023 - draft v.05/2023 EPIC

Governing Documents, the provisions of the Governing Documents shall prevail.

Authorized use of and Access to the Data:

- 8. The Receiving Institute and the Users will use the Data, to which Access is granted under this Agreement exclusively for the purpose of the Research Project (as described in **Annex 1**). The Data shall not be used in clinical trials, for diagnostic purposes involving human subjects, or for commercial profit, nor for or in connection with the filing or obtainment of any intellectual property protection. Furthermore, in no event shall the Receiving Institute seek to obtain intellectual property protection in respect of the Research Results without prior written approval from and a separate agreement to be established and negotiated in good faith between the parties concerned.
- 9. Access to the Data will be granted by IARC only and solely to the authorized Users who are listed and have signed **Annex 2**. Any change to the list of Users, including adding any additional Users will require an amendment to the Agreement.
- 10. User Authentication Information will be provided by IARC to each User on an individual and personal basis, and under strict confidentiality obligations. Under no circumstances shall a User be authorized to transfer, or share its User Authentication Information with any other person or another User, nor to use it for any other purpose than as authorized under this Agreement.
- 11. The Receiving Institute must promptly notify IARC if: (a) a User or Receiving Institute's Principal Investigator ceases to be an employee of the Receiving Institute; or (b) a User or the Receiving Institute's Principal Investigator is no longer involved in the Research Project. Such User shall immediately cease any use of the Data and shall refrain from accessing the IARC Scientific IT Platform.
- 12. The Receiving Institute and the Users shall under no circumstances download, copy or redistribute the Data, or use the Data outside of the secured IARC Scientific IT Platform, unless expressly authorized by IARC in writing.

Data protection and security of operations

- 13. The Receiving Institute and the Users shall make reasonable use of the IARC Scientific IT Platform and the provided resources.
- 14. The Receiving Institute and the Users shall comply with the Applicable Data Protection Laws, including but not limited to the IARC Data Protection Policy, when accessing and processing Data on the IARC Scientific IT Platform in the context of the Research Project under this Agreement.
- 15. IARC is the host and custodian of the Data. For the purpose of identifying roles within Applicable Data Protection Laws, IARC is considered as the data controller of all Data processed on the IARC Scientific IT Platform. None of the activities carried out by IARC under this Agreement shall be deemed as data processing activities on behalf of a User or Receiving Institute.
- 16. The Parties confirm that they have implemented and shall maintain appropriate technical and organizational measures as required to ensure an appropriate level of protection and security of the Data.
- 17. Data provided via the IARC Scientific IT Platform will be de-identified. The Receiving Institute and the Users represent they shall not attempt to reverse engineer or re-identify the Data in any way whatsoever to establish the identity of or attempt to contact any of the data subjects.
- 18. The Receiving Institute and the Users shall Access the IARC Scientific IT Platform only from remote systems that are safe from malicious programs and activity and shall not engage in activities that

compromise or weaken the security of IARC systems.

- 19. The Receiving Institute and the Users shall not attempt to access any data or programs contained on systems for which the Users do not have authorization or explicit approval from IARC.
- 20. The Receiving Institute and the Users shall promptly report any security weaknesses, data breaches, or IT security incidents including misuse or violation of this Agreement that they become aware of, to IARC via dpo@iarc.who.int.

Violation of this Agreement

21. IARC reserves the right to monitor and review all traffic and data on the IARC Scientific IT Platform for potential violations of this Agreement. Violations of this Agreement that are not promptly remedied by the Receiving Institute shall result in termination of Access to the IARC Scientific IT Platform and termination of the Agreement as deemed necessary by IARC.

Intellectual Property Rights and Ownership

- 22. Except for the rights explicitly granted hereunder, nothing contained in this Agreement shall be construed as conveying any rights under any patents or other intellectual property which either Party may have as of the start date of this Agreement, or may hereafter obtain, independently of and without reference to the Research Project, the Data and/or any Research Results.
- 23. The ownership of the Data shall remain with the originating EPIC Centre(s) and custody shall remain under IARC. The Receiving Institute acknowledges and agrees that nothing contained in this Agreement shall be deemed to grant them any intellectual property rights in any of the Data provided hereunder.
- 24. Any Research Results shall be used for the on-going enrichment of the EPIC cohort. In line therewith, the Receiving Institute and the Users agree to provide a copy of any Research Results arising from the use of the Data provided hereunder to IARC.

Publications

25. Subject and without prejudice to the aforementioned proprietary rights, the Research Results obtained through use of the Data within the Research Project may be published by the Receiving Institute. Any such publication shall remain subject to prior review by the EPIC Steering Committee and shall comply with the Governing Documents.

Confidentiality

26. The Receiving Institute agrees to keep the Data in confidence, except for Data that: (a) are publicly known, or available from other sources which are not under a confidentiality obligation to the source; (b) have been made available by its owners without a confidentiality obligation; (c) are otherwise already known by or available to the Receiving Institute without a confidentiality obligation; or (d) are required to be disclosed by operation of law, provided that the Receiving Institute immediately so notifies IARC in writing and provides adequate opportunity for IARC to object to, or restrict, such disclosure or request confidential treatment thereof.

Warranties and liability

27. IARC makes no warranty of the fitness of the Data for any particular purpose or any other warranty, either express or implied.

- 28. The relationship between the Parties shall be that of independent contractors. Each Party shall be solely responsible for the manner in which it carries out its own research or any of its activities under this Agreement. Each Party shall therefore be liable for direct losses, claims, damages, or liabilities that said Party incurs to the extent such losses, claims, damages or liabilities arise as a direct result of said Party's activities under this Agreement.
- 29. No Party shall be responsible or liable to the other Party for any indirect damages, including but not limited to all indirect, consequential, special, incidental, punitive and aggravated damages and losses.
- 30. IARC/WHO does not indemnify the Receiving Institute, User or any third party for any loss, claim, damage or liability, nor for third party claims, in connection with the Access to and use of the Data and the IARC Scientific IT Platform.

Settlement of disputes

31. Any dispute relating to the interpretation or application of this Agreement will, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute will be settled by arbitration. The arbitration will be conducted in accordance with the modalities to be agreed upon by the Parties or, in the absence of agreement, with the rules of arbitration of the International Chamber of Commerce. The Parties will accept the arbitral award as final.

Privileges and immunities

32. Nothing contained in this Agreement will be construed as a waiver of any of the privileges and immunities enjoyed by IARC/WHO, as part of the World Health Organization (WHO) and the United Nations system, under national or international law, and/or as submitting IARC/WHO to any national law, regulation or court jurisdiction.

Amendment, Extension and Termination

- 33. This Agreement may be amended only by written agreement duly signed by the authorized representatives of the Parties. Neither Party will assign, transfer, or deal in any other manner with its rights and obligations under this Agreement without the express prior written consent of the other Party.
- 34. Either Party reserves the right to terminate this Agreement at any time without cause, by providing the other Party at least thirty (30) days' written notice.
- 35. Upon expiry or earlier termination of this Agreement, the Receiving Institute and the Users shall immediately cease any use of the Data and shall refrain from accessing the IARC Scientific IT Platform.
- 36. Those rights and obligations of the Parties as set forth in this Agreement that are by their nature or implication intended and/or required to survive the expiration or earlier termination of this Agreement shall survive such expiration or termination.

Final Provisions

- 37. Each Party represents that: (a) it has the full corporate right, power and authority to enter into this Agreement and to perform its obligations under this Agreement; (b) the execution of this Agreement and the performance of its obligations do not and will not conflict with or violate any agreement to which the Receiving Institute is a party or by which it is bound.
- 38. The Receiving Institute further represents that their use of the Data will not violate any acts, laws, bylaws, rules and regulations applicable to the Data.

- 39. This Agreement together with the Annexes hereto and the applicable Governing Documents constitute the entire understanding between the Parties in relation to the subject matter and supersede any prior arrangements, understandings, promises or agreements made or existing between the Parties regarding the subject matter.
- 40. This Agreement will in no way be construed as creating the relationship of principal and agent, of partnership in law or of joint venture as between the Parties or any other person involved in the Research Project.
- 41. This Agreement may be executed in counterparts and may be exchanged by electronic mail in .pdf format. All properly executed counterparts will constitute one document.

[Signatures/acknowledgements follow on next page.]

This Agreement is duly signed on behalf of the Parties as follows:

IARC Signature		RECEIVING Signature	INSTITUTE
Name	Charu Mehta	Name	LEGAL REPRESENTATIVE
Position	Director of Administration and Finance	Position	POSITION/TITLE
Date		Date	
Read and acknowledged by the Principal Investigator of IARC Signature		Read and acknowledged by the Principal Investigator of the Receiving Institute Signature	
Name	IARC PI	Name	RECEIVING SCIENTIST
Position	Scientist, Nutrition and Metabolism Branch	Position	POSITION/TITLE
Date		Date	

Annex 1 Description of the Data, Research Project and the use of Data

Description of the Data

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Description of the Research Project and use of the Data

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Annex 2 List of authorized Users

DTA Reference Number: TO BE INSERTED BY IARC

Research Project: INSERT PROJECT TITLE

Receiving Institute: INSERT NAME AND ADDRESS OF RECEIVING INSTITUTE and NAME OF RECEIVING SCIENTIST

Access to the Data will be granted by IARC, upon its sole discretion, only and solely to the Receiving Institute's authorized personnel who have a need to access and use the Data for the purpose of carrying out the Research Project, as described in **Annex 1**, under the responsibility and supervision of the Receiving Institute's Principal Investigator. Such Access will be granted only to those Users who have signed this **Annex 2**.

By signing below, I confirm that I have read and understood the provisions of the Agreement and that I will adhere to all terms and conditions set out in the Agreement.

Name	NAME OF USER	Signature	Date
Name _	NAME OF USER	Signature	Date