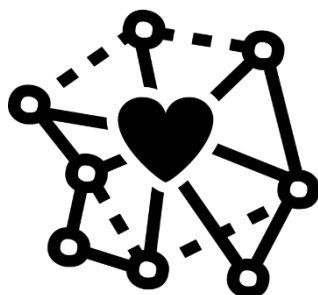




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OPENCARE

Open Participatory Engagement in Collective Awareness for REdesign of Care services

Deliverable 6.1: Consent funnel

<i>Project Acronym</i>	OPENCARE	
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Data protection guidelines for OpenCare

OpenCare is a H2020 funded project, under the action “Collective Awareness Platforms for Sustainability and Social Innovation” (CAPS)¹.

The goals of OpenCare imply that the Consortium will be running an online platform to host EU citizens’ conversation about their care needs, worries, and personal experiences, or ideas to work within the current welfare ecosystem, whether as practitioners, beneficiaries, or stakeholders.

These data could a priori be mapped along the spectrum from sensitive to outright medical data.

The EU has produced a rich literature about data protection, and it is beyond the scope of this document to offer a full educational resource on the topic.

The scope of the present document is to clarify how to behave with respects to either of data, to describe how to classify them appropriately, and how to protect the users of the platform to the best of today’s best practices.

It is important to notice here that the most recent EU rulings on data protection capture well the ill-posedness of all and any effort to protect data 100%, both when it comes to anonymization², and data repurposing³. And acknowledgement that has been expressed with even more clarity at the *High Level Conference of the European Parliament on protecting on-line privacy by enhancing IT security and EU IT autonomy*⁴. This should reassure that the purpose of EU normative is not to prevent all actions on data, but rather to enforce the best reasonable protection of public and individual interest.

However, the intention of the EU regulators is to commensurate the fallibility of defense devices with their accountability, and transparency towards the users whose data may be exposed⁵. In facts, a **data breach notification duty** is expected to be included in the EU General Data Protection Regulation, which is expected to come in force by the end of 2017. At present, the best proxy for the implications of this rule

¹ http://cordis.europa.eu/project/rcn/198824_en.html

² *Opinion 5/2014 on e-Privacy Directive 2002/58/EC* http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2014/wp216_en.pdf

³ *Opinion 3/2013 on e-Privacy Directive 2002/58/EC* http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2013/wp203_en.pdf

⁴

http://www.europarl.europa.eu/stoa/webdav/site/cms/shared/2_events/workshops/2015/20151208/Anonymous%20versus%20personal%20data%20from%20a%20binary.pdf

⁵ http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf



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would be the *Bill on Notification of data leaks*⁶, approved by the Dutch Parliament in May 2015. This sets the maximum responsibility for data controllers, and data processors (who can be deemed accomplices in breaches) up to €810,000 or 10% of the company's net annual turnover, should they fail to notify the authority, and the individuals potentially affected, of a potential breach within 24-72 hour.

OpenCare's platform will be hosted by the Edgeryders, a company registered in the UK (Company number 8506384), on a directory⁷ of their preexisting web platform, whose data protection policies are described in ⁸, and as the latter will be hosted on servers that are physically based in Germany, managed and made available by Ecobytes⁹.

The Edgeryders platform is usually concerned with openness and co-creation, hence the emphasis on open licensing of any content contributed by the users, and the possibility to browse in clear most of the content for visitors not logged in the system. Hence, on the Edgeryders web platform visitors can visualize full text posts, accompanied by authors' pictures and identifiers, and time stamps, among else, it is possible in principle that a malignant party download in full all the disclosed information without any traceability, and utilize them them for other purposes than those agreed upon at the registration on the platform, as is acknowledged in the *terms of use*³ (#Transborder hosting and transfer of information).

OpenCare's platform being a fundamental component of the OpenCare project, the Consortium has to appropriately inform the contributors about its data handling policies. Information is classified as *personal*¹⁰ whenever it relates to an identified or identifiable natural person, independently of the private, professional, or the circumstances under which it is disclosed. It is clear that the level of traceability and accountability which is desired by the EU regulators and which will soon be formulated as an absolute requirement would be incompatible by design with the choice to maintain conversations on the platform in clear to occasional visitors. However, OpenCare can be interpreted as a co-creative micropublishing service (or co-creative blog), which is the social contract we recommend to propose to its contributors. The contributors will retain their right to amend/remove their personal information, but will be otherwise informed that what they post is shared under a CC-BY¹¹ license, and is as such accessible and usable by anyone.

⁶https://autoriteitpersoonsgegevens.nl/sites/default/files/downloads/rs/rs_2013_richtsnoeren-beveiliging-persoonsgegevens.pdf

⁷ <http://edgeryders.eu/en/opencare>

⁸ <https://edgeryders.eu/en/edgeryders-lbg/privacy-policy-and-terms-of-use>

⁹ <https://co-munity.net/ecobytes>

¹⁰ Article 2(a) of EU Directive 95/46/EC)

¹¹ <http://creativecommons.org/licenses/by/3.0/>



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The person responsible for the information contributed by users to OpenCare is Noemi Salantiu. This should be clearly indicated, together with her relevant contact details (noemisalantiu@gmail.com), and clear instructions should be offered to the users of the platform about how to obtain copies of their data, or how to have them removed. It would be this person's duty to inform all the consortium partners of the eventual changes to the previously shared datasets, and to coordinate the process of erasure of the affected data when necessary.

In fact, it is understood that the Edgeryders will share via secured and encrypted means access to research data, marked up for ethnographical study, after pseudonymization. Samples of these data in the form under which they are handled during transfer should periodically undergo remapping testing, to verify experimentally how difficult it is to identify individuals, and to restrict profiles by sensitive properties (e.g.: health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction,...), to offer an experimental estimation of the solidity of procedures, and to update the information and guidelines shared with the website users.

Even though anonymized data are generally considered no longer sensitive, and even though the sensitive data still included in the research dataset would be covered by an informed consent from the users, each partner will be responsible of data security when data are transmitted and stored under their premises. This include the obligation to store them under encryption, to prevent unwarranted disclosure of the keys to third parties even within the same organization, and lastly to report to the consortium about data loss and breaching, to maintain the highest reasonable standard of protection and accountability. Each consortium partner planning to handle data from the platform will have to identify a primary responsible for these operations, in charge of coordinating with Edgeryders's data responsible.



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Ethical guidelines for OpenCare

OpenCare is a social innovation project at heart. As described above, the Consortium is aware of its data protection responsibilities, and ready to put in place the necessary devices.

However, the ultimately social nature of this experience forbids from a fully prospective approach to data, and ethical policies. By design the community will generate new meanings and scopes, while interacting with the consortium partners, and may find workarounds to share data of a different nature from that which the consortium originally planned to deal with (e.g. health trackers log, direct to consumer genetics, ...), by exploiting the possibility of linking to services outside the OpenCare platform.

The measures described above should act as a risk moderation device for the first instances in which such events would occur, ensuring the consortium room to adapt to the newly occurred scenario, and to update its informative to the users.

OpenCare does not envision any direct intervention on human subjects, and should such an activity emerge as a proposal from the community experiment, it will be formalized in detail by the management of the consortium together with the relevant partner, and submitted to the evaluation of the relevant/s ethical committee/s before receiving a green light.

However, the community itself could run activities affecting human individuals. The Consortium is aware of the challenges of accountability at the border of its own organization, and will periodically share information and invites to disclose eventual initiatives in advance, in search of advice from the consortium members.

The funneling procedure for consent by the users will also include a clear disclaimer that OpenCare is not a source of instruction for care, or substitute to education, and medical and legal advice, in order to reduce the risk of experiments informed by a misunderstanding of the scopes of the proposed social platform.



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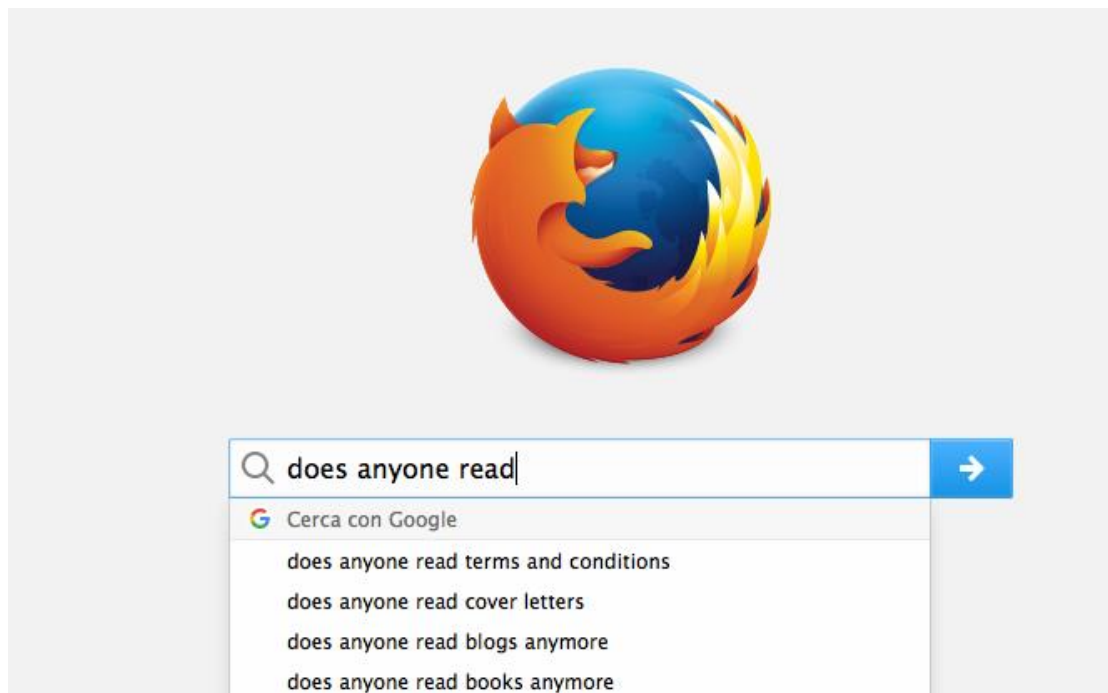
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Consent funnel

The scope of the funnel procedure is to ensure a clear understanding of the rules of engagement, and purposes of the community in OpenCare, and is at once the tool to obtain an explicit informed consent to the use of any data disclosed by users for research.

It is web wisdom that "I have agreed to the above terms and conditions" is one of the biggest lies on earth.

In fact, Google's auto-completion for "does anyone read..." looks like this:



In order to avoid this effect, the funnel on OpenCare should be organized in a brief questionnaire about the users' understanding of the scopes of the platform and its community, and the policies ruling the disclosed information.

We propose that this is organized according to the following scheme (in red the wrong one, in square parenthesis the information that should appear whether the reply has been right or wrong):

1. This micropublishing platform is only loosely moderated, to avoid harassment and exploitative behaviours, but to allow unconstrained conversation.



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Knowing this:

- **Would you share your credit card data if asked?**

Y|N

[This is seriously the kind of sensitive information that you should only share with secure services, when it is fully clear to you what the purpose of the transaction is, i.e.: purchase of a good/service]

- **Would you engage in a conversation about your last experience with the National Health Service?**

Y|N

[This platform is explicitly meant to host and facilitate conversations on topics akin to this. While you are of course free to avoid engaging in this kind of discourse, we encourage you to reflect on the purpose of your joining this community]

- **Would you look for contacts sharing experiences about a procedure you may undergo in the next future?**

Y|N

[One of the goals of this platform and its community is to nurture a network of people whose experiences can inform others' way of dealing with events / issues, or to detail unsolved needs for volunteers who might commit some time to help]

- **Would you accept to connect to a user outside of the platform to continue the conversation away?**

Y|N

[Whilst we do our best to ensure that everyone here is authentic, please bear in mind that everyone else followed just the same procedure as you to access this community, and we have no seal of guarantee. Keeping your conversation on the platform, while offering us the possibility to work on your data, also helps all of you playing your conversation of safe ground.]

2. How is sharing your data here different from sharing them on a commercial social platform (e.g.: Facebook, Instagram ...)?

- It is the same, in any case they may be sold to third parties **X** [OpenCare will not sell, or disclose your data to third parties. All the information contained on this platform is only accessible to registered users, and to the consortium members <http://edgeryders.eu/en/opencare/partners>.

These are committed to analyse the data on this platform solely with the purpose of studying how community dynamics influence cooperation.]



- Other social platform gain from advertising, surely you will profile me to match me with some offers **X** [While match making for solutions would be a very cool feature, we are not there yet. Any data shared will be used to study the conversation around care, and won't be repurposed for profiling or anything like that. Any new use intended for data on the platform will be rolled out only after updating all the users about the change of scope]

- All these platforms could conduct small social experiments by modulating exposure to information of certain groups **X** [As in the famous 2014 Facebook experiment :

<http://www.theguardian.com/technology/2014/jun/29/facebook-users-emotions-news-feeds>

OpenCare may steer some conversation to explore the impact of certain information, or the reaction of public to certain scenarios. However, **UNLIKE** Facebook, OpenCare will be supervised by an ethical advisory and will undergo ethical review, and will be very transparent later about the scopes and results of its experience]

3. Is OpenCare offering health care or social care advice?

Y|N

[OpenCare is a platform for users to freely share their experiences with health- and social- care, or their ideas to solve related problems. It is by no means a substitution for your doctor, nurse, or social worker... although we would love if they could join us too ;)]

4. Can you modify or delete your data once you have started using this platform?

Y|N

[It is important that you know: yes, you have a right to delete your profile in full, by contacting this person (Noemi Salanitu, noemisalantiu@gmail.com), who will be responsible of removing your profile data and conversation from the servers, and from the datasets shared with the research groups. Should you want a copy of these data, make your request clear, or they may be lost forever]

5. What does contributing to a conversation on OpenCare imply?

a. I share my opinion with a closed community of experts

Y|N

[While there will be "experts" starting/joining conversations at times, and definitely we hope "experts" to take note of the shared information and opinions available on the platform, by contributing to an OpenCare conversation you are really publishing your thoughts, making them available to read for everyone interested in the topic]



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- b. **I am sure that no ill-intending person/entity will ever discover what I shared**

Y|N

[In OpenCare publishing is intended in its fundamental meaning, and anyone can read everything, unless specifically stated at the beginning of a thread. We believe the community has a competitive advantage in joining the conversation, which is that of creating meaning, over any exploitative attempt at just reading/analysing the conversations. However, as it is for culture, nobody will play gatekeeper with what is published in OpenCare]

- c. **I will be involved in interesting new initiatives**

Y|N

[It is not possible to promise that this will happen, but there is good reasons based on past experiences that participating actively in conversations that are “close to home” can lead to spinning off interesting initiatives. The OpenCare consortium hopes to see this happening, and is there to advice and support when this is sought by the community]

6. **Whose responsibility is it if I try something read on OpenCare and fail?**

Mine | **The proponent of the idea** | **The Consortium**

[While this platform invites you to share and discuss problems and workarounds to health and social care needs, its moderation is not indeed to judge the validity of the exchanged informations. We invite you to complete-and-compare any information sourced from OpenCare with external authoritative sources (e.g.: GP, consultant, nurse ...). Should the nature of the suggestion be extremely novel, please do raise a flag of uncertainty inviting the attention of one of our consortium members to try and assist you, if possible]

7. **Does OpenCare need my health data, or information about my beliefs?**

Y|N

[OpenCare does not need any specific “data”, the analyses will focus on conversations and their networks. We invite you to avoid disclosing health data or other sensitive/personal data when not strictly needed, and to use analogies or other means to describe the information you want to share. Should you still want to share them, be reminded that any registered user may read them?]



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8. **Do we have your consent to analyse your data, and do you consider yourself informed about the scopes of our research?**

Y|N

[OpenCare will study the conversation on health and social care, and whether this can inform new bottom up workarounds to scale, with ethnographic methods.

If you want to know more, we have openaccess-ed our full proposal <http://edgeryders.eu/en/opencare/project>, or you can just participate to one of our hangouts (<https://edgeryders.eu/en/op3ncare/op3n-meetups>) before deciding to give your consent and join in)



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Ethics Advisory Board

Prof Antonio Vittorino Gaddi, MD, PhD

Education:

- Degree in Medicine and Surgery with honors and dignity of publication of the thesis
- Postgraduate Diploma in Cardiovascular Diseases, with honors.
- Specialization diploma, with honors, in Geriatrics and Gerontology
- PhD in "Experimental Medicine: Atherosclerosis" with publication of the thesis



Professional career:

- University Internal Medicine practitioner (University of Bologna) with care duties at the Institute of General Clinical Medicine and Medical Therapy (since 1978)
- Confirmed University researcher (disciplinary group "Clinical Medicine") (1980)
- 2nd layer University Professor, in the area of Internal Medicine (1992)
- Director of the Gerontology Service at Polyclinic S Orsola Malpighi (1993, later waiving directorship)
- Secretary of the Council of the Master Course in Medicine and Surgery, University of Bologna (1994-1998)
- Chairman of the Council of the Master Course in Medicine and Surgery, University of Bologna (1999-2002)
- Coordinator of the National Committee for the quality certification of education in Medicine and Surgery (2000-2004), and later of the Committee for the Core Curriculum
- Expert of the Ministry of Health and Social Policy, for the drafting of the National Prevention Plan, for the report on the health of the Country, and the Notebooks of Health (cardiovascular area) (2009-2011)
 - cooperated with the General Directorate for the informatization and education on eHealth



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- Consultant of the Emilia Romagna Region (Service of Drug Policies) in the preparation of regional plans for lipidology and cardiovascular prevention, and on eHealth (2006-2011).
- Ideator, and Director for the first 5 years, of the higher education course on “e-health and technological networks for healthcare” at the University of Bologna.
- Scientific director of the academic spin-off company Health Research and Development, and the Massa Lombarda Project (Pres. George Noera)
- National Secretary of the Metabolic Diseases and Atherosclerosis Study Group (Pres. Prof. Rodolfo Paoletti), and Director of the Bologna Center
- Vice President of the Italian Society for Telemedicine (Pres. Prof. Gianfranco Gensini)
- Scientific attaché for Emilia Romagna of the ACSA non-profit organization (Chairman Prof. Lentini)
- He left his academic career in 2012 and is currently 100% devoted to clinical activity.

Research activities:

The scientific production is vastly visible on the web:

<http://www.ncbi.nlm.nih.gov/pubmed/>

Or www.gruppostudioaterosclerosi.it (the H1 is about 34, RU 450, RGI 41)

Or else www.researchgate.net



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Professor Tim Spector, MB, MSc, MD, FRCP

Tim Spector is a Professor of Genetic Epidemiology and Director of the Twins UK Registry at Kings College, London.

He trained originally in rheumatology and epidemiology. In 1992 he moved into genetic epidemiology and founded the UK Twins Registry, of 13,000 twins, which is the richest collection of genotypic and phenotypic information worldwide.

He is the former President of the International Society of Twin Studies and directs the European Twin Registry Consortium (Discotwin) and collaborates with over 120 centres worldwide. He has demonstrated the genetic basis of a wide range of common complex traits, many previously thought to be mainly due to ageing and environment.



Through genetic association studies (GWAS), his group found over 500 new gene locks in over 50 disease areas.

He has published over 800 research articles and is ranked as being among the top 1% of the world's most published scientists by Reuters.

He held a prestigious European Research Council senior investigator award in epigenetics and is a NIHR Senior Investigator.

His current work focuses on omics and the microbiome and directs the crowdfunded British Gut microbiome project.

He is a prolific writer with several popular science books and a regular blog, focusing on genetics, epigenetics and most recently microbiome and diet (The Diet Myth).

He has published over 690 peer-reviewed papers in International Journals.



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Advisory Board rules of engagement

The above-mentioned high profile academics have agreed to share their extensive experience dealing with bioethics and privacy according to pragmatism and accountability, with our Consortium, SCImPULSE Foundation acting as the mediator. The agreement is unconstrained by payments or reimbursements, and it is of the purest voluntary nature, free of conflict of interest with respect to OpenCare and its agenda.

In practice, they will engage in conversations with SCImPULSE Foundation during the design of protocols and documentation concerning informed consent, ethical governance, and privacy, to inform the choices according to current best practices. They will also participate in processing the ad interim progress reports that will be regularly made available by the consortium, to suggest directions for the ethical self-evaluation of OpenCare.

The advisors commit to joining the yearly ethical review of the project, in person or via videoconferencing, to contribute their unbiased review to the process of self-evaluation, and to its results. In exchange, the consortium will have to share partners' and whole consortium yearly activity reports, and draft self-evaluations, at least 1 week ahead of the scheduled meeting, to ensure that the advisors can be filled in the details without excess efforts.

In understanding the evolving nature of some activities within OpenCare, the advisors commit to trying their utmost to be available to contribute to, or review, dedicated ethical documentations and guidelines that could become needed during the process, or to helping identifying the most relevant vicarious advisor should the request fall too far from their expertise.

It is understood that to respect their full calendars and the voluntary nature of their commitment, the OpenCare consortium will not abuse their availability, and will only make contact with the Chairman of SCImPULSE Foundation acting as a mediator, who will have the burden of verifying that, and contributing to, the request is well-informed and defined, to minimize the overheads of communication outside the scheduled commitment.