



Deliverable 7.1

Ethics Requirements 4





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1. General Approach to Ethics Requirement No. 4

This deliverable responds to the Ethics and Security section (see section 5.1 of the GA – Part B) in the Ethics Requirement Description No. 4 described as “An external independent Ethics Advisor must be appointed to oversee the ethical concerns arising in this proposal. A report by an Ethics Advisor must be submitted to the REA in advance of the interviews being conducted with business persons“.

This deliverable describes how the COMPASS project and its parties (as outlined in the COMPASS Consortium Agreement, p. 3) will implement the before-mentioned procedures during the course of the project running time (01 May 2016 to 30 April 2019).

The COMPASS project has appointed an independent Ethics Advisor. Details will be outlined in the following.

2. Appointment of Ethics Advisor

Dr. David Coles, Director of Enhance International Ltd., has been appointed as external independent Ethics Advisor. Dr. David Coles is a specialist in research ethics. He will provide advice to partners needing ethics review or data protection approvals for individual work packages or overarching studies and read through any ethics or data protection application before submission to the appropriate ethics panel or data protection body. Dr. Coles will work with the COMPASS consortium to ensure that all studies involving humans or their data have approval from the relevant ethics committees and data protection bodies before the studies commence. Copies of the approvals from the relevant authorities will be submitted to the European Commission and to the Coordinator for their records prior to the start of the relevant work. Dr. Coles will submit the required report to the REA before interviews will be conducted.

Dr. Coles developed the FP6 ethical review system for the European Commission and also led their ethics review team for that Framework programme and previously worked as head of the medical ethics unit for the Department of Health in the UK. His many years of experience in ethics review will be highly useful in COMPASS. Necessary shifts in the project budget (without effect on the overall budget) will be carried out following the appointment of the external ethics advisor.

COMPASS project and its parties confirm to act in line with all suggestions and procedures described in the report by Dr. Coles. The complete report is presented in the following (see Annex).

3. Annex Report by Ethics Advisor Dr David Coles

Report
by
Dr David Coles
Independent Ethics Advisor
On Ethical Aspects of the H2020 project
COMPASS

(Evidence and Opportunities for Responsible Innovation in SMEs)

Introduction

The objective of the COMPASS project is to collect, process and deploy evidence of the benefits of and business governance for Responsible Research and Innovation (RRI) across industries in key European areas of innovation, both in terms of process and in terms of outcomes. The project will do this by integrating findings from previous research, collating existing best practice and success factors across a range of industries and pilot testing, demonstrating and disseminating a RRI “Compass” and roadmap to SMEs and other target audiences. As part of this programme they will be carrying out a series of interviews with stakeholders and will also provide virtual and in situ “Responsible Innovation Labs” for both stakeholders and SMEs.

Background to this Report

The European Commission (EC) Ethics screening process identified that there were some ethical issues associated with both Workpackage 1 (WP 1) and Workpackage 2 (WP2) of the COMPASS proposal that had not been fully addressed by the consortium. i.e. that:

“Interviews will be conducted with business persons; recording of conversations and observation of behaviours.”

The interviews relate to WP1. The recording of conversations and observation of behaviours relate to WP2.

Following the conclusions of the ethics screening report, the EC included four specific ethics requirements in the research contract for this project. These are as follows:

Ethics Requirement 1 requires details on recruitment, informed consent procedures and templates of informed consent documentation to be provided to REA.

Ethics Requirement 2 requires an authorization of the data protection measures taken to ensure compliance with the Data Protection Directive as well as providing a data protection narrative to the funder.

Ethics Requirement 3 requires an ethics approval for the interviews to be provided to REA.

Ethics Requirement 4 requires the appointment of an external independent Ethics Advisor who submits a report to REA in advance of the interviews.

My appointment as independent ethics advisor and this Report is in response to Ethics Requirement 4.

Having been appointed as the Ethics Advisor by COMPASS, I originally suggested that all four deliverables could be incorporated in the one single report. However for understandable reasons, it appears that REA prefers to retain four distinct deliverables as specified by the requirements of the ethics screening report. COMPASS has therefore incorporated these four requirements into a single separate Workpackage (WP7) and will provide Requirements 1, 2 & 3 as three deliverables which will be separate from this report.

I understand that the four Deliverables of WP7 which reflect the ethics screening Requirements, will be:

Deliverable D1:- Report by Independent Ethics Advisor (this Report)

Deliverable D2:- Details on recruitment, informed consent procedures and templates of informed consent documentation

Deliverable D3:- Ethics approval for the interviews

Deliverable D4:- An authorisation of the data protection measures taken to ensure compliance with the Data Protection Directive as well as providing a data protection narrative to the funder

However, despite requirements 1-3 being separate deliverables, as Ethics Advisor I have been able to provide input and advice into each of the other deliverables through discussions with the project PI and the collaborators responsible for the Interviews and Responsible Innovation Labs in WP1 and WP2.

Conclusions and Actions by Independent Ethics Advisor

I initially reviewed all the documentation available on the submitted project proposal together with the conclusions and reports of the ethics screening process together with the responses of the COMPASS PI. Having familiarised myself with the Project objectives and methodology and clarified the ethical issues to be addressed, I then discussed these together with the ethics screening requirements with both the Project PI and the leaders of WPs 1 & 2.

Attention to ethics in the COMPASS project

The original project proposal was identified by the ethics screening process as not having given sufficient attention to ethical issues, resulting in the requirement to appoint an independent ethics advisor. However, in dealing with the various member of the consortium, particularly those responsible for WPs with ethical issues, it has become apparent that, even if this was not

clarified in the original proposal documentation to the satisfaction of the REA ethics screening process, amongst the project partners there is extensive awareness and knowledge of the ethical issues associated with this project together with the experience of how to deal with these correctly. For example the Workpackage leaders responsible for the Interviews and the Responsible Innovation Labs are respectively Prof. Doris Schroeder and Dr Catherine Flick, both of whom are widely respected internationally for their work on research ethics. In addition among other relevant ethics expertise, the consortium has recruited as external advisor Dr Maurizio Salvi who amongst a number of other roles has been Head of the Secretariat of the EGE and Policy Advisor to the President of the EC (BEPA) with specific tasks on ethics. Despite such internal experience on ethics and even though there were already plans in place to address most of the issues subsequently raised by ethics screening, the WP leaders have been more than willing to engage with me as an external Ethics Advisor in order to discuss, modify and/or refine the necessary documentation and procedures.

Actions on Ethics Requirements

Ethics Requirement 1 (*details on recruitment, informed consent procedures and templates of informed consent documentation*). This requirement will be fulfilled through **Deliverable D2**. However, I have discussed the EC Requirements with the WP leaders and having reached agreement on what was required, was provided with the following documents which can be found in the relevant Annexes to this report. This is for completeness of this report but overlaps significantly with Deliverable D2.

ANNEX 1: Interviewers Guide, explaining in detail all aspects of how to prepare for the interviews, recruit participants, provide appropriate information, obtain informed consent, and conduct the interviews.

ANNEX 2: Interviewers Schedule, laying out the approach and exemplar questions to be used for the interview.

ANNEX 3a: Interviews: Participant Information Sheet providing each participant with a comprehensive explanation of the purpose of the research together with all the details one would expect to find in a consent information sheet.

ANNEX 3b: Informed Consent Form for Interviews. A form providing the participant with the opportunity to identify exactly what consenting involved, to specify their acceptance of each element and to sign the document confirming their consent to participate.

ANNEX 4: Details on recruitment of participants for the Responsible Innovation (RI) Labs. This provides those researchers involved in the labs with a clear structure and procedure for identifying and recruiting appropriate participants.

ANNEX 5a: Participant Information Sheet for RI Labs

ANNEX 5b: Informed Consent form template for RI Labs

ANNEX 6: Ethics Committee Approval in Austria – Email from Austrian Contact Point

ANNEX 7: Detailed information on the procedures that will be implemented for data collection, storage, protection, retention and destruction and confirmation that they comply with national and EU legislation.

These documents demonstrate that the WP leaders responsible for the Interviews and the Labs studies have taken great care to ensure that procedures for recruitment are carefully and consistently implemented. Potential participants will be fully informed of the details for the research and their part in it. Interviewers will be fully briefed and prepared in terms of how to approach, recruit and deal with participants, how to answer any questions relating to the information sheet. A schedule of questions is provided to ensure scientific and ethical rigour through both consistency and appropriate flexibility.

Ethics Requirement 2a (*Copies of opinion or confirmation by the competent Institutional Data Protection Officer and/or authorisation or notification by the National Data Protection Authority must be submitted (which ever applies according to the Data Protection Directive (EC Directive 95/46, currently under revision, and the national law).*)

I have worked closely with the PI and leaders of WP1 and WP2 on the process of obtaining opinions from the appropriate data protection officers. I do not believe that such approvals or opinions are necessary in relation to the data that will be collected in either WP1 or WP2 as no sensitive personal data will be collected or processed. The only personal data to be collected are: Name, Age, Gender, Contact information (email, Skype address etc.), Occupation, Responsibility, and Employer. In addition neither the participant nor their employer will be identified in any publication. As, in accordance with Article 7 of 95/46/EC, full informed consent will be obtained for the personal data that will be collected and having seen the consent documentation, I find this fully satisfactory. DMU and WU do each have a DPO from whom they can (and will) seek approval for the data to be collected (and indeed University of Vienna has already done so); there is no mechanism for Belgian SME's to be able to do this as national legislation in Belgium does not require it nor provide for it in this case (This is also the case for SMEs in many other countries). In addition UCLan CY also has no DPO who can give an opinion. However, in order to explore every possibility, both the Belgian SME and UCLan CY have contacted their respective National DP Authorities to find out what is required. The DP Authority of both Cyprus and Belgium have already said that there is no national requirement in respect of collection of the proposed data. However, the partners concerned will in any case, send a written notification of what they propose to their respective National Authorities. The Spanish partner, (FBLC) is a foundation and not an SME. They also have contacted the Spanish National DP Authority and have been told that in their case registration on the national database is required. They are currently in the process of doing this. As soon as approval or acknowledgement of registration is received a copy of this will be forwarded to REA.

However, even where there is a lack of compliance requirements for DP opinions or authorisations at either the institutional and national level, the WP leaders have gone to considerable lengths to meet their contractual obligations by ensuring a strict standardisation of protocols and procedures for both the Interviews and the Labs across all participating partners, (see Annexes). In fact DMU are proposing on-site monitoring so that when the Labs are carried out by the partners in Spain and Belgium, a member of the DMU team will also be present to ensure that protocols are fully adhered to.

Ethics Requirement 2b: (*Detailed information on the procedures that will be implemented for data collection, storage, protection, retention and destruction and confirmation that they comply with national and EU legislation).*

This requirement will be fulfilled through **Deliverable D4** in the form of a data protection narrative. I have had opportunity to have input into and to discuss this with the Consortium members including discussing detailed information on collection, storage, protection, retention and destruction procedures both for the Interviews and Responsible Innovation Labs. A copy of this narrative document can also be found in Annex 7 of this Report.

The Consortium has confirmed to me that wherever Data Protection Authorisations or opinions are possible, these will be forwarded to the REA before the relevant work commences.

Ethics Requirement 3 (*Before the beginning of any of the studies involving the observation and recording of participants entailing the collection of sensitive data, a copy of any ethics committee opinion required under national law must be submitted*”).

The underlined phrases in the requirement are important as they are very specific and I assume deliberate statements by the ethics screeners to limit the scope of this requirement to obtaining an ethics opinion for collection of sensitive data only, in countries where this is required under national law. In addition, I have reviewed the methodology for these WPs and repeatedly questioned the WP leaders and others about the nature of the data they propose to collect and as previously stated it is clear that they will not, either intentionally or incidentally, be collecting any sensitive personal data as defined by either Directive 95/46/EC or by Article 19 of the new EU DP Regulation (GDPR Regulation (EU) 2016/679). The only personally identifiable data that will be collected will be Name, Age, Gender, Contact information (email, Skype address etc.), Occupation, Responsibility, and Employer. Furthermore, neither any of the interviewees' names nor their company's name will be included in project reports.

Therefore it is my opinion that ethics approval is not necessary for collection of such non-sensitive data. Indeed, none of the countries involved in either the interviews or Labs have a national requirement for an ethics approval to be sought for collecting this kind of data. In fact for the SME and Foundation involved there appears to be no mechanism or body they could use to obtain such approval. This situation is frequently the case for many countries in respect of companies or other independent bodies where such research activities are not part of their core business. Universities do have their own ethics committees of course, (although policies for seeking approval for collection of such data may vary from one to the other) and it is commendable that the Consortium has already sought ethics approval from each of these. CY UClan has already obtained ethics approval for the Interviews. It should be noted that while ethics approval for laboratory studies was not a requirement of the ethics screening, it has always been the intention of the Consortium that this would also be obtained by the appropriate Workpackage and a copy sent to the European Commission REA before the relevant work commences. DMU will request this ethics approval from its ethics committee but WU has been unable to do so and has been told in writing by the Austrian National Contact Point for Research Infrastructures in H2020 that there is no mechanism in Austria for obtaining ethics approval for this study (see ANNEX 6).

Indeed, many research ethicists including myself are of the view that ethics approvals are not necessary for interviews or workshops (Labs) involving just professionals who are only asked questions related to their professional opinion and/or field of work and for whom any personal details such as name or contact details are merely incidental as a means of identifying the comments. In cases such as this, what is taking place is much closer to an “Expert Consultation” or „Forum“, rather than carrying out research on individual participants. Obviously this is not

the case if sensitive personal data is collected about individuals. In that case the reason for collecting such data must be explained and an ethics approval obtained. However, as explained above, that is clearly not envisaged as part of this project. However, this is not an interpretation that has been used for the screening requirements. Despite this, the consortium has in my view, done all it possibly can to meet and indeed exceed that which is actually required in the wording of the contract relating to the handling of ethical issues.

Conclusion

It has been a pleasure for me to work with the members of the Compass Consortium on the ethical aspects of this project. I have found all involved willing to engage readily and to creatively seek all possible alternatives in order to fulfil the Requirements set by the ethics screening. I am therefore confident that they have or will fully comply with both the spirit and the letter of these Ethics Requirements in a timely manner and have even gone beyond this as far as has been possible for them, taking into account the limitations of institutional and national mechanisms for seeking the various approvals requested.

I therefore have no hesitation in concluding that all ethical issues, including any others that may emerge during the course of this project will be appropriately handled by the Consortium in accordance with the ethical principles of Horizon 2020.



Dr David Coles

Enhance International Limited

ANNEXES

ANNEX 1



INTERVIEWERS GUIDE

Industry perspectives on critical responsibility issues, success factors, and barriers for adoption of Responsible Research and Innovation (RRI) in SMEs

Interviewer's guide

For this part of the project we will be interviewing thought leaders in the healthcare and nanotechnology industry to capture their experience and opinions.

Overall each partner will carry out and provide a transcript of up to 5 interviews. There will be three stages of interviews with one interview to be undertaken at each stage. The timescale for the interview phase is supplied separately.

The Process

1. Seek ethical and/or institutional approval to conduct the interviews from your own institution. Each interviewing team needs to obtain their own ethical approval as the requirements differ across countries.
2. Identify potential interviewees and send information sheet and consent form to them. You can contact them via email or post. Translate the paperwork if necessary. Offer to chat about queries and follow up with phone call where appropriate.
3. If a person agrees to be interviewed, and returns the consent form, make contact as they suggested in the bottom part of the consent form. Allow one hour for the interview. Agree a contact method for the interview (in person, Skype, telephone).
4. Before interview – ensure that your recording equipment is working.
5. Conduct interview (guidelines below).
6. Transcribe the interview verbatim. Please do not try to summarise or leave anything out. Once the interview has been transcribed fully please translate into English where necessary and remove any names of individuals or companies to preserve anonymity.
7. Send anonymised transcripts to Kalypso (Klordanou@uclan.ac.uk).
8. Keep audio recording in secure place for 6 months and then destroy.
9. Keep consent form and transcripts in a secure place for 5 years, then destroy. If this is not possible then give to Kalypso for safe keeping.

Important points

- Selecting the right people
- Conducting an effective interview
- Recording the interview successfully
- Transcribing the interview faithfully and swiftly

Selecting the right people

We are using purposeful sampling for the interviews which means that we want to invite those people whom we believe will best suit the purpose of this part of the project. The aim of the interview stage is to capture the experience and opinions of healthcare and nanotechnology thought leaders on the success factors, and barriers for adoption of RRI in SMEs with the following specific objectives:

- To achieve an understanding of success factors for adoption of RRI in healthcare and nanotechnology (building on the work from Responsible Industry on ICT).
- To highlight potential challenges, barriers and requirements for adoption of RRI in SMEs.
- To identify general industry concerns/positions for the adoption of RRI in SMEs.

So we have to think about who best could help us to achieve those objectives through their input. It is of primary importance that all participants come from healthcare and nanotechnology industries and are actively involved in research and innovation. Ideally we would like to have input from people who work at various stages of the research and innovation processes, from initial stages of development to final products.

It is anticipated that we will gain a broad spectrum of perspectives as each partner interviews people from different companies, in different countries. If, after the first and second stages of the interviews, some perspectives are under-represented we may ask you to target your recruitment more specifically for the last phase.

Conducting an effective interview

We will be using semi-structured interviews for data collection. Semi-structured means that we will be starting with a list of questions (see interview schedule) but you do not need to adhere to the way in which these are worded strictly and neither to the order in which they are asked. You can incorporate different questions as and when required. This will allow you to explore alternative issues if they arise.

You will find a lot of information available on the internet about the skills required for effective interviewing. Some helpful information is included at the end of this guide.

Audio recording your interview

All interviews must be recorded as it is not possible to take full notes and conduct an effective interview at the same time.

If conducting an interview face to face you can use a hand held recording device.

If you are using Skype you can use software that is compatible with Skype for recording. It is very simple to set up and easy to use. You may need to download the software but there are many free alternatives. You can find information about that here:

<https://support.skype.com/en/faq/FA12395/how-can-i-record-my-skype-calls>

If you are conducting your interview via telephone it is recommended that you use Skype to call the participant on their telephone. That way you can make use of the same recording software described above. Please note that Skype is not free when used to call a telephone number but the cost is very low. You will need to credit your Skype account with some funds before the call.

Whatever you use, it is essential that you try out your recording system before the interview to ensure that it works well.

Transcribing your interview

After you have conducted your interview you will need to transcribe it. Play back the recording and write down exactly what was said and by whom. The whole conversation needs to be faithfully recorded. You can add notes in the margin where necessary for comments. 30 minutes of interview should take 1-3 hours to transcribe, depending upon your typing speed.

Before sending transcripts to Kalypso please ensure they are anonymised by removing any reference to particular persons or companies.

Some helpful notes from:

Conducting an In-depth Interview by Lisa A. Guion, David C. Diehl, and Debra McDonald

In-depth interviews are a useful qualitative data collection technique that can be used for a variety of purposes, and most appropriate for situations in which you want to ask open-ended questions that elicit depth of information from relatively few people (as opposed to surveys, which tend to be more quantitative and are conducted with larger numbers of people). They allow the interviewer to deeply explore the respondent's feelings and perspectives on a subject resulting in rich background information that can shape further questions relevant to the topic. The key characteristics of in-depth interviews are the following:

- **Open-ended Questions.** Questions need to be worded so that respondents expound on the topic, not just answer "yes" or "no." Many open-ended questions begin with "why" or "how," which gives respondents freedom to answer the questions using their own words.
- **Semi-structured Format.** Although it is important to pre-plan the key questions, the interview should also be conversational, with questions flowing from previous responses when possible. For example, if an interviewee remarks that "The elections are approaching," an appropriate response would be, "How do you feel about the candidates involved?"
- **Seek Understanding and Interpretation.** It is important to use active listening skills to reflect upon what the speaker is saying. The interviewer should try to interpret what is being said and should seek clarity and understanding throughout the interview.
- **Recording Responses.** The responses are typically audio-recorded and complemented with written notes (i.e., field notes) by the interviewer. Written notes include observations of both verbal and non-verbal behaviours as they occur, and immediate personal reflections about the interview.

In sum, in-depth interviews involve not only asking questions, but systematically recording and documenting the responses to probe for deeper meaning and understanding.

Skills and Attributes of the Interviewer

A skilled qualitative interviewer should be:

Open-minded. Judgment or criticism can act as barriers to communication, so it is important to maintain openness during the interview process. If interviewees perceive that they are being judged or evaluated, then they are less likely to share their opinions openly. Any conclusions that need to be made can be written in a journal after the interview is over.

Flexible and responsive. Human interactions are complex and people's responses to questions are rarely predictable, so good interviewers can think on their feet, respond to challenges, and make sure that the core purpose is being served.

Patient. Allow the respondent to speak freely and open up at a pace that is personally comfortable.

Observant. Good interviewers are observant, picking up subtle cues such as facial expressions, body language, and tone of voice.

A good listener. A good listener is one who listens actively, using strategies such as:

- **Attending fully** to what the speaker is saying by focusing wholly on what is being said. Active listening requires the listener to give full attention to the speaker until either the message has been received or the speaker has finished speaking.
- **Paraphrasing** what the speaker is saying to confirm to the speaker that the listener is actually listening and that the message conveyed is the message received. Paraphrasing also has the added benefit of forcing a speaker to focus wholly on the conversation, thus limiting distractions.
- **Reflecting** back to the speaker the emotions inherent in the message. By paying attention to tone and emotional content, the interviewer can gain a greater understanding of the messages being delivered.

ANNEX 2

INTERVIEW SCHEDULE



Industry perspectives on critical responsibility issues, success factors, and barriers for adoption of RRI in SMEs

Interview schedule

Welcome and thanks for taking the time.

It is important to us to gain a perspective from those actually working in industry. Therefore real-life experience and practical suggestions are very welcome.

I have some questions but our conversation does not have to be limited to those and please feel free to say if there are certain things that you prefer not to discuss.

Before we begin, do you have any questions?

Indicative questions:

1. Can you tell me about the research and innovation that is happening in your company? How do you try to make it a success?
2. The purpose of this interview is to seek your opinions about success factors and barriers for employing a relatively new idea, namely Responsible Research and Innovation, or RRI, in SMEs. Is that a concept you have ever come across before?
(Probe further here if necessary and help by offering suggestions to find out about particular ways of how RRI can be recognized in practice)
3. In your experience what are the key drivers for this type of activity? (e.g. who is in charge, are there any requirements for, and what are people's motivations for undertaking research and innovation responsibly)
4. In your experience what are the success factors for adoption of RRI in healthcare/nanotechnology? [this needs to be adapted according to interview]
5. In your experience what are the main challenges/barriers for adoption of RRI in healthcare/nanotechnology? [this needs to be adapted according to interview]
6. What do you think would need to be in place to help with those challenges/barriers?
7. What are your main concerns regarding the adoption of RRI in healthcare/nanotechnology? [this needs to be adapted according to interview]
8. In decision-making in your organization, do you involve a wide range of stakeholders?
9. In what ways is consideration paid to your target or end users in research and innovation activities? (e.g. who is consulted in the development phase, who benefits from it and why specifically these groups, do you interact with NGOs?)
10. Do you find that people you deal with in the research and innovation phases of your activities have different values, interests and ideals? If so, how do you deal with that?
11. What attention is paid to codes of conduct in your company? (e.g. Do you have any particular protocols in place to consider ethical aspects of research and innovation? Do professional

ethical codes have an impact in your view and if so, how? If you don't believe they have impact, do you have any idea why not?)

12. What attention is paid to ISO or other certifications in your company?
13. To what extent does your company attempt to predict (unintended) consequences of your businesses' research, development and innovation activities, in particular when it comes to impact on the environment, society and the well-being of users? (Ask about any methods used in this assessment)
14. Have you or would you consider making the results of your research and/or other innovation data openly available? (What would be the benefits or reasons why not?)
15. Has this interview given you any ideas that you find interesting?
16. Anything else you would like to add?

ANNEX 3a

PARTICIPANT INFORMATION SHEET



Industry perspectives on critical responsibility issues, success factors, and barriers for adoption of Responsible Research and Innovation (RRI) in SMEs

Participant Information Sheet

Dear

You are invited to participate in a research project but before you decide whether you want to take part, it is important that you understand why the research is being undertaken and what your participation will involve. Please take time to read the following information carefully, discuss it with colleagues if you wish, and ask if anything is unclear or if you would like more information.

What is the purpose of this study?

This project forms part of a much larger, EU funded, project entitled *Evidence and opportunities for responsible innovation in SMEs*. The project investigates whether the relatively new idea of “responsible research and innovation” can improve industrial research, development and innovation. Possible improvements would be investigated both in terms of processes and in terms of positive outcomes for society. Such research is new in SMEs (it has – to date –been mostly undertaken for publicly funded research and innovation) and we are excited about the project!

The *Compass* project has been broken down into different components to be undertaken by the institutions involved and you are being invited to take part in one of the first activities, namely, interviewing of key thought leaders in industry to seek their experience and opinions about critical responsibility issues, success factors, and barriers for adoption of RRI in SMEs. This part of the project is being led by researchers from The University of Central Lancashire (UCLan) in Cyprus.

Why have I been invited to participate?

You are being invited to share your experience and opinions about the conduct of research and innovation in industry because you have been identified as someone who has a key role in the healthcare or nanotechnology industry. As noted earlier, RRI is a relatively new concept. You may not have heard of it before. That is not problematic. What is important is that you have experience of working in industry where healthcare or nanotechnology research and innovation are undertaken. Your input will help us to understand the potential values, challenges, and implications for RRI in industry, and this is key to ensuring that the output of our project (for instance, a comprehensive, customizable, user friendly and up to date web portal on RRI for SMEs) has practical, real world relevance.

What will I have to do if I decide to take part?

You are asked to read this information sheet and decide if it is something you would like to do. If you are willing to participate, you will be asked to sign a consent form and we will contact you via email or telephone to arrange a time for your interview. Depending upon your location and availability the interview may be conducted face to face but it is more likely that you will be interviewed via telephone or Skype, depending upon your preference. We ask that you put aside one hour for the

interview as it should last for 45-60 minutes. During the interview you will be asked some questions about your experience and opinions and you will also have an opportunity to raise other issues that you believe may be relevant. You are under no obligation to answer the questions that are asked and you may decide not to answer any if you wish. We appreciate that there may be some restrictions upon the information that you are free to share, for example where data is commercially sensitive, and request that you only share information you are happy to have in the public domain. On request, we can send you a list of questions in advance, but we may explore other similar questions on the day.

In total 30 key personnel in the healthcare and nanotechnology industry from around Europe will be interviewed for this part of the *Compass* project. Where we have permission from interviewees, all interviews will be audio recorded and information from the interviews will be analysed by researchers from UCLan Cyprus to identify common themes, concerns and issues.

Do I have to take part in this study?

No. Participation in this study is entirely voluntary.

Can I use my preferred language?

Where requested, and if possible, the information sheet and consent forms will be supplied in your preferred language. It may also be possible for interviews to be conducted in your preferred language, depending upon the availability of an interviewer. If your interview is conducted in a language other than English then the information you provide will be translated into English for the purpose of analysis.

What will be the benefits of taking part?

No incentives will be offered for your participation and it is not intended to benefit you directly. However your input may help to benefit the project as a whole and subsequently inform debate on the future for RRI in Europe. It has also happened that a research project similar to this one discovered innovative good practice in an individual company, which then achieved a small reputational gain through the study's publications. However, this is not the norm.

What are the possible risks in taking part?

There are no anticipated risks but please ensure that you only share information that we would be allowed to use in publications and other materials. Please see below for confidentiality.

What if I wish to withdraw from the study?

You are free to withdraw from the study at any stage before or during the interview and up to two months afterwards by contacting [..... **contact details for interviewer**]. Any information you have provided up to that point will be destroyed. After this time, once analysis of the interview and write up of the study has begun, it will not be possible to isolate your contribution from the rest of the study.

Will my taking part be kept confidential?

Yes. Once the researcher has transcribed everything that was recorded during the interview, the tape will be erased. The transcript of your interview will be stored in a password protected file, accessible only by the interviewer and researcher conducting the analysis. It will be destroyed after 5 years. Some of your words and phrases will be used for reports but these will not have any identifiable information within them. Your name, your contact details or any other personal identifying information will not appear in any publications resulting from this study; neither will there be anything to identify your place of work unless you have provided explicit consent for this.

What will happen to the information I provide?

The information gained from your interview will be incorporated into project reports and may also

be included in publications and presentations about the project and RRI. Interview data will not be passed onto researchers who are not part of the Compass group.

Who is conducting the interview?

An experienced researcher from one of the 7 institutions involved in the *Compass* project will conduct your interview. They will contact you to make arrangements and will ask for your consent form. They will also be transcribing your interview and translating documents where necessary. Their contact details can be found at the end of this information sheet in case you have any queries or concerns.

Ethical Approval

This project has been approved by the [insert local committee with number and date].

What happens next?

If you would like to participate in the study please complete and return the consent form. You will be contacted by the researcher within one week for confirmation and within one month to arrange a convenient time for interview.

Further information

Can we refer to a website?

If you would like to read more about RRI, please let us know and we will send you some articles.

If you have any questions about your invitation to participate or would like further information about the interviews please contact one of the following:

Interviewer:

Insert contact details for interviewer: Name, address, email and telephone

UCLan Cyprus lead for the interviews:

Dr Kalypso Iordanou

University of Central Lancashire Cyprus,

University Ave 12-14,

Pyla

7080,

Cyprus

KIordanou@uclan.ac.uk

Compass project lead:

Xxxxxx

ANNEX 3b

INFORMED CONSENT FORM



Industry perspectives on critical responsibility issues, success factors, and barriers for adoption of Responsible Research and Innovation (RRI) in SMEs

Consent form

Please complete this consent form if you are willing to be interviewed for the study by placing your initial each box and then signing at the bottom.

When completed please return a copy, either by email or post to:

Insert contact details, name, address, email

Issue	Respondent's initial
I have read the information presented in the information letter about the study, "Industry perspectives on critical responsibility issues, success factors, and barriers for adoption of RRI in SMEs".	
I have had the opportunity to ask any questions related to this study, and received satisfactory answers to my questions, and any additional details I wanted.	
I understand that my participation is entirely voluntary and I am under no obligation to answer all questions during the interview.	
I am aware that some of my words and phrases from the interview may be included in the final report and publications to come from this research but any quotations will be kept anonymous.	
I give permission for the interview to be recorded using audio recording equipment.	
I understand that I am free to withdraw my consent at any stage before or during the interview and up to 2 months after the interview.	
I agree to take part in this study	

My preferred method of being contacted is:

Telephone _____

Email _____

Other _____

Participant Name:		Consent taken by	
Participant		Signature	



Signature:			
Date		Date	

ANNEX 4

RESPONSIBLE INNOVATION LAB

DETAILS ON RECRUITMENT OF PARTICIPANTS



For each lab, a group of stakeholders from industry, research and civil society will be selected and assigned the task to envision the integration of RRI in their industry-specific R&D&I processes. Stakeholders will jointly address a number of questions, which will guide the development of the individual roadmaps. These include: What are the responsibility standards business ought to uphold concerning R&D&I in relation to RRI, including gender? How do we deal with shared responsibility for societal impacts of innovation? What kind of guidance and support is available to business on their way towards more responsible practices, products, and business models? Which concrete strategies and activities can be implemented in the short, medium, and long term?

The process

1. Identify potential participants and send information sheet and consent form to them. You can contact them via email or post. Translate the paperwork if necessary. Offer to chat about queries and follow up with phone call where appropriate.
2. If a person agrees to participate and returns the consent form, make contact as they suggested in the bottom part of the consent form.
3. Make sure they are aware of process, aims and time frame of the Responsible Innovation Lab.
4. Workshop outputs – audio, video recordings, photographs, chat transcripts, and any materials produced in the face to face workshops, will be collated and stored on WU and/or DMU secure servers for WP2 to analyse.
5. Original audio/video/photographic recordings will be kept on WU secure servers and DMU internal secure servers for 6 months after the end of the project, unless explicit consent is obtained from participants to retain for longer, or to be used in deliverable or dissemination activities (with explicit consent).
6. After the completion of the project, consent forms and transcripts will be kept in a secure place on DMU internal servers for 5 years, then destroyed.

Selecting the right people

The primary stakeholder group of interest are SMEs involved in research and innovation in the cybersecurity, nanoelectronics & biomedicine areas. We also intend to include a small number of civil society organisations who are directly involved in these areas of interest.

Additionally, we are restricting our samples to the countries in which the partners running the face-to-face workshops are based, i.e. UK for cybersecurity, Spain for biomedicine and

Belgium for nanoelectronics. This is so that we not only build on our strengths of network contacts but to keep costs reasonable for multiple iterations of the labs. It is envisaged that each country's area of specialty will have a good understanding of the broader European context as they need to operate within these.

In being purposeful about our sample, we will ensure that we minimise risk of drop-off of participation, and that we collect accurate expert input into the outputs of the RI labs.

Data Collection and Storage

As discussed in the process above, data will be collected during the online and offline portions of the lab.

Online webinars/chats

These will be conducted online and, where audio/visual components are used, will be captured using a screen recorder. Chat transcripts from written text will be kept as if they were audio/visual transcripts. All transcripts will be stored securely on a WU secure server during the project and on a DMU server for 5 years after the project is completed. All audio/video recordings will be stored securely within WU and/or DMU secure servers for the duration of the project and for 6 months after the completion of the project unless explicit consent is sought from participants for portions of it to be kept longer or included in dissemination/deliverable activities.

Face-to-face workshops

These will be conducted in live workshop environments and video and audio recorded. Still photography may also be employed for parts of the workshop. All transcripts from these recordings will be stored securely on a WU secure server during the project and on a DMU server for 5 years after the project is completed. All audio/video recordings and photographs will be stored securely within WU and/or DMU secure servers for the duration of the project and for 6 months after the completion of the project unless explicit consent is sought from participants for portions of it to be kept longer or included in dissemination/deliverable activities.

ANNEX 5a

RESPONSIBLE INNOVATION LAB PARTICIPANT INFORMATION SHEET



Dear [FIRST NAME] [LAST NAME],

You are invited to participate in a research and innovation action, which is part of a European research project. Before you decide whether you want to take part, it is important that you understand why the research is being undertaken and what your participation will involve. Please take time to read the following information carefully, discuss it with colleagues if you wish, and ask if anything is unclear or if you would like more information.

What is the purpose of this process?

This project forms part of a much larger, EU funded, project entitled *Evidence and opportunities for responsible innovation in SMEs*. The project investigates whether the relatively new idea of “responsible research and innovation” can improve industrial research, development and innovation. Possible improvements would be investigated both in terms of processes and in terms of positive outcomes for society. Such research is new in SMEs (it has – to date – been mostly undertaken for publicly funded research and innovation) and we are excited about the project!

The *Compass* project has been broken down into different components to be undertaken by the institutions involved and you are being invited to take part in the Responsible Innovation Labs, which is the key component of this project to develop roadmaps for implementation of responsible innovation in your field. This part of the project is being led by De Montfort University, UK, with events occurring in three countries across three innovation fields, including yours. In Belgium the labs are being run by Strategic Design Scenarios; in Spain by “la Caixa” Banking Foundation.

Why have I been invited to participate?

You are being invited to co-create visions and roadmaps to successfully implement responsibility in research, development and innovation activities of SMEs active in the area of [INSERT KEY INNOVATION FIELD] in [INSERT REGION]. As noted earlier, responsible research and innovation (RRI) is a relatively new concept. You may not have heard of it before. That is not problematic. What is important is that you have experience of working in industry where security, healthcare or nanotechnology research and innovation are undertaken. You will be able to discuss potential values, challenges, and implications for RRI in industry, and develop common ideas with other SMEs, innovation service providers and civil society organisations active in [INSERT KEY INNOVATION FIELD] in [INSERT REGION].

What will I have to do if I decide to take part?

You are asked to read this information sheet and decide if it is something you would like to do. If you are willing to participate, please let us know by email. You will be asked to sign consent forms for the workshops you participate in. We would appreciate if you could commit to the full series of online and offline workshops, but we understand if this is not possible – even attendance at one would be greatly helpful to our research. We will try to arrange times for these that are suitable for the majority of our participants.

During these workshops we will be inviting companies and organisations such as yours to share your experiences and good practice with others in your field. We appreciate that there may be some restrictions upon the information that you are free to share, for example where data is commercially sensitive, and request that you only share information you are happy to have in the public domain.

The workshops will be recorded and analysed by researchers at De Montfort University, Strategic Design Scenarios and “la Caixa” Banking Foundation as part of the COMPASS project.

Do I have to take part in this study?

No. Participation in this project is entirely voluntary.

What will be the benefits of taking part?

No incentives will be offered for your participation and it is not intended to benefit you directly, however you may be presented with innovative business practices that, if implemented, could change your mid- to long-term profit making by making your company more responsible. For a full list of potential outcomes of participating in this series of workshops, please see our website. Additionally, your input may help to benefit the project as a whole and subsequently inform debate on the future for innovation in Europe. It has also happened that a research project similar to this one discovered innovative good practice in an individual company, which then achieved a small reputational gain through the study’s publications. However, this is not the norm.

What are the possible risks in taking part?

There are no anticipated risks but please ensure that you only share information that we would be allowed to use on our website and other project output. Please see below for confidentiality.

What if I wish to withdraw from the project?

You are free to withdraw from the project at any stage before or during the Responsible Innovation Lab process and up to two months afterwards by contacting [INSERT DETAILS OF PRIMARY CONTACT].

Any information you have provided up to that point will be destroyed as far as possible without compromising other actors’ input. After this time, once analysis and write up has begun, it will not be possible to isolate your contribution from the rest of the study.

Will my taking part be kept confidential?

Yes. 6 months after the conclusion of the project, all original tapes and videos will be erased (except where explicit consent has been given for prolonged use/storage). Transcripts will be stored in a password protected file, accessible only by the project team. They will be destroyed

after 5 years. Some of your words and phrases will be used for reports but these will not have any identifiable information within them. Your name, your contact details or any other personal identifying information will not appear in any publications resulting from this study; neither will there be anything to identify your place of work unless you have provided explicit consent for this. Photographs of workshop participants and their outputs may be used, but explicit consent will be requested before these are published in any way.

What will happen to the information I provide?

The information gained from the labs will be incorporated into project reports and may also be included in publications and presentations about the project and responsible innovation. Data will not be passed on to researchers who are not part of the project team.

Ethical Approval

[INSERT APPROPRIATE INFORMATION ONCE CONFIRMED].

What happens next?

If you would like to participate in the Responsible Innovation Lab taking place in [INSERT COUNTRY/REGION] from [INSERT START DATE] until [INSERT END DATE], please complete and return the consent form. You will be contacted by [INSERT CONTACT PERSON] with further information.

Primary contact:

[INSERT DETAILS OF PRIMARY CONTACT]

COMPASS project lead:

Dr. Katharina Jarmai

Institute for Managing Sustainability

Vienna University of Business and Economics

Welthandelsplatz 1, Building D1, 2nd floor

A-1020 Vienna, Austria

www.sustainability.eu

<http://innovation-compass.eu>

ANNEX 5b

RESPONSIBLE INNOVATION LAB

CONSENT FORM



Please complete this consent form to participate in the Responsible Innovation Lab taking place in [INSERT COUNTRY/REGION] from [INSERT START DATE] until [INSERT END DATE] by placing your initial in each box and then signing at the bottom.

When completed please return a copy, either by email or post to:

Insert contact details, name, address, email

Issue	Respondent's initial
I have read the information presented in the information letter about the Responsible Innovation Lab carried out within the H2020 project “COMPASS – evidence and opportunities for responsible innovation in SMEs”	
I have had the opportunity to ask any questions related to the process and received satisfactory answers to my questions.	
I understand that my participation is entirely voluntary.	
I am aware that some of my contributions to the online and offline activities in the Responsible Innovation Lab may be included in project output, while any quotations will be kept anonymous.	
I give permission to be recorded using video and audio recording equipment during the lab process.	
I understand that I am free to withdraw my consent at any stage before or during the lab process and up to 2 months after its completion.	
I agree to take part in this process.	

My preferred method of being contacted is:

Telephone _____

Email _____

Other _____



Participant Name:		Consent taken by	
Participant Signature:		Signature	
Date		Date	

ANNEX 6

ETHICS APPROVAL AND EMAIL FROM AUSTRIAN NATIONAL CONTACT POINT

Von: Manfred Halver [<mailto:Manfred.Halver@ffg.at>]

Gesendet: Donnerstag, 4. August 2016 15:06

An: Nwafor, Caroline

Betreff: AW: Antw: Ethische Richtlinien

Dear Mrs. Nwafor,

in Austria, there is no legal requirement to gather the opinion of an ethics committee or similar when sensitive data of persons is collected.

Therefore, a copy of such a decision cannot be provided by project participants in Austria.

Best regards,

Manfred Halver

National Contact Point for Research Infrastructures in H2020

Expert for Information and Communication technologies in H2020

Manfred Halver

FFG - Austrian Research Promotion Agency

European and International Programmes

Sensengasse 1, 1090 Wien

Tel.: +43 (0)5 7755 4207

Mail: Manfred.Halver@ffg.at

Web: www.ffg.at/europa

ANNEX 7

Deliverable 7.4

Ethics requirement 2

COMPASS

Grant agreement number	710543
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Deliverable number	D7.4
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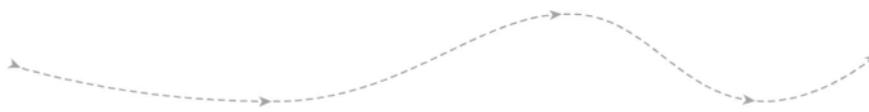


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1. Introduction

This deliverable responds to the Ethics and Security section (see section 5.1 of the GA – Part B) in the Ethics Requirement Description No. 2. b) described as “Detailed information on the procedures that will be implemented for data collection, storage, protection, retention and destruction and confirmation that they comply with national and EU legislation.” As outlined in the Ethics and Security section point of issues where ethical issues may arise are (1) Interviews with key stakeholders in the healthcare and nanotechnology sectors and (2) Responsible Innovation Labs.

This deliverable describes how the COMPASS project and its parties (as outlined in the COMPASS Consortium Agreement, p. 3) will implement the before-mentioned procedures and features during the course of the project running time (01 May 2016 to 31 April 2019).

With the finalisation and delivery of this document, the parties of the COMPASS project declare to adhere to its procedures. Each party shall be solely liable about the consequences for any indirect or consequential damage resulting from the miss-use and breach of these obligations (see also CA Section 5: Liability towards each other).

The COMPASS project planned stakeholder interactions – both online and on-site – will involve the collection of personal data, incl. names, institutional affiliations, telephone numbers and e-mail addresses of interview partners and participants in the Responsible Innovation Labs. ‘Processing of personal data’ means any operation (or set of operations) which is performed on personal data, either manually or by automatic means.

Any data collection, processing and storage activities, procedures and tools will be in line with the personal data protection and intellectual property rights of the European Union, as defined by the European Commission¹. Thus, the COMPASS project and its parties as outlined in the COMPASS Consortium Agreement will comply with all relevant EU legislation (i.e. Data Protection Directive 95/46/EC; EC Data Protection Regulation No 45/2001; EC Data Protection; Regulation EU 2016/679; EU Directive 2016/680) as regards data protection and the treatment of personal data in particular. The collection of personal data will involve **activities and spaces for data processing and storage such as the (1) operation of interviews and (2) participants of Responsible Innovation Labs**. Its procedures for storage, safety, methodologies for collection as well as transfer and retention are outlined below.

2. Procedures for the collection of personal data

The **operation of stakeholder interaction in the form of (1) interviews and (2) Responsible Innovation Labs** will include the collection of personal data (e.g. name, organisation, position, type of organisation, country, e-mail address). The interviews will be conducted face-to-face, via skype or telephone. The Responsible Innovation Labs will combine virtual and in situ

¹http://ec.europa.eu/geninfo/legal_notices_en.htm;
https://www.google.at/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKewjbmtS9uJPLAhWpvnIKHWZXCbwQFggcMAA&url=http%3A%2F%2Fec.europa.eu%2Fresearch%2Fparticipants%2Fdata%2Fref%2Ffp7%2F89827%2Fprivacy_en.pdf&usq=AFQjCNHXxMp90ZdLH9NEBPYiRtTN4Rm_FQ&sig2=eCDtTdQ7Dmkz-qvuZb5TFQ

interaction between stakeholders from industry, policy-making and civil society organisations. Any personal data collected via interviews and labs will **not be publicly available** (i.e. these personal data will not be shared with third parties and are not attribute to any commercial use).

3. Data storage procedures and data security measures

Data storage in the scope of the COMPASS project will be secured to ensure that data will not be accessible by third parties and will be protected against disaster and risk.

Spaces for data storage and respective data security measures

As regards the **(1) interviews** and **(2) Responsible Innovation Labs**, the COMPASS project members at UCLan CY, FBLC, DMU and WU will store data in state-of-the-art secured computers on secured server-based storage drives, protected by most recent and regularly updated anti-virus software. Data will not be retained on stand-alone notebook computers. Collected data will not be shared nor accessed by any third party. Any other consortium party will make sure that the necessary security operations required by their organisations will be in place to guarantee data security and confidentiality.

Sharing of sensitive data among COMPASS project team members will be organised through the server-based and protected WU Owncloud system (i.e. IT Cloud system)².

Duration of data storage and access

Data concerning **(1) interviews** and **(2) Responsible Innovation Labs** will be stored for the total duration of the COMPASS project and, if necessary (e.g. utilised in the context of an academic or other publication), after the end of the project duration. Safe procedures outlined during the project's running time will be kept active as long as the respective data is in use or until terminated. A data subject will have the right to have his or her personal data erased and no longer processed where the personal data are no longer necessary in relation to the purposes for which they are collected or otherwise processed ("Right to be Forgotten").

4. Procedures for the protection from dual or improper use of personal data

This section deals with the fact that an unlinked information may cause side effects when a) sensitive or personal information is taken out of context, or b) is subject to dual use. It is the responsibility of researchers to consider if such a possibility exists and what response is needed. In this regard, the responsible party will take into account the following considerations:

Any data (i.e. collected through **(1) interviews** and **(2) Responsible Innovation Labs**) related to personal data collected by the COMPASS project will be anonymised for further use (i.e.

² WU ownCloud Reference Guide: https://www.wu.ac.at/fileadmin/wu/s/it/documents-public/en/instructions/WU-ownCloud_en.pdf

academic or other publications) and thus avoid the breach of sensitive personal information. COMPASS parties will make sure that any data that is used outside of the scope of the COMPASS project will be unlinked (anonymised) from any personal data information.

Procedures for the circulation of personal data

Relevant personal data (e.g. name, organisation, position, type of organisation, country, e-mail address) will be circulated among consortium parties via secure channels if necessary to achieve project output.

Confidentiality and safety procedures of personal data handling

As regards the **(1) interviews and (2) Responsible Innovation Labs** all project teams will store collected data in state-of-the-art secured computers, protected by most recent and regularly updated anti-virus software. Data will only be accessible to the COMPASS project team members who will adhere to a level of confidentiality (i.e. using safe storage methods for information on personal data as outlined in the COMPASS consortium agreement section 10). Furthermore, the project team members will comply with WU institutional data protection policy (“WU Information Security Policy”³; “The Organization of Information Security at WU”; “WU Directive on Confidentiality Classification”; “WU Directive on Data Erasure and Disposal”⁴) which outlines measures guaranteeing “protection from loss and damage to information” (availability), “protection from unauthorised access and disclosure of information (confidentiality)”, “protection from unintended and manipulative modification of information (integrity)”, and “protection from loss of non-repudiation or comprehensibility of information flows”.

All team members of COMPASS consortium parties are made aware about:

- issues beyond data protection and privacy described in this document; i.e. confidentiality procedures (as outlined in the COMPASS Consortium Agreement "Section 10: Non-disclosure of information");
- of legal requirements (EU and EU MS regulations⁵ concerning data protection issues) surrounding the use of private data under an electronic form (notification of the Austrian Data Protection Agency).

³https://www.wu.ac.at/fileadmin/wu/s/it/RL-2015-2016/EN_Informationssicherheitspolitik_der_WU_2015-1.0.pdf

⁴https://www.wu.ac.at/fileadmin/wu/s/it/RL-2015-2016/EN_Loeschungs-und_Entsorgungsrichtlinie_der_WU_2015-1.1.pdf

⁵ http://ec.europa.eu/justice_home/fsj/privacy/ and <http://www.privacyconference2009.org/privacyconf2009/home/index-iden-idimp.html>

5. Procedures for data destruction/deletion

Data concerning **(1) interviews and (2) Responsible Innovation Labs** will be destroyed according to the WU Directive on Data Erasure and Disposal⁶ in order to guarantee proper off- and online data protection. COMPASS consortium parties will apply appropriate tools and procedures for data deletion in order to guarantee irreversibility.

Data collected through **(1) interviews and (2) Responsible Innovation Labs** will be deleted as outlined in the Ethics requirements 1 and as stated in the participant information sheet and the approval of the local competent authority (Austrian Data Protection Agency – Österreichische Datenschutzagentur).

⁶https://www.wu.ac.at/fileadmin/wu/s/it/RL-2015-2016/EN_Loeschungs-und_Entsorgungsrichtlinie_der_WU_2015-1.1.pdf