[**Each hospital to use its own Patient Information Sheet and Informed Consent according to local requirements on local headed paper**]

The REVERSE-QoL study (pREVention and management tools for rEducing antibiotic Resistance in high prevalence Settings – Quality of Life)

Information for ALL Legal Representatives

We are inviting your relative/friend/patient to take part in a research study called REVERSE-QoL, which is being carried out in a number of hospitals in Greece, Italy, Romania and Spain. The study is funded by the European Union.

Before you decide if you want your relative/friend/patient to take part, it is important that you understand why the research is being done and what it will involve. Please take time to read this information sheet carefully or ask someone to read it to you. Please discuss it with others if you wish. We will give you a copy to keep. Please ask the nurses or doctors if there is anything that is not clear or if you would like more information. **Joining the REVERSE-QoL study is entirely voluntary.** Please take time to decide whether or not you wish your relative/friend/patient to take part.

You may decide that you do not wish your relative/friend/patient to take part now or you may wish them to take part now but then decide later to withdraw them from the study. Your decisions will not influence the care your relative/friend/patient receives now or in future. We hope that if you decide your relative/friend/patient will join the study but withdraw later, you would give a reason for your decision, but you do not have to do this if you do not want to.

What is our reason for doing the REVERSE-QoL study?

Antibiotic resistant bacteria can cause serious infections.To be able to justify potentially expensive measures that prevent infections with these bacteria, we need to better understand the long-term impact these infections on the Quality of Life of patients.

We want to what extent and for how long patients have a lower Quality of Life due to getting an infection caused by antibiotic-resistant bacteria during the hospital admission.

This study will help to distinguish whether and how antibiotic-resistant infections are affecting patients up to 1 year after the date they got infected. It will help us to identify the impact of those infections from a patient's or their relative/friend/carer's perspective, which is also needed to work out the value for money of strategies that reduce the change of getting infected.

Why has my relative/friend/patient been invited to take part?

Your relative/friend/patient has been invited to take part in this study because they have been admitted to a hospital that takes part in a large study evaluating the impact of different types of strategies that may reduce the chances of getting infected during your hospital stay. All patients that get infected with an infection caused by specific antibiotic-resistant bacteria (Carbapenem-resistant *Acinetobacter baumannii*, Carbapenem-resistant Enterobacteriales, or Carbapenem-Resistant *Pseudomonas aeruginosa*) during their hospital stay in one of the participating hospitals are invited to take part in this study focusing on the impact of these infections on quality of life. Also a random selection of patients that are not infected by

these bacteria are invited to take part into this study (2 uninfected persons for each infected person). Hence, your relative/friend/patients is invited to take part in this study so that we can compare their quality of life, as you think they would answer the questions at this moment, to that similar patients with(out) bloodstream infection.

Does my relative/friend/patient have to take part?

No. It is up to you to decide whether or not they will take part. Even after you have signed the consent form, you are free to withdraw them from the study at any time without giving any reason, by advising us of this decision. Any personal data will be destroyed. The deadline by which you can withdraw any information you have contributed to the research is anytime priot to completing the 12 month follow up. If you decide to withdraw your data, any data that has already been collected will be removed from the database.

What will happen to my relative/friend/patient if they take part?

If you decide that your relative/friend/patient will take part in this study a nurse will ask you to sign a consent form and to complete a short paper questionnaire. The paper form will ask about how you think your relative/friend/patient would rate their current quality of life and the contact details of both you and your relative/friend/patient so we can ask your relative/friend/patient (if they are well enough by that time) or you to complete the questionnaire again 1, 3, 6 and 12 months after you have completed the form the first time. The questionnaire can be completed at your own pace, but takes usually 8-15 minutes to complete.

Are there any risks in taking part?

The risks are small. You may experience some anxiety as you reflect on the illness of your relative/friend/patient.

What are the possible benefits of taking part?

You may experience an overall positive feeling in that the illness of your relative/friend/patient is being researched and their quality of life is being given consideration. Entering this study may not directly help your relative/friend/patient, but the information we get from the REVERSE-QoL study could help patients like them in the future.

What information will be collected and why is the collection of this information relevant for achieving the research objectives?

We will collect data on the quality of life of your relative/friend/patient – as you think they would rate their own quality of life – using two validated questionnaires: the EuroQol 5D (EQ-5D) and the 36-Item Short Form Survey (SF-36). In addition, we will collect information on the age, sex, time in the hospital, any surgery performed or antibiotic used in the past 30 days, and any underlying chronic diseases of your relative/friend/patient. The latter is needed to adjust for any relevant potential differences between infected and uninfected patients that may explain (absence of) observed differences between infected and uninfected patients.
Identifiable data (including consent forms) will be stored will be stored in a secure online system behind the University of Zurich's firewall. Only researchers that need to have access to the data will be able to see it. The data will be stored for 5 years. Other research data will be stored for 10 years after publication or public release of the work of the research.

What about protecting the confidentiality of the data of my relative/friend/patient?
Information about your relative/friend/patient – and your contact details - will be kept confidential and will not be made available to anyone who is not connected with the REVERSE-QoL study. The medical notes and study information related to your relative/friend/patient will be available to study staff. Strict confidentiality will be maintained at all times. The name of your relative/friend/patient will never be used for study information; these will be identified only by a study number (hospital site number (4 digits) and sequentially assigned subject number). Your contact details will only be used to approach you for the follow-up questionnaires at 1, 3, 6 and 12 months after the initial questionnaire if your relative/friend/patient is still not able to complete the questionnaire.

Will the research be published? Could I be identified from any publications or other research outputs?

The findings from the research will be written up in an academic publication. It will not be possible to identify your relative/friend/patient from the outputs as only aggregated (not at an individual level) will be reported.

Leaving the study
You may withdraw your friend/relative/patient from the study at any time, but if you do it would help us if you are able to tell us the reason for this. However you do not need to tell us if you do not want to.

How can my relative/friend/patient join the REVERSE-QoL study?
After you have read this information sheet, we will ask you to give consent for your relative/friend/patient to be seen by the nurse.

If you would like more information or have any questions about the REVERSE-QoL study please ask the doctors, nurses or counsellors. If you still need more information, please call:

Insert names and telephone numbers as appropriate:
Name:

Telephone Number: …….

If you decide your relative/friend/patient will join the REVERSE-QoL study and have any concerns about any aspect of the REVERSE-QoL study in the future, please also contact ..... on the telephone number above. If you remain unhappy and wish to complain formally, you can do this following the standard Hospital Complaints Procedure (details can be obtained from ..... on telephone number ..... as above).

The REVERSE-QoL (pREVention and management tools for rEducing antibiotic Resistance in high prevalence Settings – Quality of Life) study

What is a legal representative?

This additional information sheet covers the role of a personal legal representative.

What is a legal representative?
Where a potential study participant is unable to decide for him or herself whether to participate in the research someone who knows them well is asked to make a decision for them. The person making the decision is known as a "legal representative".

Why have I been asked to be a legal representative?
The medical and nursing team caring for your family member or friend have suggested that you know them well and your family member or friend would trust you to make important decisions about their well being and what they would want to happen (their presumed will or intentions).

Your family member or friend is very sick and there is a research study which they could join to find out what the impact of bloodstream infections caused by antibiotic-resistant bacteria is on quality of life compared to similar patients that remained infection-free at least up to the point of recruitment into this study. We are asking you because, they are not well enough to decide for themselves. If you are the doctor who is primarily responsible for the patient's medical treatment then you may have been asked to act as a legal representative if all efforts have been made to contact family members and it has not been possible to identify one.

Do I have to be a legal representative?
No, being a legal representative is completely optional, and if you choose not to be a legal representative this will not affect the care of your family member/friend/patient in anyway. If you do not wish to be a legal representative, we would welcome any suggestions you have about whether there is anyone else who might be a good person to ask to be a legal representative.

What does a legal representative need to do?
We would like to explain the research study to you, and provide you with the same information we would offer to any potential participant. We would then like you to consider whether your family member/friend/patient would want to take part. That is, what the past and present feelings and wishes of your family member/friend/patient would have been about taking part in the study. We are asking you to consider the interests and views of the person potentially taking part in it. If you think that your family member/friend/patient would be content to take part we would like to include them in the study and to keep a record of your agreement that they should join by asking you to sign a Legal Representative Consent Form. If you decide your family member/friend/patient will take part, as soon as they feel well enough we will ask them to complete the remaining subsequent questionairres at 1, 3, 6 or 12 months after you have completed the initial questionairre.

If you have any questions please feel free to ask the member of the research team you provided you with this sheet, or to contact the team on the number below. Thank you.

Insert names and telephone numbers as appropriate:
Name:

Telephone Number:

(To be presented on local-headed paper": same version as for trial participant except "my friend/relative/patient" rather than "me")
Version 1.1 Date 11 October 2015

REVERSE-QOL: pREVention and management tools for rEducing antibiotic Resistance in high prevalence SEttings – Quality of Life

Please initial (or mark) box if you agree:

I confirm that I have read/ been read the patient representative information sheet (version 1.1 dated 11 October 2021) for the REVERSE-QoL study and that I understand what will be required of me friend/relative/patient and me if they participate in the study. The study has been explained to me and I have had an opportunity to ask any questions I have about the study.	
I understand that my friend/relative/patient's participation is voluntary and that I am free to withdraw them at any time, without giving any reason, without my medical care or legal rights being affected.	
I understand that sections of any of my friend/relative/patient's medical notes may be looked at by responsible individuals involved in the running of the study where it is relevant to them taking part in research. I give permission for these individuals to have access to my friend/relative/patient's records, but understand that strict confidentiality will be maintained.	
I understand that I will be asked to complete a questionnaire 5 times in total over a period of 1 year as long as my friend/relative/patient is not well enough to complete the questionairre themselves. As soon as my friend/relative/patient feels well enough we will ask them to complete any subsequent questionairres.	
I agree my friend/relative/patient will take part in the REVERSE-QoL study.	

	Name	Email	Telephone number
Participant			
Legal representative			

Legal representative's signature	Print name	Date (day/month/year)

Signature of person delegated to take consent	Print name	Date (day/month/year)

IMPORTANT: one signed original to be kept in REVERSE-QoL study file by the researcher
one signed copy to be given to the patient's legal representative
one signed copy to be kept in the clinic file