



Participant information sheet

PROJECT TITLE: Professional views on reporting data about international travel for organ transplantation

HUMAN RESEARCH ETHICS COMMITTEE APPROVAL NUMBER: H-2022-128

PRINCIPAL INVESTIGATOR: Dr Georgina L Irish

Dear Participant,

You are invited to participate in the research project described below.

What is the project about?

This research project aims to find out what health professionals think about collection and reporting of information about international travel for organ transplantation (ITOT). In particular, it aims to

- estimate how frequently professionals provide care for patients who have travelled to or from their country for the purpose of donating or receiving an organ transplant.
- find out what professionals know about national and international registries that collect data about organ donation and transplantation.
- Evaluate professionals' willingness to collect and report data about cases of ITOT, and factors that may influence attitudes towards reporting of data.

The study will consider the way that factors in particular countries and regions may influence participation in opportunities for collection and reporting of ITOT data. The information obtained from this anonymous survey will be used to inform strategies that address barriers to collection and reporting of data about ITOT in particular countries or regions, and support responsible use of these data at the global level.

Who is undertaking the project?

This project is being conducted by an international team led by Dr Georgina Irish at the University of Adelaide in Australia. A list of the team members is shown at the end of this information sheet:

The study is financially supported by the Declaration of Istanbul Custodian Group, The Transplantation Society and the International Society of Nephrology. Several members of these organizations have also provided guidance on the design of the study and the content of the questionnaire. Only the research team members listed above will have access to the data collected via the survey.

Why am I being invited to participate?

All health professionals with experience in providing care for organ donors or transplant recipients are encouraged to participate in this study. We welcome participation by all professionals, regardless of the country you work in, or what kind of professional role you have in transplantation.

You may have received an invitation to participate as a member of a professional society which is involved in organ donation or transplantation, or from a professional colleague who believes this may be of interest to you.

You must be aged 18 years or more to participate in the study.



The survey questionnaire is only available in English at this time. This means that you must be able to understand enough English to participate. If you are able to understand this information sheet, you should be able to complete the survey without difficulty.

What am I being invited to do?

You are being invited to complete an anonymous online questionnaire. You will be asked a few general questions about yourself and about any recent experience you may have had providing care for patients who travelled to or from your country for the purpose of organ donation or transplantation. You will also be asked some questions about your knowledge of registries that collect data about donation and transplantation activities, and about your opinions regarding collection and reporting of data about international travel for organ transplantation.

How much time will my involvement in the project take?

It should take you approximately 10-15 minutes to complete the survey. The time it takes will depend on how much experience you have had in recent years in providing care for patients who have travelled internationally for organ transplantation, and whether you choose to provide any general comments or feedback at the end of the questionnaire.

Are there any risks associated with participating in this project?

It is possible that some health professionals participating in this project may suffer some distress if the questionnaire prompts them to think about difficult experiences they have had in providing care for patients who have travelled for transplantation or donation. In some circumstances, professionals may experience anxiety if they are currently dealing with a complex case of ITOT.

If you experience any distress or anxiety about your own management of ITOT cases, or about other aspects of ITOT such as local policies or practices, we encourage you to seek support from personal or professional support services in your country. You can also contact the research team and we will help you to identify an appropriate counselling service within your country or region. You can also contact the Declaration of Istanbul Custodian Group (DICG) if you would like to discuss a case in confidence or seek general advice on how to address issues relating to ITOT in your country or region. The DICG can be contacted via admin@declarationofistanbul.org.

There is a small risk that the results of this study could be used in ways that may stigmatise some countries, for example if responses indicate high levels of incoming or outgoing ITOT in specific countries. This is because some people may associate ITOT with unethical practices such as organ trafficking. To reduce this risk, any publication of results from this study will make clear the fact that ITOT frequently involves ethically appropriate travel for transplantation, and that the data collected in this survey provides only a neutral estimate of ITOT and no estimation of levels of trafficking or other unethical practices. If some countries or countries are underrepresented in the survey, publicly available data about ITOT for these countries will be discussed wherever possible in the publication of the study results. This will help to ensure that a genuinely global overview of ITOT activity is provided and that interpretation of the study results is not skewed as a result of differing levels of participation by professionals in specific countries or regions.



What are the potential benefits of the research project?

This project is expected to produce information that may be used by health professionals and policy makers to address barriers to collection and reporting of information about ITOT. In particular, it may inform the development of mechanisms to facilitate reporting of data to national and international registries of donation and transplantation activities.

By making it easier to report data, and addressing potential concerns about data collection or use, it is hoped that more useful data about ITOT will be made available to professionals and policy makers. These data can be used to improve patient care and decision-making about ITOT, and to guide development of donation and transplantation programs around the world.

Can I withdraw from the project?

Participation in this project is completely voluntary. Your participation or non-participation will have no impact on your membership of any professional societies. No professional society will be able to know whether you have participated in the study.

If you agree to participate, you can withdraw from the study at any time prior to completion and submission of your responses to the survey questionnaire. Once your responses have been submitted, it will not be possible to remove your data because all responses are entered anonymously.

If you have provided any information in your responses which may identify you, this will be dealt with as outlined in the following section.

What will happen to my information?

Confidentiality and privacy: participation in this study is anonymous. When completing the survey, you will not be asked to provide any information that could identify you. Although you will be required to answer some questions in order to complete the survey, you will always have the option of selecting a response such as “prefer not to answer” if you are not comfortable providing an answer.

All data collected will be reported only in an aggregated manner, and any details that would potentially identify an individual participant or transplant centre will be withheld from any publications or reports arising from the research. For example, in cases where data relates to countries with known small populations of transplant professionals, or demographic groups known to be of small size such as female transplant surgeons in particular regions, demographic data will be excluded from reported results or reported at the regional level.

Storage: The data will be encrypted and stored on a secure server through the University of Adelaide with password protected access by the principal investigators. The data will be kept for a minimum of 5 years.

Publishing: The aggregated results of this study will be reported in journal article publications and presentations at professional conferences in transplantation.

Sharing: A plain language summary of the results will also be shared with a range of professional societies who will be encouraged to share it with members. It will also be published on the website of the Declaration of Istanbul Custodian Group, where you will be access it: www.declarationofistanbul.org. Information about these publications will also be shared on social media such as Twitter and LinkedIn by members of the research team and supporting organizations.



It is possible that in a few years, researchers may wish to repeat this study to see if professionals' experiences of ITOT or attitudes towards data collection and reporting have changed. The researchers may seek access to the data from this study in order to compare the results. When you provide consent to participate in this study, you will also have the option of providing consent to use of your data in a future study. Your information will only be used as described in this participant information sheet and it will only be disclosed according to the consent provided, except as required by law.

The data will only be accessed by the research team. If there are changes in the research team, new team members may have access to the data. Access to the data from this study will only be approved for use in research that aligns with the goals of this study, and if the proposed study can ensure the same safeguards are in place to protect privacy and confidentiality of the data and to manage any associated risks including those outlined above.

Who do I contact if I have questions about the project?

Please contact the research team at georgina.irish@adelaide.edu.au . if you have any concerns or questions about the project.

What if I have a complaint or any concerns?

The study has been approved by the Human Research Ethics Committee at the University of Adelaide (approval number H-2022-128). This research project will be conducted according to the *NHMRC National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)*. If you have questions or problems associated with the practical aspects of your participation in the project, or wish to raise a concern or complaint about the project, then you should consult the Principal Investigator. If you wish to speak with an independent person regarding concerns or a complaint, the University's policy on research involving human participants, or your rights as a participant, please contact the Human Research Ethics Committee's Secretariat on:

Phone: +61 8 8313 6028

Email: hrec@adelaide.edu.au

Post: Level 3, Rundle Mall Plaza, 50 Rundle Mall, ADELAIDE SA 5000

Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

If I want to participate, what do I do?

If you would like to participate in the study, please [click this link](#) to access the online survey. You will be asked to read through this participant information (if you have not already done so) and to indicate your consent to participate. You can then proceed to answer the survey questionnaire. At the end of the survey, you will need to submit your responses and a page will appear confirming you have successfully completed the survey.

Yours sincerely,

Dr Georgina Irish University of Adelaide, Australia
Prof Toby Coates University of Adelaide, Australia
A/Prof Dominique Martin Deakin University, Australia
Prof Riadh Fadhil Hamad Medical Corporation, Qatar
Dr Eric Rondeau Sorbonne Université, France
Dr Sanjay Nagral Jaslok Hospital & Research Centre, India