Gender Reassignment Surgery as a Moral Challenge: A Theological-Ethical Investigation with a Focus on the Indian Context

A Data Management Plan created using DMPonline.be

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Project abstract:

Gender reassignment surgery (GRS) is widely presented and practiced as a promising and competent treatment option for gender dysphoria in the Indian context recently. Though there occur discussions on the medical and legal aspects, the ethical discussion on GRS is almost non-existing in the present context. The absence of a normative ethical framework on GRS in India creates moral confusion among the stakeholders as well as among common people. Situating GRS within the Indian context, this research aims at providing a normative theological-ethical framework for GRS in India through the critical dialogue between the ethical arguments coming from a normative (secular and theological) ethical literature review and empirical arguments coming from the qualitative research based on individual in-depth interviews among various stakeholders of GRS in India.

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Research Data Summary

List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data.

Dataset name / ID	Description	New or reuse	Digital or Physical data	Data Type	File format	Data volume	Physical volume
		*Indicate: **N**(ew data) or **E**(xisting data)*	Indicate: **D**(igital) or **P**(hysical)	Indicate: **A**udiovisual **I**mages **S**ound **N**umerical **T**extual **M**odel **SO**ftware Other (specify)		Indicate: <1GB <100GB <1TB <5TB >5TB NA	
Bibliographic details	Bibliographic details of selected excerpts for systematic review created using Endnote software	N	D	T	.pdf/.html	<1GB	
Code book of literature review	NVivo codes with descriptions of selected literature according to thematic framework. The excerpts will be imported to NVivo and coded	N	D	T	.nvp (NVivo project file)/.pdf	<1GB	
Interview protocol	Protocol developed for individual in-depth interviews	N	D	T	.pdf	<1GB	
Informed consent	Informed consent form of interviews	N	D	T	.pdf	<1GB	
Interview transcripts	Transcripts of individual in-depth interviews. Transcription of the audio files of interviews	N	D	T	.pdf	<1GB	
Codes book of interviews	NVivo codes with descriptions of the interviews according to thematic framework. The transcripts of the interviews will be coded on NVivo	N	D	T	.nvp/.pdf	<1GB	
Demographic details	Demographic details of the interviewees. This data set will be retained only during the project.	N	D	T	.pdf/.xls	<1GB	
Fieldnotes on interviews	Personal field notes and memos on interview	N	D	T	.pdf	<1GB	
Project file	NVivo project file which includes all literature and all interview transcripts with codes, cases, annotations and memos.	N	D	T	.nvp (NVivo project file)/ .gdpx (REFI-QDA)	<1GB	
README file	README file for the whole data storage	N	D	T	.txt	<1GB	

If you reuse existing data, please specify the source, preferably by using a persistent identifier (e.g. DOI, Handle, URL etc.) per dataset or data type:

This research involves a systematic literature review, for which literature will be collected from online open access literature databases namely, *Embase*, *PubMed*, *ATLA Religion*, *Web of Science*, *Scopus*, *The Philosopher's Index*, *Index Theologicus* and *Google Scholar*.

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? If so, refer to specific datasets or data types when appropriate and provide the relevant ethical approval number.

- Yes, human subject data (Provide SMEC or EC approval number below)

This research involves individual in-depth interviews of gender dysphoric people. It involves collection of personal data like name, contact information, gender, age and education. All personal data will be pseudonymized to prevent personal identification. Adequate ethics committee approvals (SMEC approval and Local ethics committee approval from India) will be obtained before the beginning of empirical data collection.

Will you process personal data? If so, please refer to specific datasets or data types when appropriate and provide the KU Leuven or UZ Leuven privacy register number (G or S number).

- Yes (Provide PRET G-number or EC S-number below)

This research involves collection of personal data like name, contact information, gender, age and education. All personal data will be pseudonymized to prevent personal identification. Adequate ethics committee approvals (SMEC approval and local ethics committee approval from India) will be obtained before the start of empirical data collection. PRET G-number will be added as it is obtained.

Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)? If so, please comment per dataset or data type where appropriate.

- No

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material or Data transfer agreements, Research collaboration agreements)? If so, please explain in the comment section to what data they relate and what restrictions are in place.

- No

Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use? If so, please explain in the comment section to what data they relate and which restrictions will be asserted.

- No

Documentation and Metadata

Clearly describe what approach will be followed to capture the accompanying information necessary to keepdata understandable and usable, for yourself and others, now and in the future (e.g. in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, codebook.tsv etc. where this information is recorded).

Codebook: Codebook will be produced for literature review as well as interview coding (.pdf/.xls file). It will contain description of each code, case and attribute.

Interview protocol and informed consent form: A detailed interview protocol and informed consent form will be uploaded (.pdf file)
Fieldnotes and memos: will contain necessary details to further analyze the interview transcripts.
README file: README.txt files will be included in order to explain various datasets whenever it is necessary.

Will a metadata standard be used to make it easier to find and reuse the data?
If so, please specify which metadata standard will be used.

If not, please specify which metadata will be created to make the data easier to find and reuse.

- No

Data will be deposited in resource data repository of KU Leuven. Meta data standard specified by RDR will be used.

Data Storage & Back-up during the Research Project

Where will the data be stored?

- Shared network drive (J-drive)
- OneDrive (KU Leuven)

All data will be stored in KU Leuven OneDrive and shared network drive J drive. The data will be pseudonymized and will be made accessible to the PhD researcher (Bijosh Moolekkudiyil Baby) and to the promoters (Prof. Dr. Yves De Maeseneer and Prof. Dr. Kris Dierickx) using their specific employee ID. Both drives will be backed-up automatically.

How will the data be backed up?

- Standard back-up provided by KU Leuven ICTS for my storage solution

Is there currently sufficient storage & backup capacity during the project?

If no or insufficient storage or backup capacities are available, explain how this will be taken care of.

- Yes

The data sets mainly include text based files (.pdf/.xls/.txt/.nvp). Thus, it may not exceed 10 GB data.

How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

Data will be pseudonymized. Drives will be made accessible to only involved researchers with specific employee ID.

What are the expected costs for data storage and backup during the research project? How will these costs be covered?

A standard cost for accessing J drive is expected. The cost for data storage on J drive will be covered by Prof. Dr. Kris Dierickx during the project as well as until 10 years of retention period.

Data Preservation after the end of the Research Project

Which data will be retained for 10 years (or longer, in agreement with other retention policies that are applicable) after the end of the project?

In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).

- All data will be preserved for 10 years according to KU Leuven RDM policy

Where will these data be archived (stored and curated for the long-term)?

- Shared network drive (J-drive)
- KU Leuven RDR

The data will be stored for 10 years on J-drive and KU Leuven RDR.

What are the expected costs for data preservation during the expected retention period? How will these costs be covered?

A standard cost for using J drive for 10 years is expected. This cost will be paid by Prof. Dr. Kris Dierickx until 10 years of retention period.

Data Sharing and Reuse

Will the data (or part of the data) be made available for reuse after/during the project?
Please explain per dataset or data type which data will be made available.

- Yes, as restricted data (upon approval, or institutional access only)

Pseudonymized data will be published in RDR under restricted access.

If access is restricted, please specify who will be able to access the data and under what conditions.

Only pseudonymized data will be shared upon personal written request to the researcher (Bijosh Moolekkudiyil Baby) or the promotors (Prof. Dr. Yves De Maeseneer and Prof. Dr. Kris Dierickx) of the project via email. It will be shared only after the publication of the results of the research. The decision on data sharing will be made based on the nature of the request, for research purpose only accessing the reliability of the demanding party. The decision on data sharing will be taken together by the researcher and the promoters. The contact details and data with personal identifiers will not be shared.

Are there any factors that restrict or prevent the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)?

Please explain per dataset or data type where appropriate.

- Yes, privacy aspects
- Yes, ethical aspects

Pseudonymized interview transcripts will be shared on request. It will be specified in the interview informed consent form. Data with personal identifier such as demographic information will not be shared in any case.

Where will the data be made available?

If already known, please provide a repository per dataset or data type.

- KU Leuven RDR (Research Data Repository)

When will the data be made available?

- Upon publication of research results

Which data usage licenses are you going to provide?

If none, please explain why.

- Other (specify below)

Specific data usage licenses will be added if necessary according to the nature of the future project and the reliability of the requesting party.

Do you intend to add a persistent identifier (PID) to your dataset(s), e.g. a DOI or accession number? If already available, please provide it here.

- Yes, a PID will be added upon deposit in a data repository

What are the expected costs for data sharing? How will these costs be covered?

At this stage, no cost is expected for data sharing.

Responsibilities

Who will manage data documentation and metadata during the research project?

The researcher (Bijosh Moolekkudiyil Baby)

Who will manage data storage and backup during the research project?

The researcher (Bijosh Moolekkudiyil Baby). The backup is done automatically as we use KU Leuven OneDrive and J drive.

Who will manage data preservation and sharing?

The researcher: Bijosh Moolekkudiyil Baby
The promoters: Prof. Dr. Yves De Maeseneer, Prof. Dr. Kris Dierickx

Who will update and implement this DMP?

The researcher: Bijosh Moolekkudiyil Baby