## DMP title

**Project Name** The Hazards of Hormones: Risk, Regulation and Womenâ€™s Health in the History of Hormones in Belgium - DMP title

**Project Identifier** 12I9322N

**Grant Title** 12I9322N

**Principal Investigator / Researcher** Tinne Claes

**Project Data Contact** tinne.claes@kuleuven.be

**Description** Hormones today are everywhere: in pharmacies and hospitals, on bedside tables and in handbags. Millions of women ingest synthetic sex hormones to control their fertility, for menstrual and menopausal problems, to assist conception, as abortifacients, and for other reasons. In our collective memory, the rise of hormones mostly counts as a positive development, giving rise to womenâ€™s emancipation and sexual liberation. Yet there also exists a popular counter-narrative, in which the widespread consumption of hormones is seen as an unethical experiment that damages womenâ€™s health for the benefit of industry and the male medical establishment. Both these narratives lack nuance. Yet whereas scholars have corrected the idea that the pill spawned a sexual revolution, they have neglected the more sinister side of this history. The rise of hormones was unprecedented both in terms of its rapidity and range, but we know very little about the wider handling of their possible sideeffects. This project studies how the risks of hormones in Belgium were managed by five actors: the regulator, the pharmaceutical industry, the medical community, the womenâ€™s movement and the patientsâ€™ rights movement. Going beyond the history of oral contraceptives, from the diethylstilbestrol (DES) scandal to the morning-after pill, this project will produce the first monograph recounting the interwoven histories of hormones and their hazards, from their commercialisation in the 1940s up to the present day.

**Institution** KU Leuven

### 1. General Information

**Name applicant**

Tinne Claes

**FWO Project Number & Title**

12I9322N: The Hazards of Hormones: Risk, Regulation and Women’s Health in the History of Hormones in Belgium

**Affiliation**

- KU Leuven

### 2. Data description

**Will you generate/collect new data and/or make use of existing data?**

- Generate new data

**Describe in detail the origin, type and format of the data (per dataset) and its (estimated) volume. This may be easiest in a table (see example) or as a data flow and per WP or objective of the project. If you reuse existing data, specify the source of these data. Distinguish data types (the kind of content) from data formats (the technical format).**

This project collects or generates two types of sources: textual and audio/audiovisual. The textual sources will be diverse, consisting of both archival and published sources, for example, minutes of meetings, compendia of pharmaceutical products, correspondence, etcetera. All documents will be scanned and digitised, using OCR to turn them into .txt-files. This will not require a lot of storage space: taking my previous research project as a point of reference, I will collect approximately 100GB of textual data. The generated audio and audiovisual sources, namely oral history interviews, will be kept as .wav-files, which together will be circa 150GB large.

### 3. Legal and ethical issues

**Will you use personal data? If so, shortly describe the kind of personal data you will use. Add the reference to your file in KU Leuven's Register of Data Processing for Research and Public Service Purposes (PRET application). Be aware that registering the fact that you process personal data is a legal obligation.**

- Yes

Privacy Registry Reference: (G-2022-5264)
Short description of the kind of personal data that will be used: The oral history interviews may contain personal/emotional testimonies.

**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, add the reference to the formal approval by the relevant ethical review committee(s)**

- Yes

I have submitted this project for ethical review (G-2022-5264), but have not yet received a decision.

**Does your work possibly result in research data with potential for tech transfer and valorisation? Will IP restrictions be claimed for the data you created? If so, for what data and which restrictions will be asserted?**

- No

**Do existing 3rd party agreements restrict dissemination or exploitation of the data you (re)use? If so, to what data do they relate and what restrictions are in place?**

- No

## 4. Documentation and metadata

**What documentation will be provided to enable reuse of the data collected/generated in this project?**
For the interviews, details on the setting of the interviews, the informed consent process, the subjects discussed and the instructions given to interviewers will be documented in a Word document. Also steps taken to remove direct identifiers in the data will be described.

**Will a metadata standard be used? If so, describe in detail which standard will be used. If no, state in detail which metadata will be created to make the data easy/easier to find and reuse.**

- No

## 5. Data storage and backup during the FWO project

**Where will the data be stored?**
During the project, I will make use of the OneDrive cloud service provided by the Faculty of Arts at KU Leuven (2 TB storage, free of charge). This storage space is safe and automatically backed up, and allows for extra protection of sensitive data. Concretely, I use the Multi Factor Authentication and Conditional Access functions, so that I alone may access the data before anonymisation. I will anonymise the interviews with Cubase, distorting the voice and ‘bleeping’ any identifiable information.

**How is backup of the data provided?**
The data will be stored on the university's central servers with automatic daily back-up procedures.

**Is there currently sufficient storage & backup capacity during the project? If yes, specify concisely. If no or insufficient storage or backup capacities are available then explain how this will be taken care of.**

- Yes

2 TB storage is enough for this project.

**What are the expected costs for data storage and back up during the project? How**

**What are the expected costs for data storage and back up during the project? How will these costs be covered?**

The OneDrive cloud service is provided by the Faculty of Arts at KU Leuven, free of charge.

**Data security: how will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?**

Since we will be working with sensitive personal data that will only be anonymised at the end of the project, the data will be stored in the university's secure environment for private data. I use the Multi Factor Authentication and Conditional Access functions.

## 6. Data preservation after the FWO project

**Which data will be retained for the expected 5 year period after the end of the project? In case only a selection of the data can/will be preserved, clearly state the reasons for this (legal or contractual restrictions, physical preservation issues, ...).**

I use personal and/or sensitive data. I will deviate from the principle of preservation of data and/or the minimum preservation term only when legally required to do so, concretely, when interviewees do not give their informed consent for the preservation of oral history interviews or personal archives.

**Where will the data be archived (= stored for the longer term)?**

The data will be stored on the university's central servers (with automatic back-up procedures) for at least 10 years, conform the KU Leuven RDM policy.

**What are the expected costs for data preservation during the retention period of 5 years? How will the costs be covered?**

As mentioned above, I will make use of ‘Archive storage’ at KU Leuven after the project. The cost for this (€75/500GB per year) will be covered with the bench fee.

## 7. Data sharing and reuse

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

- Yes. Specify:

The data will be destroyed at the end of the project if the participants have not given consent for the data to be kept beyond the project.

**Which data will be made available after the end of the project?**

All interviews, with the informed consent of the interviewees, will be kept in an oral history repository (working title ‘Hormone Stories’) at the archives for women’s history AVG Carhif in Brussels (http://www.avg-carhif.be/). Copies of the collected textual sources will also be given to, inventoried by and kept at, the patient organisation DES in Belgium (http://www.desinbelgium.be/).

**Where/how will the data be made available for reuse?**

- Other (specify):

See question above.

**When will the data be made available?**

- Immediately after the end of the project
- After an embargo period. Specify the length of the embargo and why this is necessary

If interviewees only want their data to be made public after a longer period or after their death, I will respect their wishes. This information will be registered on the informed consent forms.

**Who will be able to access the data and under what conditions?**

This is dependent on the wishes of the interviewees (as indicated on the informed consent form).

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

This will be free of charge, as the access will be provided by the organisations mentioned above.

## 8. Responsibilities

**Who will be responsible for data documentation & metadata?**

Tinne Claes

**Who will be responsible for data storage & back up during the project?**

Tinne Claes

**Who will be responsible for ensuring data preservation and reuse ?**

Kaat Wils

**Who bears the end responsibility for updating & implementing this DMP?**

The PI bears the end responsibility of updating & implementing this DMP.