Research Data Management for getting started on a new project

Whenever setting up a project there are relevant processes and documentation that should be in place. As a PhD supervisor, it is important that all this preparatory work is in place before the candidates begin their project in order to avoid any delay with their start, or any of the steps in their PhD development cycle.

You should make sure to inform the PhD candidates about any relevant framework agreement, policy, legal documentation in place for their project if they will affect their research activities, publications and/or defence process.

You can find below a set of checkpoints that can help you prepare for the processes and complete the necessary documentation when starting any new research project at TU Delft.

You will see that some of the preparatory work and documentation involves the drafting of the data management plan (DMP) where the PhD candidate has an active role. But, it is your responsibility as a supervisor to guide the PhD candidate and make sure that processes and documentation associated with their DMP have been correctly completed.

New Research Project

Check relevant institutional code of conduct, policies, internationally approved guidelines, and other discipline-specific protocols:

- TU Delft Code of Conduct and Regulations: <u>https://www.tudelft.nl/en/strategy/integrity-policy/codes-of-conduct-and-regulations</u>
- Research Data and software management policies: <u>https://www.tudelft.nl/en/library/research-data-management/r/policies/tu-delft-faculty-policies</u>
- Personal Research Data Workflow: <u>https://www.tudelft.nl/en/library/research-data-management/r/manage/confidential-data/personal-data</u>
- Other internationally approved guidelines e.g. <u>https://cioms.ch</u> for health-related studies such guides may be useful if you engage in a domain in which TU Delft has less expertise.
- Other domain-specific protocols such as the Nagoya protocol (utilisation of genetic resources), Laboratory safety measures and/or protocols.

New Research Project with partners

Collaboration with other institutions should be formalised in agreements describing the roles of each institution and lay down basic expectations related to all project outputs. Things to consider when setting up the agreements of your projects:

- Collaboration agreements including consortia and internship agreements need to include data management rights and responsibilities
- Intellectual Property (IP) and other data management needs require formal agreements with third parties by setting up consortium/collaboration agreements with support from the Faculty Contract Management team
- If your activity is part of a funded project (such as NWO, ERC, HorizonEurope) a template for a consortium agreement may already exist.
- If no consortium or collaboration agreement template is available from a funding agency, TU Delft offers a <u>Model Agreement for Academic and Scientific Cooperation</u> template. This document must be signed by the dean of your faculty (generally via the contract managers), and the legal representative of the partner organisation(s)
- When you talk to the contract manager, have at hand:
 - · the project proposal, describing the expected activities of each partner
 - · the expected/estimated outputs
 - A description of the activities that you as TU Delft partner will contribute to the project (Section I of TU Delft template)

Note: Project partner is who actively contributes to the research activities in the project as opposed to a participant institution which only provides access to information (for case studies, for instance).

Project partners outside the EEA

Specific rules may apply when you are collaborating with organisations located outside of the European Economic Area (EEA). This may include differences in privacy laws, or restrictions regarding knowledge transfers. The applicable rules will depend on the country in which your project partners are located.

Things to take into consideration when establishing a project collaboration with partners outside the EEA include:

Your point of contact point about Knowledge security with partners outside the EEA is the <u>Faculty</u>
 <u>Knowledge Security Coordinator</u>

- Setting up the appropriate agreements may take longer when collaborating with partners (private companies and/or research institutions alike) if they are from outside the EEA.
- Make sure to get a local reference point for legal / ethical concerns in the institution of your project partner.TU Delft may not have the legal expertise to ensure that your activity will comply with local laws. You will rely on the partner institution's legal services to guide us in such processes.
- Knowledge transfer in any form (such as information, data, materials) might be restricted with certain countries. Please visit the intranet page provided by our <u>Knowledge Security team</u>, and check if this may affect your project.
- In the current geo-political situation, partnering with some institutions within certain research fields is considered unsafe. Please check <u>The Knowledge Security FAQ</u> for more information.
- Check if the country, in which the intended partners are located, is on the European Union Sanction List (<u>https://www.sanctionsmap.eu/#/main</u>). If this is the case, this may affect our ability to work with them.
- Check if the country of the project partner is listed as an "orange" or "red" country in the Dutch Government travel advice, as this may limit your ability to travel for field campaigns or meetings (in Dutch): <u>https://</u><u>www.nederlandwereldwijd.nl/reisadvies</u>. For questions regarding your insurance during work travel, you can contact: insurance@tudelft.nl
- When you talk to the Faculty Knowledge Security Coordinator, have at hand:
 - the project outline describing the expected activities of each partner,
 - the expected/estimated outputs.
 - The focus should be on what information will be shared/transferred between institutions during the research project, as well as the usage of the expected results/output by partners.

Working with Personal Data and/or Human subjects

If your project involves the work with Human Subjects (either collecting their data and/or making them part of trials, co-creation sessions, technology testing, and so forth) you have an extra responsibility to comply with all ethical and legal requirements as a PhD supervisor, researcher and employee of TU Delft.

Important things to consider:

- Whenever working with human subjects in your projects (including PhD and MSc projects) you have to
 prepare an <u>HREC application</u>. This also applies when using data from Statistics Netherlands (Centraal
 Bureau voor de Statistiek CBS).
- The Responsible Researcher (supervisor or PI) is responsible for assessing the ethical concerns and the quality of HREC applications. The corresponding researcher is the main contact point with HREC and can be the PhD candidate.

- The HREC application requires three main documents:
 - The Data Management Plan (DMP), with the Data Steward as main contact point for support
 - A completed, <u>HREC Checklist</u> that has been signed by the **Responsible Researcher**
 - (in most cases) completed Informed Consent materials
- If running a medical trial and/or the testing of a medical device, the HREC has no mandate to assess clinical or medical research, and an application to the Medical and Ethical Testing Committee (external) will be needed. In case of queries you can contact the TU Delft Medical (Devices) Policy Advisor and/or Biomedical Safety Advisor. Look at this page for more information on <u>Legal requirements and Ethical</u> <u>standards</u>.
- If the project is also collecting **personal data** from participants, it is necessary to comply with the General Data Protection Regulation (GDPR) legal obligations
- Collaborations with third parties, inside and/or outside The Netherlands, and the exchange of
 personal data with them requires a set of documentation to be in place in order to protect the human
 subjects and minimise any risk of harm. It is important that you as a supervisor inform yourself about these
 requirements in order to better support the PhD candidates. Please visit the section '<u>TU Delft Personal
 Data workflow and the related agreements and documents</u>' where you can find more detailed information
 about the relevant steps, questions and documentation that you and the PhD candidates might need
 before you can start collecting the personal data for your research project.