**'Tips and tricks' for preparing a clinical study in Princess Máxima Centre**

1. For your protocol: use the CCMO template available on the CCMO website: https://english.ccmo.nl/investigators/standard-research-file/c.-protocol. This is part of the standard research file that is available at the CCMO website, that can help you to decide which documents you need to draft for your study.

2. Please realize that clinical research that is not subject to the "Medical research involving human research act (WMO)" still needs to be submitted to the ethics committee, as the final decision on whether a study is subject to this act is their capacity. In case of doubt you can discuss with the TDC and look at the CCMO website: https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/your-research-is-it-subject-to-the-wmo-or-not.

In case of submission of a dossier that is not subject to this act a very limited dossier can be submitted to the ethics committee: https://www.metcutrecht.nl/nl/Is-toetsing-nodig. Note that submission will **always be done** by the TDC (Trialsupport; trialsupport@prinsesmaximacentrum.nl).

3. Submission to ethics or a grant application can only take place AFTER approval from the 'Clinical Research Committee'(CRC).

4. When you prepare a study please consider very early on whether you need statistical support with the design, sample size considerations and the writing of the statistical analysis part. Please contact the TDC to consult the statisticians. This will also be discussed during the intake by the TDC intake committee.

5. In the Máxima only study or trial databases from Castor or Open Clinica may be used. Central Datamanagement can provide explanation and help your with your questions. Do NOT use excel. This will also be discussed during the intake by the TDC intake committee.

6. Patient information sheets are required for:

- parents/legal guardians
- children aged 16 years and over
- children 12-16 years old

Template forms are available through trialsupport (trialsupport@prinsesmaximacentrum.nl). These templates include the mandatory text from the CCMO template and the GDPR language, as well as some Máxima specific adaptations. Note that any other formats will be rejected by the Ethics Committee as of April 1st 2019. Consent forms need to be signed by both parents or legal caretakers and by the treating physician or investigator. Documentation of

the informed consent procedure in HIX is mandatory. No study-related procedures can start prior to obtaining informed consent.

7. Studies that are ***Not*** subject to the 'Medical Research Involving Human Subjects act' are still subject to the WGBO and to the privacy regulation (GDPR). Subjects still need to be appropriately informed and consented to participation. The CRC will consider whether this has to be done in writing. In case written informed consent is considered required it is mandatory to use the format under point 6.

8. Trial subject insurance and liability insurance are covered by the Máxima. The insurance certificates are available via trialsupport: trialsupport@prinsesmaximacentrum.nl.

9. Doing studies incurs costs – so please discuss your budget with the TDC (to determine which personnel or other support is needed for your study), and the financial controllers of the research department (e.g. mandatory for KIKA/KWF grant applications) before submitting a grant application. Contact through trialsupport@prinsesmaximacentrum.nl (TDC) and via ResearchFinance@prinsesmaximacentrum.nl (financial controllers).

10. Your grant application also needs to be approved by the CRC before you can submit it. Please contact the CRC at scicom@prinsesmaximacentrum.nl, when you want your grant application to be reviewed by the CRC.

11. Monitoring is obligatory for all research subject to the WMO. Limited monitoring/auditing will be arranged for research subjected to the WMO – mainly focusing on the patient information and consent process. You can apply for a study specific quotation for monitoring via the TDC.

11. You may need contracts for your study – please liaise with the Trial and Datacenter through trialsupport. Contracts need to be reviewed with the legal representative of the Maxima for clinical studies (Germaine Biber), which can be arranged by Trial Support. A contract may be relevant for who owns the data, authorships and grants, hence in your own best interest.

12. Define who will be the sponsor of the study (a sponsor is not necessarily the grant provider but the legal institution that has end-responsibility and hence needs to be in control of the study). Investigator-driven studies run in the Maxima are usually sponsored by the institution although exceptions may apply. Especially when Maxima is considered as sponsor an early discussion with the TDC is required given the legal obligations that this implies.

13. After approval by the ethics committee and the competent authority be aware that you need approval of the Board of Directors of the Maxima before the study can be opened for inclusion of patients. This can be arranged via trialsupport: trialsupport@prinsesmaximacentrum.nl.

14. If you need central or specific local lab services please discuss early with Edwin Sonneveld (e.sonneveld-2@prinsesmaximacentrum.nl).

15. Before a study can be opened a start-up meeting named site-initiation visit needs to be scheduled in which all participants are trained for the study.