The Hague, the 19th of October 2020

Dear sir, madam,

In view of the consultation of national bodies with regard to Guideline 07/2020 on the concepts of controller and processor in the GDPR, the Central Committee on Medical Research involving Human Subject (CCMO) of the Netherlands herewith kindly sends its comments on the Guideline. In particular, the CCMO wishes to share its view on the example regarding clinical trials as set out on page 21 and 22 of the Guidelines.

The CCMO is of the opinion that this example is rather confusing and not an adequate representation of existing relations between investigators and sponsors in human subject research. As such, the example gives rise to questions regarding the existing legal and medical-professional tasks and responsibilities of medical researchers and healthcare providers that also carry certain responsibilities towards the subjects' data they collect in the context of a clinical trial.

In this regard, the CCMO has considered the following:

The question is whether the roles of processor and controller in medical research involving human subjects can be (sub)separated as strict, as set out in the example Clinical trials. As research practice shows, more situations are likely to exist in the way data processing is organized by sponsor and research institution, rather than the two ultimate examples mentioned here, i.e. studies in which a participating investigator has no role at all in the composition of a sponsored research file and those in which an investigator takes care of the drafting process. In the first case, the investigator would be expected to leave the determination of the data processing goals and means solely to the discretion of the sponsor. In our view, this seems to be incompatible with legal and professional duties of the researchers carrying out (a major part of) the protocol as they apply in the Netherlands as well as – probably – in other countries. More specifically, the health care provider/investigator/research institution is – within the role of researcher – responsible for e.g.:
-complying with confidentiality and privacy agreements regarding participants;
-informing participants about so-called new findings and, if necessary, informing the attending physician about such findings;
-reporting a data breach concerning the study's source files to the Dutch data protection authority;
-providing the Health Care Inspectorate (IGJ) and the CCMO access to source files within the framework of supervision;
-publishing the results through the use of their own expertise (via the freedom of publication enshrined in the contract, parties that carry out the research must be able to fulfil this task).

In short, even if one does not contribute to the writing of a study file by a sponsor, the aforementioned tasks and responsibilities of a medical researcher & healthcare provider may hardly be limited to those of a 'processor' in the sense of the Guideline definition (Article 4 paragraph 8: "a natural or legal person, public authority, agency or another body, which processes personal data on behalf of the controller"; see p. 24).

Additionally, the CCMO wonders how this "processing ... on behalf of the sponsor" should be interpreted. Do investigators by definition process their research data in sponsored

research situations entirely for the benefit of a sponsor? Our Dutch national policy stating that sponsors are not entitled to have access to keys of encrypted human subject data demonstrates that the professional role of medical investigators themselves requires more than just demonstrating service to (the data needs of) a study sponsor.

Therefore, the CCMO holds the view that investigators and sponsors in a clinical trial always (more or less) work together, if only because of their goal-identical processing of health data, they should in principle be regarded as "joint controllers". In our opinion, this is also in line with the wording on "joint controllers" on page 16 et seq. of the Guideline concept ("43. The qualification as joint controllers may arise where more than one actor is involved in the processing"). To put it differently: the CCMO believes that the role of 'processor' as further clarified in the 'Guidelines 07/2020 on the concepts of controller and processor in the GDPR' in virtually no setting fits the position, function and responsibilities of the practitioner (facility institution/researchers) of medical scientific research, as regulated in European and Dutch law because the practitioner of (externally funded) research.

Finally, the CCMO has always understood that, in the light of the GDPR, one should not assume too easily that processor-ship applies, since this could be assessed as avoiding / evading the GDPR responsibilities. The following passage in the summary of the Guidelines also points in that direction:
A processor infringes the GDPR, however, if it goes beyond the controller's instructions and starts to determine its own purposes and means of the processing. The processor will then be considered a controller in respect of that processing and may be subject to sanctions for going beyond the controller's instructions.
It seems to us that the controller should not want to end up in that water at all.
In conclusion, the CCMO is of the opinion that joint controllers' is the correct and most adequate legal qualification to apply to the abovementioned relation between medical investigators and sponsors of medical research involving human subjects.

We therefore strongly recommend you to refrain from using the example.

Yours sincerely,

CCMO