

## RESEARCH REVIEW PROCESS POLICIES METC VUMC – based on JCI standards

Of all standards in which the Medical Ethical Review Committee (METc) of VUmc is involved the role and policy of the METc VUmc is described. This document will be used to write a Dutch Standard Operating Procedures (SOP) document that describes the entire process of a research review by the METc VUmc. This document is still under construction.

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### THE JCI STANDARDS

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#### **Norm HPR.1 ME4 → Hospital leadership assumes responsibility for patient protection irrespective of the sponsor of the research**

*The Hospital Board is responsible for all scientific research involving human subjects that is carried out at VUmc. VUmc researchers and physicians remain responsible for their actions and protection of the patients, regardless of who the sponsor of the research is. The principle investigator is responsible for the design, implementation and completion of the research (according to articles 8-12 of the Medical Research Involving Human Subjects Act (hereafter [WMO](#))).*

#### **Norm HRP.1.1 ME1 → Hospital leadership recognizes and establishes mechanisms for compliance with all regulatory and professional requirements related to research.**

*According to the WMO all research with humans that subjects persons to research actions or interventions or that impose behavior, should be reviewed by an accredited committee. According to this legal task the METc VUmc reviews research proposals. In addition to her legal task, the METc also fulfills an advising role; she helps researches to comply with regulatory and professional requirements by advising through her website, e-mail, phone or personal contact, see website [METc](#).*

#### **Norm HRP.1.1 ME2 → Hospital leadership has a process for budgeting to provide adequate resources for effective operation of the research program**

*The METc considers research that cannot be performed or that cannot be completed unethical, she wants to ascertain that the research is financially and logistically feasible. Therefore, she requires a signature of the department head as well as the business manager of the concerning division on the submission letter. With their signature, they acknowledge that the department has adequate facilities to carry out the research. If research involves medical imaging, the department of Radiology and Nuclear Medicine needs to sign the submission letter or research protocol as well to assure that scanning costs are covered and scanning time and personnel is available*

*Resources: - submission letter (see [website](#))*

#### **Norm HRP.1.1 ME3 → Hospital leadership provides or ensures that there is adequate indemnity insurance to compensate patients participating in clinical research who experience and adverse event**

*The WMO specifies that a 'WMO-research subject insurance' must be taken out for research. The insurance must provide coverage for any unexpected injury or adverse event resulting from the research. Since 15 July 2015, it is the responsibility of the sponsor (initiator) of the research to take care of the 'WMO-research subject insurance' for all participating centres in the study. Researchers need to submit information about the 'WMO-research subject insurance' to the METc (according to article 7 of the [WMO](#)). Under certain conditions, exemption from the 'WMO-research subject insurance' is possible. When the researcher has the opinion that the research involves no or minor risks, they can request the METc to grant exemption from the 'WMO-research subject insurance' (according to article 7, clause 5 of the WMO). The committee will decide whether exemption is allowed. The certificate of the 'WMO-research subject insurance' needs to be submitted to the METc. If a commercial partner (e.g. pharmaceutical industry) is the sponsor of the research, the*

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policy conditions must be added. At all times, a liability insurance needs to be present for all participating centres (locations).

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**Resources:**

- insurance policies VUmc by Centramed (see [website](#))
- website METc VUmc: [verzekeringen](#)

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**Norm HRP.2 ME2 → Hospital leadership identifies the facilities and resources that support the research program**

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*The METc belongs to the staff service 'Research support' of VUmc. The METC reviews protocols from her legal task and advises researchers from her supportive task.*

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**Norm HRP.2 ME3 → Hospital leadership identifies the qualifications of staff permitted to participate in the research program as principal investigator or other members of the research team.**

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**Norm HRP.2 ME4 → There is documentation of the qualification of staff permitted to participate in the research program**

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*According to the WMO, research must be conducted in appropriate institutions and by, or under the supervision of, persons with appropriate training in scientific clinical research, of whom at least one is an expert in the procedures that will be carried out in or with the human subject (according to article 3, clause f; article 13, clause c and d of the [WMO](#)). The METc VUmc assesses if the researcher(s) are competent in carrying out the research that is being reviewed on the basis of their curriculum vitae (CV). Furthermore, the METc VUmc checks if every researcher involved in the research protocol has a BROK certificate, in accordance with the NFU advice "Kwaliteitsborging mensgebonden onderzoek 2.0".*

*Information about the BROK needs to be indicated on the submission letter. CV's and submission letters become part of the METc file and stored conform METc VUmc requirements.*

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**Resources:**

- checklist 'indienen WMO', see [website METc](#)
- submission letter WMO, see [website METc](#)
- BROK, see [website METc](#)

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**Norm HRP.2 ME5 → Hospital leadership identifies those circumstances in which staff can serve as research subjects**

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*VUmc employees cannot participate as healthy subjects or as patients in scientific research carried out by their own department because of dependence in the work relation and impossibility to ensure consent is given freely. VUmc employees are permitted to participate in scientific research of other departments under the condition that there was no undue inducement or relationship of dependence between the employee and the researchers and the employee in question was free to decide on participating in the research (according to article 5 of the WMO). In cases like this, the METc VUmc therefore demands an open passive recruitment strategy, for example by posters. The incentive to participate must lie with the employee.*

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**Norm HRP.3 ME2 → The requirements include that sponsors use research teams that are trained and qualified to conduct the research**

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*For sponsored research the METc VUmc demands the same requirements as for investigator initiated research (see HRP.2 ME3 en ME4). In addition, a VUmc researcher has to be involved in research performed in VUmc, otherwise the METc VUmc and Hospital Board will not allow the research (to be performed in VUmc).*

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**Norm HRP.3 ME3 → The requirements include that sponsors protect the privacy and confidentiality of the subject data**

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According to the WMO, the person who carries out the research must ensure that the human subject's personal life is protected as much as possible (article 12 of the [WMO](#)). One of the required experts in an METC is a legal expert. All documents that involve the privacy and/or confidentiality sensitive data of the research subject, will be subjected to his/her review. Most data will be handled in coded or anonymous form. If a researcher wants to diverge from that criteria, it must be motivated to the committee why less private forms of data handling and storage are necessary for the research. Data transfer abroad is only allowed when researchers have explicit consent from the research subjects for this transfer and data sharing and data processors agreements are present. The human subject information form (PIF) also needs to contain information about the privacy legislation and how the sponsor protects their privacy.

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Resources: - Standard ICF of the CCMO, see [website METC](#)

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**Norm HRP.3 ME5 → The requirements include that sponsors do not permit patient or researcher incentives that would compromise the integrity of the data**

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The METC ensures that all research being reviewed must comply with article 3, clause 1, sub g and h of the [WMO](#). This article states that it must be reasonably plausible that there are no undue inducements for research subjects or researchers which affect the integrity of the research. In the "Algemeen Basis registratieformulier" (ABR), which is a required document in METC submission in the Netherlands, there are two questions addressing these incentives (D11, D12, and G3). On the basis of this form and the information in the ICF and protocol, the METC VUmc determines whether incentives are suitable.

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Resources: - ABR-form, see METC [website METC](#)

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**Norm HRP.5 ME1 → The hospital specifies the requirements for managing conflicts of interest, both financial and non-financial**

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The METC VUmc assesses conflicts of interest between researchers and sponsors, as well as between researcher and possible participants. This assessment is based on the research protocol, the CV's and the ABR-form (G4, whether or not the researcher has had any personal financial relations with the sponsor of the study during the previous five years). The METC VUmc also ensures that there are no conflicts of interest between the members of the METC VUmc and the research that is being reviewed. If any such conflicts exists (e.g. a member advised a researcher), the member cannot take part in the review of that specific protocol and is asked to step outside.

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Resources: - ABR-form, see METC [website METC](#)

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**Norm HRP.4 ME1 → Hospital leadership identifies and supports the structure and operational requirements of the research review function**

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According to the WMO all research involving human subjects must be reviewed by a METC that is recognized by the national supervisory body, the Central Committee for Research involving human subjects (CCMO). At the request of the Hospital leadership, the METC VUmc was recognized by the CCMO on 11<sup>nd</sup> of November 1999 by the CCMO. The Hospital board of the VUmc thereby recognized the METC VUmc and her regulations.

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Resources: - Official regulation METC, see [website METC](#)

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**Norm HRP.4 ME2 → The research review function complies with applicable laws and regulations**

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The Official Regulations of the METC VUmc have been prepared in compliance with the WMO and are approved by the supervisory body (CCMO). The METC VUmc reviews according to the WMO and other applicable legal and regulatory framework. When VUmc participates in a clinical research that has been reviewed by a different recognized METC, the Regulations of that review committee will apply. Exclusively METC's that are recognized by the CCMO, are allowed to review WMO-research. METC's are obliged to review conform current national laws and regulations.

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**Norm HRP.4 ME3 → Hospital leadership specifies the requirements of entities outside of the hospital that provide all or a portion of the research review function, such as a contract research organization**

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*Research initiated by VUmc or primarily performed in VUmc must be submitted for review to the METc VUmc. If clinical research involving human subjects is initiated by a sponsor other than the VUmc and there are more participating centres than VUmc, the initiating party is free to choose a different recognized METC. After approval of a recognized METC, the research needs the permission of the Hospital Leadership.*

**Norm HRP.4 ME4 → Hospital leadership ensures research that is exempt from the research review process is identified**

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*Hospital leadership has decided that all medical scientific research that is initiated by VUmc or performed primarily in VUmc, must be reviewed. Depending on the nature of the research, WMO protocols are reviewed by the CCMO or by a recognized METC. Research that is reviewed by a different recognized METC will need the permission of the VUmc Hospital Board to be performed in VUmc. This permission is given with a 'lokale uitvoerbaarheidsverklaring', which - at the request of the Hospital Board – is provided by the METc VUmc. Requests to start a collection of patient material for future research and the release of this material for actual research questions, is reviewed by the Review Committee for Biobanks (TcB) of VUmc. All other research with humans is called 'non-WMO research' and is reviewed by the Executive Board of the METc, according to relevant laws and regulations such as the GDPR and Medical Treatment Contracts Act (WGBO). Therefore, no research is exempt from review, only different review procedures are followed. Criteria for WMO research, biobanks and 'non-WMO research' are provided by the METc.*

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**Resources:** 'Beslisboom niet WMO-onderzoek', see [website METc](#)  
'Flowchart Biobank', see [website METc](#)  
'niet-WMO onderzoek' see [website METc](#)  
'Biobank', see [website METc](#)

**Norm HRP.4 ME5 → Hospital leadership specifies the requirements for documentation of the activities of the research review function**

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*With the exception of the CCMO, there is no party that can impose requirements with regard to which documents need to be documented by the METc VUmc for WMO research. Documenting the research file of WMO research review is a requirement of the [Dutch Archives Act](#) and the '[Basis selectielijst METC's](#)'. It determines the documents that need to be stored, the way the documents need to be stored and the duration of storage. Documenting the file of a local feasibility (lokale uitvoerbaarheid LU) request, biobank research and non-WMO research is a request of the Archives Act, the GDPR, and the VUmc Hospital board. All documents that are related to a review of WMO research, non-WMO research or biobank by the METc VUmc, TcB VUmc or EB of the METc VUmc, are filed in the METc's document management system: Corsa.*

**Norm HRP.4 ME6 → Hospital Leadership provides for a review of all research review processes at least annually**

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*The METc VUmc is an independent review body. With the exception of the CCMO, there is no party that can impose requirements with regard to the research review processes of the METc VUmc. By law, the CCMO is responsible for the supervision of the tasks, composition, and working procedure of the METc VUmc. Accordingly, the METc submits its annual report and revised official regulations to the CCMO. The METc registers information about its reviews via Toetsing Online (national accessible internet portal of the CCMO). The CCMO uses this information to continually monitor the activities of all recognized committees. The CCMO also performs audits to randomly monitor the activities of recognized committees. The METc VUmc annually sends an overview of her review activities to the Hospital board. Twice a year the METc conducts a self-evaluation and asks all its*

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members to fill in an evaluation form. Additionally, the METc asks researchers to evaluate the experiences with METc VUmc on a continuous basis. The METc VUmc uses these two evaluations to improve her procedures, her advisory role and the information she offers.

**Norm HRP.6 ME1 → The research program is a component of the hospital's processes to report and act on sentinel events adverse events of other types and the processes to learn from near misses**

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*In accordance with article 10 of the WMO and the GCP, all Serious Adverse Events (SAE's) and Suspected Unexpected Serious Adverse Reactions (SUSAR's) must be reported to the METC according to the procedures stated in the protocol. The sponsor must report the SAE's to the METC within 7 days of first knowledge for SAE's that result in death or are life threatening followed by a period of maximum 8 days to complete the initial preliminary report. All other SAE's must be reported within a period of maximum 15 days after the sponsor has first knowledge of the SAE, unless otherwise stated in the protocol. In Investigator initiated research, the SAE's and SUSAR's must be reported through ToetsingOnline. The researchers need to submit an annual progress report and for drug studies additionally an annual safety report, to the METC. When, during the research, there are good reasons to assume that continuation of the research would lead to unacceptable risks for the subjects, the sponsor of the research shall suspend the execution of the research until a further positive judgment has been obtained from the METC. When a DSMB is installed for the research, the METC needs to be informed about interim analyses and other relevant decisions of the DSMB. In case monitoring by the CRB leads to a second 'inadequate' monitoring report conclusion, the METc VUmc is informed by the CRB to come to a mutual action plan.*

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**Resources:** Voortgangsrapportage, see [website METc](#)  
Veiligheidsrapportage, see [website METc](#)  
SOP 'Opschalen CRB naar METc VUmc en RvB', see [Kwaliteitsnet CRB](#)

**Norm HRP.6 ME2 → The research program is included in the hospital's programs for hazardous material management, medical equipment management, and medication management**

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*A clinical physicist (who is a member of the METc VUmc), reviews the research protocols on the basis of the medical device directive with a focus on the safety of the medical device. Research involving medical devices that do not have a CE quality mark or will be used for purposes other than the intended use (off-label), must meet the following requirements:*

- 1) *the researchers need to deliver an Investigational Medical Device Dossier (IMDD) to the METc Vumc.*
- 2) *the researchers need to have approval from the medical technology department of the VUmc to use the medical device.*
- 3) *the researchers must register the medical device with the inspection health care and youth (IGJ).*

*Researchers submitting a research protocol involving medical devices that do have a CE quality mark need to provide evidence of the CE quality mark to the MEC.*

*A pharmacologist (who is a member of the METc VUmc), reviews the research protocols on the basis of the medicine directive with a focus on the safety of the medicinal product. The pharmacologist reviews the drug labels and production licenses for every drug used in the research protocol. Research involving non-registered drugs or drugs that will be used for off-label purposes, must meet the following requirements for product information:*

- 1) *the researchers need to deliver an Investigational Medical Product Dossier (IMPD) to the METC.*

- 2) *the researchers need to deliver an Investigator's Brochure (IB) to the METC. The IB includes, among other things, information on the dose of the study drug, the frequency of dosing interval, methods of administration and safety monitoring procedures.*

*For research involving registered drugs, the researchers need to deliver a Summary of Product Characteristics (SPC) to the METC. The SPC is a specific document required within the European Commission before any medicinal product or biocidal product is authorized for marketing.*

*A radiation expert (who is a member of the METc VUmc), reviews every protocol that involves radiation with a focus on radiation safety. The radiation expert reviews the research protocols on the basis of the medical exposure directive and on the basis of the European radiation protection guidelines. These guidelines include the following documents:*

- 1) *Radiation Protection 102: Implementation of the "Medical Exposure Directive" (97/43/Euratom).*
- 2) *Radiation Protection 116: Guidelines on education and training in radiation protection for medical exposures.*
- 3) *Radiation Protection 109: Guidance on diagnostic reference levels (DRLs) for medical exposures.*
- 4) *Radiation Protection 100: Guidance for protection of unborn children and infants irradiated due to parental medical exposures.*
- 5) *Radiation protection 118: Guidelines for referral to imaging research.*
- 6) *Radiation protection 91: Criteria for the acceptability of equipment for Radiology (including Radiotherapy) and Nuclear Medicine.*
- 7) *Radiation protection 97: Radiation protection after iodine-131 therapy (exposure by outpatients or discharged clinical patients).*
- 8) *Radiation Protection 136: European guidelines on radiation protection in dental radiology (the safe use of radiographs in dental practice).*
- 9) *Radiation Protection 154: European Guidance on Estimating Population Doses from Medical X-ray Procedures.*
- 10) *EUR 19793: Optimisation of Protection in the Medical Uses of Radiation*
- 11) *EUR 16260 EN: European Guidelines on Quality Criteria for Diagnostic Radiographic Images.*
- 12) *EUR 16261 EN: European guidelines for quality criteria for diagnostic radiographic images in paediatrics.*
- 13) *EUR 16262 EN: European Guidelines on Quality Criteria for computed tomography.*
- 14) *EUREF, 2001: European Guidelines for Quality Assurance in Mammography Screening (Third edition).*

*(see: [https://www.rivm.nl/Onderwerpen/M/Medische\\_Stralingstoepassingen/Trends\\_en\\_stand\\_van\\_zaken/Wetgeving\\_en\\_richtlijnen/Europese\\_Aanbevelingen](https://www.rivm.nl/Onderwerpen/M/Medische_Stralingstoepassingen/Trends_en_stand_van_zaken/Wetgeving_en_richtlijnen/Europese_Aanbevelingen)).*

*The METc VUmc demands that the radiation is described in the ICF, in a comprehensible and honest way, conform the CCMO format.*

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Resources: - *Proefpersoneninformatie en toestemmingsformulier', the CCMO format for the ICF, see [website METc](#)*

**Norm HRP.7 ME1 Patients asked to participate are informed about the research, duration of patient's participation, procedures to be followed, and who to contact with questions about the research**

**Norm HRP.7 ME2 Patients asked to participate are informed about the expected benefits, potential risks, and alternative treatments and procedures that might help them**

**Norm HRP.7 ME3 Patients asked to participate are informed about the extent to which confidentiality of records will be maintained**

**Norm HRP.7 ME4: Patients asked to participate are informed about the compensation or medical treatments available if injury occurs**

**Norm HRP.7 ME5: Patients asked to participate are assured that participation is voluntary and refusal to participate or withdrawal at anytime will not compromise care or access to hospital services**

**Norm HRP.7 ME6: Through the research review function the hospital establishes and implements how consent for participation will be obtained and documented and under which circumstances consent will be obtained again during the research**

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*All JCI required elements are also legal requirements of the WMO. The METC reviews the Human Subjects Information Form (PIF) and the Consent Form (CF), together called the Informed Consent Form (ICF). According to article 6, clause 5 of the WMO, the METC has to approve the ICF before it can be used. The METC also needs to approve all recruitment material and other information that possible participants will see.*

*The CCMO has provided a format ICF (see <http://www.ccmo.nl/nl/standaardonderzoeksdossier-1>). The METc VUmc insists that researchers use this format. According to article 6, clause 5 and article 9 of the WMO, the PIF is legally required to include the following information: 1. The purpose, the nature and the duration of the research; 2. The risks that the research would entail for the health of the research subject; 3. The risks that an interim termination of the research would entail for the health of the research subject; 4. The burden that the research could have on the research subject. In compliance with the guideline for Good Clinical Practice (GCP), the ICF is required to state the following:*

- (a) That the trial involves research.*
- (b) The purpose of the trial.*
- (c) The trial treatment(s) and the probability for random assignment to each treatment.*
- (d) The trial procedures to be followed, including all invasive procedures.*
- (e) The subject's responsibilities.*
- (f) Those aspects of the trial that are experimental.*
- (g) The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, foetus, or nursing infant.*
- (h) The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.*
- (i) The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks.*
- (j) The compensation and/or treatment available to the subject in the event of trial-related injury.*
- (k) The anticipated prorated payment, if any, to the subject for participating in the trial.*
- (l) The anticipated expenses, if any, to the subject for participating in the trial.*
- (m) That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.*
- (n) That the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulation and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.*
- (o) That the records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.*
- (p) That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.*
- (q) The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury.*
- (r) The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.*

(s) *The expected duration of the subject's participation in the trial.*

(t) *The approximate number of subjects involved in the trial.*

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Resources: ICF CCMO format, see [website METc](#)

7.ME1: *Conform the WMO, the ICF must include information about the research that will be executed, the duration of the participation, procedures that must be followed and who can be contacted with questions about the research.*

7.ME2: *Conform the WMO, the ICF must include information about the expected benefits of the research, possible risks of the research and alternative treatments and procedures that may also benefit the research subject.*

7.ME3: *Conform the WMO, the ICF must state to what extent patient files and data will remain confidential during the research. The PIF must state and explain to which extent data will be coded and what the retention period of the data is.*

7.ME4: *Conform the WMO, the ICF must include information about compensation for injuries that occur on account of the research. If the research needs an WMO subject insurance, an insurance appendix needs to be included in the ICF.*

7.ME5: *Conform the WMO, the ICF must state that participation is voluntary and that refusal to participate or termination of participation at any time, never jeopardizes the quality of care the patient receives and the access the patient has to the services of the hospital.*

7.ME6: *The METC reviews how the consent procedure is carried out and keeps in mind the legal requirements and ethical aspects. The consent procedure must be documented in the research protocol and the ABR-form. If any changes are made to the study protocol by the researchers, an amendment must be submitted to the METC and the METC reviews all revised documents (as established in the WMO, article 13k). If any changes are made to the study protocol that have consequences for the demands or stress imposed on the research subject or the research subject's safety or if additional information becomes available that could influence the participation of the research subject, the researcher must submit an amendment of the protocol and ICF to the METC. Changes cannot be carried out without approval of the amendment.*

**Norm HRP.7.1 ME1 → Patients and families are identified and informed about how to gain access to clinical research, clinical investigations, or clinical trials relevant to their treatment needs.**

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*The METc VUmc always considers the recruitment strategy to ensure every eligible patient has access to the study and no bias can arise.*

**Norm HRP.7.1 ME2 → Through the review function, the hospital established and implements safeguards to protect the safety, rights, and well-being of vulnerable patients, including children, prisoners, pregnant women, persons or are mentally disabled, persons who are economically or educationally disadvantaged, and other who may be at risk for coercion or undue influence**

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*Article 4, 5 and 6 of the [WMO](#) set out the requirements that research with above-mentioned vulnerable groups must comply with. Research with incompetent subjects (e.g. children under the age of 16 years, people with advanced dementia or some mentally disabled people) is forbidden unless the research therapeutically beneficial to the subject or it needs to be impossible to carry out the research without cooperation of these subjects (group affiliation, 'groepsgebondenheid'). In the case of non-therapeutic research involving incompetent research subjects, there are additional requirements of minimal risk and burden in comparison to the standard treatment and the subject does not resist during the research (articles 4 and 6 of the WMO). The METC evaluates whether the protocol and other documents meet these requirements and evaluates the arguments to include the specific group of research subjects, the 'groepsgebondenheid'. Incompetent research subjects are entitled to receive information appropriate to their level of comprehension and, when possible, their assent must be obtained. When scientific research can only be carried out in emergency*

situations in which consent required cannot be obtained and the research can benefit the person who is in the emergency situation, the research may be carried out without consent of the research subject as long as the circumstances prevent the researchers from obtaining consent (according to article 6, clause 4 of the WMO). That means that explicit written consent from the research subject is requested when the research subject becomes competent during or after the research. In all cases, a legal representative must give permission for the participation of the incompetent subject. Incompetent subjects must be distinguished from other vulnerable subjects such as those who have a relationship of dependency with the researcher who takes care of the recruitment, the researcher that performs the research or the sponsor. Research subjects that have a relationship of dependency are, for example: soldiers, prisoners, research subjects that are recruited by their attending physician, students who are recruited by a professor or employees of a particular company or a particular organization recruited by a supervisor. The WMO has similar demands for this group of subjects (WMO, article 5). In addition to the WMO, the GDPR states that there needs to be a fundamental base to use data for research. Normally, consent is a valid base, but in the case of a relationship of dependency, it cannot be proven that consent was given freely. Therefore, consent is no fundamental base for the inclusion in research in the case of relationship dependency. The METc VUmc is especially critical when the research under review involves these kind of groups. She evaluates the burden for the research subjects, how voluntary the participation of the research subjects is, the apprehension level of the research subjects, and the extent of the dependency of the relationship. The METc VUmc will always carefully consider whether the expected benefits of the research are in proportion to the expected risks and burden for the research subjects and if the PIF is completely clear about the (non-) therapeutic nature of the research. [The CCMO](#) reviews all non-therapeutic intervention research that involves incompetent research subjects or children.

**Norm HRP.7.1 ME3 → Through the review function, the hospital establishes and implements safeguards to protect the safety, rights, and well-being of hospital staff who may be at risk for coercion or undue influences.**

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*The METc reviews the independence of the research with respect to sponsor and research integrity and the possibility for hospital staff to refuse participation. VUmc employees cannot participate as healthy subjects or as patients in scientific research carried out by their own department. VUmc employees are permitted to participate in scientific research of other departments on the condition that the recruitment is passively and informed consent is obtained (according to article 5 of the [WMO](#)). Researchers may not actively approach potential research subjects, but can use passive recruitment strategies such as leaving leaflets in the VUmc. Subsequently, the potential subjects needs to show initiative, e.g. contact the researcher, to participate.*