Belgian Association of Research Ethics Committees (BAREC)

Guidance on fair compensation of subjects for their participation in clinical research in Belgium

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Inhoud

1. Objective 1
2. Definition of terms used 1
3. Scope 2
4. Potential reasons for compensation 3
5. Basic principles 3
6. Fair amounts of compensation 4
7. Modalities and timing of compensation 8
8. Information on compensation as part of the consent/assent process 8
9. Fiscal aspects 9
10. Special issues 9
11. Overview document 10

1. Objective

This Guidance provides recommendations for fair compensation of subjects for their participation in clinical research in Belgium ("Guidance"), and is issued by the Belgian Association of Research Ethics Committees (BAREC). The objective is to present a common framework with practical guidance of interest to Ethics Committees (ECs), sponsors, investigators and participants involved in clinical research in Belgium.

2. Definition of terms used

Compensation

General term reflecting something (financial or non-financial) given to research participants to make up for expenses, time investment, inconvenience, and willingness in relation to their participation in clinical research.

It does ***not*** refer to indemnification for research-related injury, e.g. no-fault compensation; and it does ***not*** refer to study-related costs legally to be borne by the sponsor, such as all costs of the intervention(s) investigated, investigational site visits or admissions, investigations and procedures, and co-treatments required by the study protocol.

Incentive

In this context, a means to motivate a subject to participate in a clinical research project, or to maintain his/her participation in the study (till its completion). It is forward looking in nature.

Payment

Compensation restricted to financial or monetary forms, e.g. bank transfer, cash payment, gift certificate or voucher.

Reimbursement

The act of compensating research participants for their study-related out-of-pocket expenses, e.g. for travel, meals or accommodation, by giving them an amount of money equal to what was spent.

Undue influence

Undue influence, according to the Belmont Report (US Department of Health & Human Services, 1979), occurs 'through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance', i.e. agreement to participate in clinical research. The US Office for Human Research Protections (OHRP), in its recommendation 'Addressing Ethical Concerns Regarding Offers of Payment to Research Participants', considers compensation/payment as undue influence 'when it could compromise a prospective subject's examination and evaluation of the risks or affect the voluntariness of his or her choices'.

3. Scope

3.1 Types of studies

All categories of clinical research involving human subjects (healthy volunteers or patients), requiring a positive opinion of an appropriate EC in Belgium.

These include:

1°/ Interventional clinical research, concerning:

- Investigational medicinal products, defined as 'clinical trials' in the CTR and the corresponding Belgian law (2017).
- Medical devices, defined as 'clinical investigations' in the MDR and the corresponding Belgian law (2020).
- *In vitro* diagnostics, defined as 'clinical performance studies' in the IVDR and the corresponding Belgian law (2022).
- Interventions not regulated in the 3 previous EU regulations and their corresponding Belgian laws, but qualified as 'experiments' in the Belgian law of 2004 related to experiments, such as studies that test surgical techniques or that impose changes in human behaviour (physical training for instance).

2°/ Prospective non-interventional clinical research, which also qualifies as 'experiments' in the same Belgian law (2004) related to experiments.

This Guidance is **not applicable to** research on already available human bodily material (although also legally requiring a positive opinion of an EC in Belgium) or research making secondary use of already available personal data (qualified as 'retrospective studies' but not as an 'experiment' in the Belgian law of 2004 related to experiments, and thus not legally requiring a positive opinion of an EC).

3.2. Types of sponsors

From an ethical perspective, the rules governing compensation of research participants should be similar for clinical research sponsored by commercial sponsors as for clinical research sponsored by academia or not-for-profit funders.

3.3. Eligible subjects for compensation

All participants in clinical research should have equal rights to compensation, whether they are patients or healthy volunteers.

Additionally, also the research participants' appropriate representatives, companions, guardians or supervisors, such as parents, a legal representative, or a caregiver are eligible to compensation.

4. Potential reasons for compensation

4.1. Study-related expenses

Study-related expenses concern those expenses that can be reasonably expected to apply for the average participant in the study.

Examples include, but are not limited to:

- Expenses for travel to and from the investigation centre
- Food and drinks during long centre visits
- Mandatory or recommended use of (a specific form of) contraception
- Nearby accommodation
- Study specific diet
- Babysitting
- Mandatory use of a sun blocker
- Mandatory or recommended cryopreservation of oocytes or sperm.

4.2. Loss of earnings, time Investment

Although the terminology 'Loss of earnings' is used in the legislation, this reason for compensation is potentially better qualified as 'time investment'.

4.3. Burden, discomfort, or inconvenience

Some investigative procedures, examinations, tasks or restrictions can be considered burdensome to clinical research participants, and may lead to some form of compensation.

On the FAMHP website on clinical investigations (MDR), a guidance document can be found that covers the topic "Which procedures in clinical investigations are considered burdensome or invasive?". Examples of burdensome procedures are sedation, invasive cardiac procedure (catheterization, stent, angioplasty), blood tests, etc. Examples of non-burdensome procedures are patient surveys, thermography, …

4.4. Willingness to participate

This form of compensation includes tokens of appreciation or incentives for recruitment or retention in the study.

5. Basic principles

5.1. participants cannot be compensated for risk taken

It is the consensus view of the ECs members of BAREC that a study can only take place if the benefit-risk ratio of such study is positive, meaning that the risks for the individual study participants cannot be higher than the potential benefits for such participants or society. This benefit-risk ratio is to be evaluated by the EC. In other words: studies where a specific risk could be compensated separately because the benefit-risk ratio is negative, are to be considered unethical and should not be carried out

in the first place. Offering additional compensation to candidate participants for such studies does not change the unethical character thereof and can therefore not be accepted. This does not mean there cannot be a compensation in for example phase I trials with healthy volunteers. If the EC deems the benefit-risk balance positive in view of the combined societal and personal impact, the participant can be compensated according the principles in this document.

5.2. Participation in a study should not bring costs to the participant

Participating in clinical research shouldn't cost the participants anything (on top of standard of care costs, if applicable). Therefore, as a general rule, all study-related expenses should be reimbursed (when advanced by the participant) or compensated for (when a reasonable fixed lump-sum has been agreed upon). This should be the case for all clinical research within the scope of our Guidance, and should be independent of the type of sponsor (commercial or non-commercial) or the type of participants (patients or healthy volunteers). The EC evaluates whether the compensation package offered by the sponsor to the participant sufficiently covers the costs of the participant or whether the rationale not to do so is acceptable.

5.3. Other forms of compensation should be balanced vis-à-vis undue influence

Additional compensation, such as for time investment, inconvenience, or willingness to participate can be offered, but should be well-justified.

Such compensation is more easily justified in clinical studies of interventions without (sufficiently) proven therapeutic benefit, i.e. in early phase clinical development, such as in human pharmacology studies (e.g. First-in-Human trials or other phase 1 studies, both in healthy volunteers or patients) or exploratory safety and efficacy studies (e.g. phase 2a dose-response or Proof-of-Concept studies), according to the definitions used in ICH guideline E8(R1) (ICH, 2021). The EC evaluates whether the justification to include these forms of compensation is acceptable vis-à-vis undue influence. As healthy volunteers mainly participate in view of monetary compensation, the EC should safeguard that such compensation is not exorbitantly high (see section 6).

6. Fair amounts of compensation

In this section, only monetary amounts (in euro) are specified for each reason for compensation. They can be paid as such, i.e. by bank transfer or in cash, or, alternatively, an equivalent amount can be made available as a gift card, a voucher, or a ticket. When non-monetary forms of compensation are proposed instead, they should represent an equivalent amount. As expenses or costs may vary according to geographic region, these amounts may vary between participating centres. Though such differences should be rather small within Belgium and therefore, if Belgium is to be included in a multi-country study, the costs for that study should be identical for each Belgian participating site. All amounts recommended are valid for 2025. Whenever possible, a reference is added which can be used to verify indexation of such costs (e.g. revised annually on the basis of the evolution of the Belgian consumer price index (Statbel/cost of living). In general, indexation of costs in line with the spirit of this document is acceptable.

6.1. Compensation for study-related expenses/costs

Reimbursement of actual study-related expenses/costs is acceptable. Though preferred by tax controllers, this may lead to burdensome administrative procedures. Compensation in the form of a

fixed amount or lump sum can be offered instead. The amount of the lump sum should be in line with the average costs participants in the study can be expected to incur.

Travel

Costs for travel from home to the investigational centre and back, can be compensated by:

- Reimbursement of real expenses, e.g. ticket(s) of public transport, a car parking ticket, or taxi fare receipt(s) if judged appropriate.
- Mileage allowance per km, preferably at the official rates published each year by the Federal Public Service Finance. The car allowance 2025, valid from 1 January 2025 till 31 March 2025, equals 0.4290 euro per km (Moniteur Belge, 2025). The bike allowance for the fiscal year 2023 equals 0.27 euro per km (SPF Finances, 2023). If higher amounts can be justified (e.g. reimbursement of cancer patients by RIZIV), these can be acceptable.
- Fixed amount or lump-sum. This should be based on judgement about the average distance participants have to travel to participate in the study (e.g. 50 km roundtrip for local studies or 100 km roundtrip for regional studies). The table includes examples calculated according following formula: highest number of km in the range x official car allowance per km (0.4290 EUR in 2025) plus 10 EUR for parking, rounded to the nearest 5 or 10 EUR. However, any other realistic modality of lump-sum calculations can be agreed upon, if properly justified.

Table 1: Fixed amounts for travel expenses

Roundtrip in km	Amount in euro
Up to 25	20
26-50	30
51-75	40
76-100	55
101-125	65
126-150	75
151-175	85
176-200	95

In Belgium, reimbursement of air fare tickets is uncommon, but could be justified in certain circumstances, e.g. to allow the participation of non-Belgian residents in clinical studies taking place in Belgium where patients with orphan diseases are recruited, or to allow participation of non-Belgian residents in clinical studies conducted by/in a Belgian investigational centre that is designated as centre of excellence in a certain field. For such participants (and their accompanying person, if needed), reimbursement of a return trip by air in economy class could be deemed acceptable by the assessing EC.

Food and drinks

For study centre visits lasting over 4 hours, and especially when the participant had to fast before any such visit, a meal or a compensation for a meal and drink(s) should be provided. This should also be the case for their accompanying person, if help is needed.

The most practical solution is to provide a reasonable lump-sum payment, e.g. 15 EUR in 2025, equivalent to the average cost of a sandwich, some fruit and a drink. Another amount can be acceptable, if justified by the average price of a simple meal in the cafeteria of the investigational centre.

Accommodation

If, for well-argumented reasons, accommodation or lodging near the investigational centre during 1 or several days is foreseen in the study protocol for the participant and, if needed, for their accompanying person, then 2 options are acceptable, either:

- Payment of a fixed amount, corresponding to the average budget price of a double hotel room in Belgium, which is 126 EUR in 2025 (Budget Your Trip, 2025).
- Reimbursement of real costs, limited to the fixed amount mentioned here above, except when a higher amount is justified due to a more expensive geographic location or high-season rates.

Babysitting

This can be considered whenever a research participant is unable to leave a young child (or children) or another helpless cohabitant alone at home during study visits to the investigational centre.
For this service, the average hourly rate for a babysitter in Belgium in 2025 is 10.04 EUR, ranging per province between 8.84 in West-Flanders and 11.82 EUR in Luxemburg (Webpage Babysits, 2023). The mean day price for childcare in Belgium is +/- 35 EUR (Parentia, 2025).

Mandatory use of products

If the study imposes the use of certain products (e.g. specific diet, sun blocker), these costs should be borne by the sponsor. In such case, the most practical solution is to reimburse the real costs.

Mandatory use of contraception

This is a specific case of the above. Such Mandatory (change in) contraceptive measures, for participating women of child-bearing potential (WOCBP), fertile male participants, and their (non-) pregnant WOCBP partner, according to the current guidelines (CTFG, 2020 and EMA, 2022) and, if applicable, the cost of pregnancy tests during the contraceptive period in WOCBP should be borne by the sponsor. This is the case, even if the participant is already on appropriate anticonception. WOCBP under age 25 can be excluded if appropriate anticonceptives are available to them free of charge (see list).

- Reimbursement of real costs is acceptable
- A cap to such real costs is acceptable (e.g. the sponsor cannot be obliged to pay for a vasectomy)
- A lump sum is acceptable, but should be sufficient to obtain an appropriate contraceptive.

Cryopreservation of oocytes or sperm

If cryopreservation of oocytes or sperm is recommended before starting the study for participating WOCBP or fertile males with a desire to have a child/children in the future, then the costs therefore should be borne by the sponsor. Reimbursement of the real costs is the most practical solution.

6.2. Compensation for time investment

Legal texts mention compensation for 'loss of earnings' which is translated here as compensation for 'time investment' as it is not the objective to compensate for the real salary loss that a participant may be suffering during the time spent at the research centre. Instead, the international consensus is to compensate time investment on the basis of the national minimum wage (NMW), rather than based on the real wage or revenue of the participant.
The current gross NMW for adults in Belgium, since February 2025, is 2111.89 EUR per month for a 38h work week (Wage Indicator Foundation, 2025), i.e. 12.82 EUR per hour.
Compensation for time investment is fairly well introduced in healthy volunteers, as well as in patients participating in clinical research without expected therapeutic benefit, i.e. exploratory early phase studies. It is far less common practice when it comes to patients participating in confirmatory late

phase studies, arguing that participants in these studies have a far greater chance to benefit from the experimental or comparative standard-of-care (SOC) intervention. Therefore, extra forms of compensation are considered by some as not being needed.
It is deemed acceptable that a longer time investment (over 2 hours spent at the investigational centre) can be compensated for all participants, if well justified, and agreed upon by the assessing EC.

6.3. Compensation for burden, discomfort and inconvenience
A compensation for burden, discomfort and inconvenience can be acceptable, but as it is difficult to estimate in monetary value. It is recommended to compensate for burdensome study procedures or investigations by a fixed reasonable amount, e.g. 50 EUR for a gastroscopy, 70 EUR for an arterial catheterisation.

6.4. Compensation for willingness to participate
As compensation for willingness to participate, essentially 2 forms are distinguished: as a token of appreciation on one hand, and as incentives, rewards or bonuses on the other hand.

Token of appreciation
As a token of appreciation, 2 approaches are frequently practised:

1°/ Items, goods or services of relatively low value
Items, goods or services of relatively low value are especially suitable to compensate children directly, independent from their parents or legal representative. They are also often proposed to students or participants in studies using qualitative research methods that are not very time-consuming nor very burdensome, such as taking an interview, filling out some questionnaires, or participating in a focus group. Examples are numerous: e.g. a ticket for a visit to a cinema or an entertainment park, a gift card, a subscription (limited in time) to a music or video streaming platform, a games app, a goody bag, a toy, a book, or a small lump-sum. It is recommended that the value of these items does not exceed 50 EUR.

2°/ Items, goods or services with higher (non-material) value
Another category of compensation concerns items, goods or services with higher (non-material) value. This category comprises several forms of compensation that might be considered valuable by research participants. Examples include training or nutrient advice or access to training facilities, keeping a device or app used in the study (or purchased at a discount), and course credits for students. The precise value of these forms of compensation is difficult to estimate. They are often appreciated as useful and valuable by the participants, so much so that they might more easily accept not to be extra compensated for, for instance, study-related expenses or time investment. In general, this practice is considered to be acceptable if considered balanced vis-à-vis undue influence by the EC.

Incentives, rewards or bonuses
Incentives, rewards or bonuses are sometimes proposed to (potential) research participants in order to stimulate study recruitment, study retention or study completion.
This practice should be carefully reviewed, as it may induce undue influence. However, there may be instances where an incentive of a reasonable value might be useful and acceptable, e.g. to stimulate the often very difficult recruitment of patients with certain orphan or rare diseases, to retain patients

in long-term studies thus limiting an otherwise to be expected high drop-out rate, or to encourage participants in an event-driven study to stay in the study until the end in order to maximally support the chance of a robust statistical analysis and more meaningful study results.
It is recommended that the assessing EC evaluates each proposal on a case-by-case basis, and that the amount paid to a subject as an incentive remains reasonable without exerting undue influence.

7. Modalities and timing of compensation

Compensation for participating in clinical research can be offered either in the form of a monetary transaction, such as payment of a given amount, or gifts of a certain value (e.g. voucher, gift card, ticket); or can be of non-monetary nature, offered as items or goods (e.g. book, goody bag, study device, toy) or services (e.g. course credit, training advice). It is primarily up to the sponsor and the investigational centre teams to decide which modality they find most suitable and practical, without too much administrative burden for both the investigational centre staff as well as the participants. Some centres may work with a processing fee to handle modalities of compensation with extra workload.

They should also propose an arrangement about the timing and conditions of offering payments. For short-term studies (a few days up to less than 3 months), it is acceptable to compensate or pay participants only at the end of their participation. For longer-term studies (as of 3 months), intermediate payments should be the rule, or, alternatively, per centre visit. If a subject is only participating in a particular phase of a study, or does not participate until the study is completed, a *pro rata* compensation or payment can be proposed, based on the actual time spent in the study and the actual number of investigations/procedures undergone. The timing of payment should be reflected in the ICF.

A candidate participant who has been screened but finally not enrolled, may be offered a specific compensation just for the screening.

8. Information on compensation as part of the consent/assent process

Candidate participants to a particular clinical study should be well-informed about the study, so that they can decide entirely out of free will whether they will participate or not. The current guideline on Good Clinical Practice (GCP) outlines all that is needed for an adequate informed consent process (ICH, 2025), including all necessary information to clinical research participants in writing through the informed Consent Form (ICF) for adults, and the Informed Assent Form (IAF) for minors.
In advertisement material for recruitment, it is recommended not to mention detailed amounts of compensation offered, in order not to unduly influence candidates to participate. The information should be limited to for instance ‘A fair compensation for participation will be offered’.
However, oral explanation as well as information in writing (ICF and IAF) should be as clear and explicit as possible. Therefore, it is recommended that this information should include:

- The different categories of compensation.
- Per category for which compensation or payment is offered: for what exactly, under which form, and equivalent to which amount.
- The timing and conditions of payments.

- The provision that the compensation offered is exempt from income tax declaration for Belgian residents, but that it might be different for residents of foreign countries.

For vulnerable participants, e.g. minors or incapacitated persons, the ICF for their parents or legal representative should give details on compensation to the participant as well as to the accompanying person. The information given to minors, as part of the assent process, should be adapted to their age and maturity.

9. Fiscal aspects

In Belgium, 4 advance tax rulings in relation to compensation offered to research participants have been published by the Tax Ruling Service, being part of the Federal Public Service Finance (FPS Finance, 2010, 2013, and 2015/1 and 2). The first one has been prolonged twice, the last time as of 1 July 2020 for another 5 years (FPS Finance, 2021).

These rulings clarify that such compensations, including for the time spent in the research centre (although not very clearly stated), are not to be considered as taxable income for the participant, as participation in clinical research is not considered to be a job or to generate 'diverse income'. On the part of the ultimate payer, they are considered as tax-deductible business expenses.

In principle, such tax rulings are only valid between the anonymous applicant and the tax authority for a limited period of time (usually 5 years, but can be prolonged). In practice, the provisions can be extended to similar situations, but be aware that tax controllers could still interpret the tax law differently. In addition, and as already mentioned before, if fixed amounts or lump-sums are used, they should be as close as possible to the real expenses or costs.

The laws mentioned above only apply to research participants who are Belgian residents. Residents from other countries participating in a Belgian centre in clinical research might fall under a different regime. For instance, residents from The Netherlands should include compensation for their participation in clinical research in their tax declaration. It should be clearly specified in the ICF that the research participant is responsible for this potential declaration.

10. Special issues

10.1. Vulnerable participants

Apart from the usual subjects qualified as vulnerable participants, such as minors, incapacitated adults, pregnant and breastfeeding women, other participants can also be very fragile, e.g. homeless persons, persons who inject drugs (PWID, formerly known as drug abusers), gambling addicts, and prisoners, all financially vulnerable people. Compensating these subjects can be very challenging, because these groups may be at a higher risk of undue influence. Any recommendation can only be general.

For vulnerable participants, the CTR states: 'No incentives or financial inducements are given to the subjects or their legally designed representatives, except for compensation for expenses and loss of earnings directly related to the participation in the clinical trial'. In addition, a small token of appreciation is not considered an incentive (Q&A document on the CTR (Eudralex, 2022) under Question 9.1). Similar provisions can be found in the EU Medical Devices Regulation or MDR (Official Journal of the EU, 2017), the EU In Vitro Diagnostic Medical Devices Regulation or IVDR (Official Journal of the EU, 2017), and the corresponding Belgian Laws (Moniteur Belge, 2020 and 2022).

10.2. Studies with fairly high amounts of compensation

Some types of clinical research studies can result in fairly high amounts of compensation offered to the participants. For instance, in longer term phase 1 and Controlled Human Infection Model (CHIM) studies, usually in healthy volunteers, the proposed compensation for time investment and inconvenience can amount to (several) thousands of euros. As an example, in the COVHIC002 Coronavirus Human Infectious Challenge Study at the Imperial College London (UK), participants are offered 200 GBP per day of quarantine stay at the centre (Imperial College London, 2022).

Especially in these circumstances, the sponsor and the investigation site(s) should carefully detail and justify the proposed amounts and modalities of payment. It is up to the evaluating EC to carefully assess whether the compensation offered is considered fair and without undue influence. In Belgium, these phase 1 studies are evaluated by a limited number of specially recognised ECs with appropriate expertise in this field, which is expected to contribute to a somewhat harmonised attitude towards these studies.

10.3. Privacy issues

The act of offering monetary or non-monetary compensation to research participants should be handled in the strictest respect of privacy regulations, including the EU General Data Protection Regulation 2016/679 (" GDPR") (GDPR.EU, 2023), and, additionally, in Belgium, the Law of 30 July 2018 on the protection of individuals with regard to the processing of personal data (Moniteur Belge, 2018). This implies that the sponsor cannot have access to the identity of the participants, so that the transfer of money, gift cards, goods, services,... to the participants should be handled by the investigator/ the investigational centre, or a third-party service provider, each time also with respect to the legislation in force. It is the sponsor's obligation that such third party providers adhere to these privacy regulations. Participants should be informed about the exact role of the selected service provider and the steps taken to respect their privacy.

10.4. Prize draws versus contests

When the number of participants in a clinical research project is high, sponsors are not always able or willing to compensate every participant. Then only a limited number of participants can be compensated by winning a prize. Prize draws, such as a lottery or a raffle, in which the winner(s) is/are picked at random (by pure chance), are illegal in Belgium. In contrast, a contest can be legally organised, in which participants can try to do something better than others. In this case, some skill is required to win a prize, for instance by using a simple tiebreaker question reachable for all participants. If such a contest is organised to allocate compensation only to a limited number of participants, the contest rules should be adequate and submitted to the EC for agreement.

11. Overview document

It is recommended to sponsors of clinical research that they present all necessary information on compensation or financial transactions in an overview document as part of the application dossier.

This can greatly facilitate the work of the assessing ethics committee.

For clinical trials, the template 'Compensation for trial participants', developed and endorsed by the EU CTEG, can be used (EudraLex, 2020/2).

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Appendix: Checklist

Compensation for trial participants (Belgium)

This checklist can be used by sponsors as part of the application dossier to provide information on financial transactions and compensation provided for participation in the trial; including to persons supporting a subject to participate.

This template is fully in line with the Belgian Ethics Committee's viewpoint on compensation for participants, as developed by BAREC in its *Guidance on fair compensation of subjects for their participation of clinical research in Belgium*, available on its website under Advices.

The template can be filled by ticking boxes, by adding amounts or values in euro, and by giving information justifying certain choices. *Text in italic* is meant to give additional information that can help the applicant to fill out the form as best as possible.

This template is not mandatory. Trials under CTR can make use of the European template.

Overview of compensation offered to participants in a clinical trial in Belgium

EU trial number	
Title of clinical trial	

Compensation of study-related expenses (section 1) is considered mandatory, while additional forms of compensation (section 2) can be offered but may need justification in view of undue influence.

1. Mandatory compensation of study-related expenses

The Belgian viewpoint of Ethics Committees is that all study-related expenses should be reimbursed or compensated (= mandatory), as participation in clinical research should not cost anything to the participant. This general rule can only be waived by the evaluating Ethics committee upon well-argued justification.

1.1. Travel (per roundtrip from home to investigational centre)

Will it be offered? ☐ Yes ☐ No > Justification: …….

If yes, to whom? ☐ Participant ☐ Accompanying person

An accompanying person can be a partner, parent, legal representative, caregiver, or other.

Compensation modality:

☐ Reimbursement > According to expense notes submitted

e.g. public transport ticket, taxi fare receipt (if appropriate), parking ticket, or other.

☐ Compensation > According to offered modality

Amount for car: ……. EUR/km

Amount for bike: ……. EUR/km

☐ Fixed amount or lump sum > Amount: ……. EUR

Can be modulated into categories according to the number of km per roundtrip.

1.2. Food and drinks (if centre visits over 4h, or after pre-visit fasting)

Will it be offered? ☐ Yes ☐ No > Justification: …….

If yes, to whom? ☐ Participant ☐ Accompanying person

Compensation modality:

☐ Reimbursement > According to expense notes submitted

e.g. note of cafeteria, ticket of food or drinks vending machine,…

☐ Compensated by fixed amount or lump sum: ……. EUR

1.3. Accommodation (near the centre, if needed)

Will it be offered? ☐ Yes > Justification: …….

☐ No > Justification: …….

If yes, to whom? ☐ Participant ☐ Accompanying person

Compensated by a fixed amount per person per night B&B > Amount: ……. EUR

1.4. Study-imposed behaviour or practice

☐ Mandatory contraception (participant and partner)

☐ Pregnancy tests

☐ Advisable cryopreservation of oocytes or sperm

☐ Mandatory sun protection/sun blocker

☐ Required adherence to an expensive specific diet

☐ Other, please specify: …….

In all cases, reimbursement of real expenses is recommended.

1.5. Child or personal care attendance (babysitter, caregiver)

Should be offered whenever a participant is unable to leave a young child or help-needing cohabitant alone at home during study visits to the investigational centre.

If not, justification: …….

If yes, amount per hour: ……. EUR

2. Additional compensation

Additional compensation can be offered for time investment (substitute for 'loss of income' in legal texts), burden or inconvenience, or willingness to participate.

This should normally only be offered to the participant, although an accompanying person may well receive a small token of appreciation.

2.1. Time investment

The international consensus is to compensate time investment on the basis of the national minimal wage (NMW), either on an hourly or a daily basis.

☐ Rate per hour: ……. EUR ☐ Rate per day: ……. EUR

Total amount per (type of) study visit: ……. EUR

Total amount for the entire study (according to the regular schedule of study visits): ……. EUR

2.2. Burden, inconvenience, discomfort

When this type of compensation is offered, it is usually at a fixed amount or lump sum.

☐ Per burdensome study procedure or investigation, please specify type and amount:

1) …….

2) …….

☐ As a lump sum, either per study visit (amount: ……. EUR) or for the entire study (amount: ……. EUR)

2.3. Willingness to participate

Essentially 2 forms of compensation are distinguished: as a token of appreciation, or as incentive, reward or bonus.

Token of appreciation

Particularly well suited for minors, incapacitated adults, and breast-feeding women (or their legally designated representatives), as for these individuals this is the only additional compensation modality – on top of compensation of study-related expenses and 'loss of income' – accepted in the concerned EU Regulations (CTR, MDR, IVDR) and their Belgian legal counterparts.

A token of appreciation of relatively low value is also especially suitable to compensate participants in studies using qualitative research methods that are not very time-consuming nor very burdensome, such as taken an interview, filling out some questionnaires, or participating in a focus group.

☐ As items, goods or services of relatively low value (< 50 EUR)
e.g. ticket for a visit to a cinema or an entertainment park, a gift card, a subscription (limited in time) to a music or video streaming platform, a games app, a goody bag, a toy, a book, or small lump sum.
Please specify, with value per item or the entire package: ……. EUR.
☐ As items, goods or services of higher (non-material) value
e.g. long-term post-study drug or (implanted) device availability, availability of future useful screening or other study results, training advice to sportspersons or athletes, keeping a medical device or app used in the study (or purchased at a discount), and course credits to students.
Please specify: ……. (No need to add estimated value)
NOTE: Sharing of specific study results with participants, or post-study availability of experimental study treatment(s) to participants, should not replace the mandatory compensation for their study participation.

Incentives, rewards or bonuses

Can be an acceptable practice, if well justified.
☐ To stimulate an expected difficult study recruitment:
Amount: ……. EUR, justification: …….
Offering finder or referral fees is not recommended.
☐ To retain participants as long as possible in a long-term study (e.g. event-driven study):
Amount: ……. EUR (may be different according to specific target reached)
Justification: …….
☐ To reward full study completion:
Amount: ……. EUR, justification: …….

3. Modalities of compensation/payment

3.1. Form of compensation/payment

Compensation for participation in clinical research can be offered in the form of a monetary transaction, or can be of non-monetary nature. It is up to the sponsor, the investigator centre team, and the participant to decide which modality is most suitable and practical.
Possible monetary or financial transaction forms offered:
☐ Direct bank transfer(s), from the centre's bank account to the participant's bank account

☐ Indirect transaction(s), via a 3rd party service provider, under the following conditions:
- ☐ The collection of personal participant data adheres to the GDPR provisions, and is strictly limited to the data needed to handle the transaction(s).
- ☐ If the participant refuses payment through a 3rd party, an alternative anonymous modality is foreseen. Please specify: …….

☐ Allocation of vouchers
Although vouchers or gift cards may be considered practical for the centre team, they are not recommended for several reasons, e.g. some can only be used in specific stores, they may expire, and they can easily be lost.
If they are proposed in the study, participants who feel uncomfortable with using them should be offered an alternative modality of payment.

3.2. Timing of compensation/payment
☐ At the end of study participation (only if less than 3 months)
☐ Quarterly (for longer-term studies or longer-term participation)
☐ At the end of each study centre visit
☐ Other: …….

3.3. Conditions of compensation/payment
Specific conditions may be applicable, such as:
☐ *Pro rata* compensation/payment, based on actual time spent in the study
☐ *Pro rata* compensation/payment, based on actual number of investigations undergone
☐ Specific compensation/payment for screening without further recruitment
☐ Compensation/payment only to a limited number of participants
In Belgium, this can only be legally organised by a contest, requiring some skill to win a prize.
Please justify this choice and specify the contest rules: …….