

**LIST OF ALL SPECIAL CLAUSES
APPLICABLE TO THE IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT
ANNEX VII**

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SPECIAL CLAUSE 1. PARTICIPATION BY THE JOINT RESEARCH CENTER (JRC)

When the *Joint Research Centre (JRC)* participates to an *IMI JU* funded *project*, the following conditions apply:

- (a) For the purposes of this *grant agreement*, the *JRC* shall be considered as a *research organisation*.
- (b) For the purposes of this *grant agreement*, the *JRC* shall be considered as a *beneficiary*. It shall have the same rights and same obligations as the other *beneficiaries* and shall be a member of the *consortium* identified in Article 1.1.
- (c) This *grant agreement* takes precedence over any *project agreement* signed by the European Commission, represented by the *JRC*.

SPECIAL CLAUSE 2. INTERNATIONAL ORGANISATIONS (general rule)

1. Arbitration

- a. Any dispute between the *IMI JU* (“Party”) and (an) *international organisation(s)* (“Party”) acting as *participant(s)* (collectively referred to in this Article of the *grant agreement* as the “Parties”) relating to the *grant agreement*, which cannot be settled amicably shall be referred to an arbitration committee in accordance with the procedure specified below.
- b. When notifying the other Party of its intention to resort to arbitration, the notifying Party shall also inform the other Party of its appointed arbitrator. The second Party shall appoint its arbitrator within one month of that written notification.
- c. The two arbitrators shall, by joint agreement and within three months of the appointment of the second Party’s arbitrator, appoint a third arbitrator who shall be the chairman of the arbitration committee, unless a sole arbitrator is agreed by both Parties.
- d. Within one month of the appointment of the third arbitrator, the Parties shall agree on the terms of reference of the arbitration committee, including the procedure to be followed.
- e. The arbitration proceedings shall take place in Brussels.
- f. The arbitration committee shall apply the terms of the *grant agreement*. The arbitration committee shall set out in the award the detailed grounds for its decision.
- g. The arbitral award shall be final and binding upon the Parties, who hereby expressly agree to renounce any form of appeal or revision.
- h. The costs, including all reasonable fees expended by the Parties to any arbitration hereunder, shall be apportioned between the Parties by the arbitration committee.

2. Certificates on the financial statements

With reference to Article II.4.4, certificates on the financial statements to be provided by an *international organisation* may be established by its regular internal or external auditor, in accordance with its internal financial regulations and procedures.

3. Controls and audits

The competent bodies of the *IMI JU*, the European Commission (including Olaf) or the Court of Auditors shall address any requests for controls or audits pursuant to the provisions of Article II.21, to the Director General of the *international organisation*.

The *international organisation* shall make available to the competent bodies of the *European Union*, upon request, all relevant financial information, including statements of accounts concerning the action, where they are executed by the *international organisation* or by a subcontractor. In conformity with the *grant agreement*, audits and on-the-spot checks related to the action financed by the *European Union* may be undertaken.

Any control or audit shall be carried out on a confidential basis.

4. Governing law

Notwithstanding the law applicable on a subsidiary basis mentioned in Article 9 first paragraph, this *grant agreement* shall be governed on a subsidiary basis by [the law of (*insert law of a Member State or an EFTA country*)].

5. Privileges and immunities

Nothing in this *grant agreement* shall be interpreted as a waiver of any privileges or immunities accorded to [*insert name of the International Organisation*] by its constituent documents or international law.

SPECIAL CLAUSE 3. PROJECT REVIEW

1. A *project review* shall be held [at a mid-term stage] [and/or at the end of the project].

2. At least two months before the date of the review the *IMI JU* shall communicate to the *consortium* in accordance with Article 8 the modalities of the *project review*, including, where appropriate, any meeting it may propose to convene and that it may request the *consortium* to organise. [Each *participant* is requested by the *IMI JU* to attend such meeting in accordance with Article II.3.h.].

Costs incurred by the *participants* in relation to the *project review* may be declared as eligible under the activity referred to in Article II.15.3.

3. The *project review* shall be made on the basis of the satisfactory completion of due deliverables, milestones listed in Annex I as well as on the progress reported in the periodic report for the period.

SPECIAL CLAUSE 4. THIRD PARTIES LINKED TO A PARTICIPANT [Joint Research Units (Unités Mixtes de Recherche, Unités Propres de Recherche, etc.) European Economic Interest Groupings (EEIGs) / groupings / affiliates which are not *affiliated entities of EFPIA companies*]

1. The following *third parties* are linked to [*name of the participant*]

-[*name of the legal entity*]

-[*name of the legal entity*]

2. This *participant* may declare costs incurred by the above-mentioned *third parties* in carrying out the *project*, in accordance with the provisions of the *grant agreement*. These contributions shall not be considered as receipts of the *project*.

The *third parties* shall identify the costs to the *project* mutatis mutandis in accordance with the provisions of part B of Annex II of the *grant agreement*. Each *third party* shall charge its eligible costs in accordance with the principles established in Articles II.13 and II.14. The *participant* shall provide to the IMI JU:

- an individual financial statement from each *third party* in the format specified in Form C. These costs shall not be included in the *participant's* Form C.
- certificates on the financial statements and/or on the methodology (if applicable) from each *third party* in accordance with the relevant provisions of this *grant agreement*.
- a summary financial report consolidating the individual financial statements of the *third parties* and the *participant*, shall be appended to the *participant's* Form C.

When submitting reports referred to in Article II.4, the *consortium* shall identify work performed and resources deployed by each *third party* linking it to the corresponding *participant*.

3. The eligibility of the *third parties' costs* charged by the *participant* is subject to controls and audits of the *third parties*, in accordance with Articles II.21 and II.22.

4. The *participant* shall retain sole responsibility towards the IMI JU and the other *participants* for the *third parties* linked to it. The *participant* shall ensure that the *third parties* abide by the provisions of the *grant agreement*.

SPECIAL CLAUSE 5. ETHICAL RULES

1. The *participants* shall comply with the ethical framework of FP7, all applicable legislation, any relevant future legislation and FP7 specific programmes on "Cooperation", "Ideas", "People", "Capacities" (2007-2013) and "Euratom" (2007-2011)¹.

2. The *participants* undertake not to carry out research under this *project* involving any of the following activities:

- (a) research activities aiming at human cloning for reproductive purposes,
- (b) research activities intended to modify the genetic heritage of human beings which could make such change heritable, and
- (c) research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

SPECIAL CLAUSE 6. RESEARCH ACTIVITIES INVOLVING THE USE OF HUMAN EMBRYOS AND HUMAN EMBRYONIC STEM CELLS

The *participants* shall inform the IMI JU in writing of any research activities that may involve the use of human embryos or human embryonic stem cells, unless such provisions in Annex I to the *grant*

¹ Council Decisions on the specific programmes: 2006/971/EC on "Cooperation", 2006/972/EC on "Ideas", 2006/973/EC on "People", 2006/974/EC on "Capacities" and 2006/976/Euratom on "Euratom".

agreement have specifically been approved. Such research may not take place without the prior written agreement of the *IMI JU*. The agreement of the *IMI JU* shall be subject to its internal procedures. Should such research not be approved, the *IMI JU* will not fund it as part of the *project* and may terminate the *grant agreement* if the *project* cannot continue without that research.

SPECIAL CLAUSE 7. ETHICAL REVIEW

1. The *participant(s)* shall provide the *IMI JU* with a written confirmation that it has received (a) favourable opinion(s) of the relevant ethics committee(s) and, if applicable, the regulatory approval(s) of the competent national or local authority(ies) in the country in which the research is to be carried out before beginning any *IMI JU* approved research requiring such opinions or approvals. The copy of the official approval from the relevant national or local ethics committees must also be provided to the *IMI JU*.

2. The *participant(s)* shall ensure that, where an ethical review has been carried out by the *IMI JU*, the research carried out under the *project* fully complies with the following additional requirements resulting from the ethical review:

SPECIAL CLAUSE 8. CLINICAL RESEARCH (specific to biomedical research involving human beings)

1. The *participant(s)* shall provide the *IMI JU* with a statement confirming that it has received (a) favourable opinion(s) of the relevant ethics committee(s) and, if applicable, the regulatory approval of the competent national authority(ies) in the country concerned before beginning any biomedical research involving human beings.

2. (For biomedical research involving human beings including clinical or other trials) The *IMI JU* shall never be considered as a sponsor for clinical trials in the sense of Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

Annex I shall indicate the name(s) of any such sponsor(s).

For trials not covered by Directive 2001/20/EC, Annex I shall indicate the name of the person or organisation that is responsible for the initiation, co-ordination and monitoring of the trial.

SPECIAL CLAUSE 9. SPECIAL CASE WHEN SECONDARY AND HIGHER EDUCATION ESTABLISHMENTS AND PUBLIC BODIES ARE MANAGING ENTITY OF THE IMI JU FUNDING AND THERE IS AN "AUTHORISATION TO ADMINISTER" GIVEN TO A THIRD PARTY CREATED, CONTROLLED OR AFFILIATED TO THE MANAGING ENTITY OF THE IMI JU FUNDING

The bank account mentioned in Article 5 is the bank account of [*insert third party with an "authorisation to administer"*]. The *IMI JU* financial contribution shall be paid to [*insert third party with an "authorisation to administer"*] which receives it on behalf of the *managing entity of the IMI JU funding*, which in its turn receives it on behalf of the *consortium*. The payment of the *IMI JU* financial contribution to this entity discharges the *IMI JU* from its obligation on payments.

The *managing entity of the IMI JU funding* may delegate its tasks mentioned in Article II.2.3 to this entity. The *managing entity of the IMI JU funding* retains sole responsibility for the *IMI JU* financial contribution and for the compliance with the provisions of the *grant agreement*.

SPECIAL CLAUSE 10. CERTIFICATE ON THE FINANCIAL STATEMENTS BY THE EFPIA COMPANIES

With reference to Article II.4.1 c), the certificate on the financial statements to be provided by the following *EFPIA company(ies)*:

-[legal name of the *EFPIA company*]

-[legal name of the *EFPIA company*]

may be submitted to the *IMI JU* within 60 days after [*day/month*] of the year when the certificate is due and covering all concerned reporting periods.

SPECIAL CLAUSE 11. PARTICIPANT(S) WHICH ARE NEITHER A BENEFICIARY NOR AN EFPIA COMPANY

1. Costs incurred by the following *participant(s)* shall not be taken into consideration for determining the *IMI JU* financial contribution nor the *in kind contributions* made by *EFPIA companies*:

-[*name of the participant*]

2. Part B of Annex II, with the exception of Article II.22, and any other financial and payment provisions contained in the *grant agreement* do not apply to *participant(s)* mentioned in the previous paragraph.

3. By way of derogation, for the sole purpose of the evaluation, by the *IMI JU*, of the *project* reports and deliverables set out in Annex I, as required by Article II.4.1, this(ese) *participant(s)* shall declare, in accordance with Article II.4.1.c), the costs incurred for the implementation of the *project*, as determined according to its(their) usual accounting and management principles and practices.

4. When providing services or resources to another *beneficiary*, this(ese) *participant(s)* shall be considered as (a) *third party(ies)* for the purpose of the application of Article II.3 paragraphs c) and d).

SPECIAL CLAUSE 12. OPEN ACCESS

In addition to Article II.26.5, *participants* shall deposit an electronic copy of the published version or the final manuscript accepted for publication of a scientific publication relating to *foreground* published before or after the final report in an institutional or subject-based repository at the moment of publication.

Participants are required to make their best efforts to ensure that this electronic copy becomes freely and electronically available to anyone through this repository:

- immediately if the scientific publication is published "open access", i.e. if an electronic version is also available free of charge via the publisher, or
- within 6 months of publication.

SPECIAL CLAUSE 13. **IN-KIND CONTRIBUTION FOR PROSPECTIVE RESEARCH CONDUCTED OUTSIDE A MEMBER STATE OR ASSOCIATED COUNTRY**

a) [For standard *projects* where a maximum limit of 10% per *project* applies but where a global cap at programme level of 5% of the total committed EFPIA in-kind contribution shall apply:

"Notwithstanding point g) of Article II.13.1 and without prejudice to the other cost eligibility conditions, up to [X]% ($0 < X \leq 10$) of the costs incurred by *EFPIA companies* for the implementation of the *project* may be incurred outside a Member State or *associated country*, and therefore may be accepted as part of the *in-kind contribution* for the *grant agreement*, provided that the amount of such eligible costs incurred outside a Member State or *associated country* does not exceed € [Y] (*Y being X% of the estimated in-kind contribution mentioned in Annex I*)."

b) [For special *projects* where there is no maximum limit of 10% per *project* but where a global cap at programme level of 30% of the total committed EFPIA in-kind contribution shall apply:

"Notwithstanding point g) of Article II.13.1 and without prejudice to the other cost eligibility conditions, up to X% ($0 < X \leq 100$) of the costs incurred by *EFPIA companies* for the implementation of the *project* may be incurred outside a Member State or *associated country*, and therefore may be accepted as part of the *in-kind contribution* for the *grant agreement*, provided that the amount of such eligible costs incurred outside a Member State or *associated country* does not exceed € [Y] (*Y being X% of the estimated in-kind contribution mentioned in Annex I*)."

SPECIAL CLAUSE 14. **COMPLEMENTARY GRANT AGREEMENT(S)**

1. In addition to the provisions of Article II.1, the following definitions shall apply to this *grant agreement*.

(a) *Complementary grant agreement(s)* means *grant agreement(s)* concluded with the *IMI JU* in respect of work complementary to the *project* and referred to in paragraph 2 below.

(b) *Complementary participant* means a *participant* of a *complementary grant agreement* to this *grant agreement*.

2. This *grant agreement* is complementary to [the grant agreement(s): numbers, title/coordinator][the grant agreement(s) resulting from the selection of Call(s) [name of the Call(s)]].

3. *Complementary participants* enjoy the rights and bear the obligations of *participants* with regard to Articles II.28, II.29, II.30, II.31 and II.32 {*Access Rights*}. However, for *complementary participants*, these rights and obligations are limited to *foreground* only and do not extend to *background* unless otherwise agreed in the respective *project agreements*.

Complementary participants are not members of the *consortium* for the purpose of this *grant agreement*.

4. The *coordinator* shall provide copies of the reports referred to in Articles II.4.1 a), II.4.2 a) and II.4.2 b) of Annex II to the *coordinator(s)* of the *complementary grant agreement(s)*. *Complementary participants* shall treat this information in accordance with Article II.9 {*Confidentiality*} and Part C of Annex II {*Intellectual Property Rights, Use and Dissemination*}.

5. Coordination between *complementary grant agreements*:

(a) The *complementary participants* shall have concluded a written agreement regarding the coordination between *complementary grant agreements*.

(b) In order to ensure coherence of the work undertaken under *complementary grant agreements*, *participants* will be required to create and participate in boards and advisory structures together with representatives from *complementary grant agreements*. The *participants* of these *complementary grant agreements* shall collectively address collaboration and synchronisation of activities, including on issues such as management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.