

# Terms and Conditions

## DEBRA International Research Grants

### Definitions

Award Letter	shall mean the letter sent by DEBRA to the Recipient and the Grantholder which specifies the amount awarded, the final Research Project and the duration of the Grant, and which incorporates these Terms and Conditions.
DEBRA	means either DEBRA International, DEBRA UK, DEBRA Austria, or another DEBRA, as specified in the Award Letter.
EB Field	means treatment, prevention or diagnosis of Epidermolysis Bullosa (EB).
Grant	means the Grant awarded to the Recipient and the Grantholder in order to carry out the Research Project.
Grantholder	means the Principal Investigator (PI) to whom the Award Letter is addressed.
Recipient	means the university, hospital, research institution or company which is the Grantholder's employer.
Research Project	means the research project proposed in the grant application as amended by any revisions suggested or required by DEBRA (or its reviewers) which are agreed by the Grantholder. Acceptance of the Grant implies agreement by the Grantholder to implement requirements contained in these Terms and Conditions and any supplementary provisions in the Award Letter.
Results	shall mean the results of the Research Project and any intellectual property, whether registerable or not, including clinically relevant know-how, subsisting in such results.

The Recipient and Grantholder will use the Grant in accordance with the following terms:

### 1. GRANT ADMINISTRATION

- i. The Recipient and the Grantholder shall use the Grant for the purpose stated in the Research Project and according to the budget in the Award Letter.
- ii. The Research Project may be amended only by the written agreement of DEBRA, the Recipient and the Grantholder.
- iii. Any proposed virement of funds greater than 10% of the total Grant value between budget headings must be approved in writing by DEBRA.
- iv. The Recipient acknowledges that DEBRA will not fund any overheads, administrative costs, salaries of the Grantholder or attendance at conferences or meeting (unless reporting Results at such meeting). DEBRA will fund actual costs of open-access publication of Results, up to one year after completion of the grant, subject to a maximum of €5000 in total. The Recipient will ensure that sufficient resources are dedicated to support the Research Project.

- v. Payment for all expenditure under the Grant shall be made quarterly in arrears and against a valid invoice. Recipient shall submit invoices in accordance with the instructions given in the Award Letter. The Recipient shall not include on any such invoice any finance or service charges imposed in respect of this arrangement. No reimbursements will be made for invoices submitted more than one year after the end of the grant period.
- vi. If costs incurred by the Recipient, in carrying out the Research Project, amount to less than the maximum amount of the Grant initially approved, DEBRA shall be obliged to pay only such amount as may be necessary to discharge the actual costs, and if the costs incurred by the Recipient exceed the amount of the maximum Grant approved, such excess shall be borne by the Recipient. Reasonable bank transaction fees and charges related solely to currency exchange in paying invoices shall be borne by DEBRA.
- vii. Any part of the Grant that remains unused or uncommitted at the end of the Research Project, or its earlier termination, or is subsequently found to have been incorrectly attributed to the Research Project, shall be returned by the Recipient to DEBRA, unless DEBRA has agreed otherwise in writing.
- viii. Unless stated otherwise in the Award Letter, all equipment purchased using the Grant shall belong to the Recipient unless the Grantholder leaves the Recipient's employment during the Grant, in which case DEBRA shall decide to whom such equipment shall belong.

## 2. EMPLOYMENT

- i. DEBRA is not an employer with respect to the Grant. Where the Grant provides for employment of staff on the Research Project, the Recipient undertakes to ensure a contract of employment to such staff that is compliant with the relevant laws.
- ii. The Recipient is responsible for all employment costs, including but not limited to special inventor's remuneration, salary increments as a result of pay awards subsequent to award of the Grant, and any maternity, sickness and redundancy payments awarded by the Recipient to staff employed on the Research Project.
- iii. In the event that the Grantholder leaves the employment of the Recipient, the Recipient, the Grantholder and DEBRA shall discuss in good faith whether the Research Project can continue at the Recipient under the supervision of another researcher, or whether the Grantholder wishes to take the Grant to his/her next employer. DEBRA shall have the right to withdraw the Grant if it is not satisfied that the Grantholder and Recipient's proposal will ensure that the Research Project is completed in a satisfactory manner.

## 3. RESEARCH PRACTICE

- i. The Recipient shall ensure that the Research Project is carried out in accordance with relevant laws and regulations.
  - a. In particular, research using protected animals must be carried out under the appropriate licences and certificates and any other relevant national regulations in the country/ies where the research will be carried out. DEBRA will only support the use of protected animals where no valid alternative exists, and the applicant must have regard to animal welfare and advances in the refinement, replacement and reduction of animal uses.

- b. The Recipient shall ensure that the Grantholder and any other investigators involved in clinical trials are authorised health professionals in accordance with the applicable laws and regulations. The Recipient acknowledges that DEBRA shall not take on any liabilities relating to any clinical trial or study.
  - c. The Recipient must ensure that appropriate ethical approval, applicable in the country/ies where the research is carried out, is obtained, for the research funded by the Grant and must accept full responsibility for ensuring that any such ethical approval is in place at all relevant times during the Grant.
- ii. Where the Research Project involves collaboration with other institutions as stated in the research proposal or otherwise agreed with DEBRA, the Grantholder and Recipient undertake to ensure that the subcontracted institutions adhere to the same standards of research practice.
  - iii. The Recipient is responsible for ensuring that subcontracted work is completed satisfactorily and expenditure accurately attributed and auditable.

#### 4. REPORTING AND PUBLICITY

- i. The Recipient and Grantholder shall report to DEBRA, in accordance with the instructions on the Award Letter, as follows:
  - a) The Recipient and Grantholder shall submit annual reports which shall be due within one (1) calendar month of each anniversary of the start date of the Research Project and within three (3) calendar months of the end date. All reports must include the information outlined on the Reporting Requirements document provided with the Award Letter, or such document as amended during the period of the Research Project.
  - b) During and after the end of the Grant, the Recipient (through its technology transfer office or similar) and Grantholder shall notify DEBRA within fifteen (15) days of the occurrence of the following:
    - 1. publication of a paper or abstract which includes Results, (and an electronic copy of the publication), however in a way that does not obstruct or prejudice any patent filings, if any;
    - 2. the generation of any invention, or other results which may be suitable for commercialisation, arising in whole or in part from the Research Project (and a summary of such invention or results);
    - 3. filing of a patent application based on such an invention (and a copy of the application);
    - 4. the Recipient intends to drop such a patent or patent application;
    - 5. an agreement with a third party (whether commercial or not-for-profit) is concluded concerning or relating to the Results.
- ii. In the event that the Grant is composed, in part or in whole, of monies donated to DEBRA from a third party, such third party may have specific reporting requirements. Any additional reporting requirements of this third party shall, where known at the time of award, be stated in the Award Letter but otherwise shall be notified to the Recipient and Grantholder after the start date. DEBRA shall ensure that such reporting requirements shall not be onerous. The

Recipient and Grantholder shall comply with third party reporting requirements included in the Award Letter and shall use reasonable endeavours to comply with any changes in reporting requirements notified after issue of the Award Letter.

- iii. DEBRA may withhold any funds not yet paid to the Recipient under the Grant if the Recipient and Grantholder fail to report in accordance with this section 4 and in detail that is to DEBRA's satisfaction, or fail to demonstrate in the reports scientific progress that is to DEBRA's reasonable satisfaction. No payment of Grant owing will be made until any outstanding report has been received and accepted by DEBRA and any shortfall in progress has been rectified. DEBRA may withhold the greater of 10%, or 3 months of the Award, until a satisfactory final report and accounts are provided.
- iv. The Grantholder and Recipient acknowledge that reports will be circulated to members of the DEBRA International Medical and Scientific Advisory Panel or other Expert Advisory Panel used to review this Grant. If there is any reason, e.g. conflict of interest, why this should not occur with an individual report, the Grantholder and/or Recipient should inform DEBRA at the time of report submission. The lay summary may be circulated to other grant holders and national DEBRAs or other Epidermolysis Bullosa support groups, and may be used in publicity such as being placed on DEBRA websites.
- v. It is DEBRA's policy to publicise as widely as possible its Grants and the scientific progress achieved through them, and encourages publication in open-access journals, whilst also taking into account any consideration for protecting intellectual property. In accepting the Grant the Grantholder and Recipient agree to co-operate in such publicity efforts. DEBRA requires the findings of the research it funds in full or in part to be published promptly, but with due regard to protecting the intellectual property of research outputs.
- vi. The support of DEBRA must be acknowledged in all publications or other public output arising from the work funded, whether written or oral (e.g. scientific or popular publications, press releases, conferences, seminars, etc.). The Recipient and Grantholder must acknowledge DEBRA explicitly as the sponsor or co-sponsor of the research using the following phrase "supported by DEBRA International – funded by DEBRA Austria" or "supported by DEBRA International – funded by DEBRA UK" or other as indicated on the Award Letter. The Recipient and/or Grantholder shall submit a copy of any journal article or abstract in accordance with this section 4.

## 5. AUDIT

- i. The Recipient will maintain accurate, detailed and complete records of all expenditure with respect to the Grant. These records should be subject to the same formal audit arrangements as exist in the Recipient, and which include procedures for anti-fraud and corruption control.
- ii. DEBRA has the right to request from the Recipient, at any time, any financial information relating to the Grant, and confirmation that the Recipient's Auditors have raised no concerns with respect to accounts for the Grant.
- iii. DEBRA reserves the right to undertake a formal audit and review at DEBRA's expense, of the Research Project, if reports fail to demonstrate scientific progress to DEBRA's reasonable satisfaction, or if DEBRA or its Auditors request clarification or detail of Research Project expenditure invoiced.

- iv. The Grantholder and Recipient agree to cooperate with DEBRA by provision of any reasonable information requested.

## 6. CONFLICT OF INTEREST

- i. The Grantholder and Recipient must inform DEBRA if any conflicts of interest arise that have the potential to impact upon the direction or outcomes of the Research Project, or their possible exploitation.

## 7. INTELLECTUAL PROPERTY AND COMMERCIAL EXPLOITATION

- i. DEBRA requires the Recipient to have in place, and implement, processes for the identification, protection, management and exploitation of intellectual property (IP) derived from the Research Project.
- ii. The Recipient shall ensure that all personnel (including employees, students, and subcontractors) working on the Research Project have signed a contract with the Recipient under which any IP developed under the Grant is automatically assigned to the Recipient.
- iii. The Recipient and the Grantholder shall notify DEBRA of any new invention or any other Result arising from the Research Project and of any patent filed on such invention in accordance with section 4 above.
- iv. Should the Recipient not protect, manage or exploit any IP arising from the Grant, to the reasonable satisfaction of DEBRA, then DEBRA or its appointed agents shall have the right but not a duty to manage protect or exploit IP, six months after giving the Recipient notice in writing that the Recipient is failing to do so. DEBRA may exercise this right if it reasonably considers opportunity to benefit its membership might be lost if more rapid action is not taken. The Recipient and Grantholder agree to act as required to assist DEBRA or its agents to achieve this.
- v. The Recipient agrees to use reasonable endeavours to exploit the Results for the benefit of Epidermolysis Bullosa patients, and to ensure that any licensee in the EB Field develops the relevant Results in the EB Field. In addition, DEBRA explicitly wishes to prevent the blocking of development of Results in the EB Field. To achieve this the following restrictions apply, as appropriate:
  - a. In the event that the Recipient desires to grant to a third party a commercial licence to any of the Results in the EB Field, but in no other field, it may do so on a non-exclusive basis without the prior consent of DEBRA, or on an exclusive basis only with the prior consent of DEBRA. Such consent shall however not be unreasonably withheld.
  - b. In the event that the Recipient desires to grant to a third party a commercial licence to any of the Results in a field that excludes the EB Field, it may do so without the prior consent of DEBRA.
  - c. In the event that the Recipient desires to grant to a third party a commercial licence to any of the Results in a field broader than the EB Field (but including the EB Field) it may do so on a non-exclusive basis, without the prior consent of DEBRA; alternatively, the Recipient may licence Results in the EB Field non-exclusively along with other fields exclusively, without the prior consent of DEBRA.

- d. In no event may the Recipient assign the Results to a third party without the consent of DEBRA.
- e. In the event that Recipient is to enter into a license agreement with a commercial third party, in relation to the Results and in the EB Field, the Recipient shall use reasonable endeavours that such license does not have the effect of unreasonably restricting the academic freedom of the Grantholder, taking all the circumstances into account.
- vi. The Recipient shall notify DEBRA of any licence concluded under which rights to any Results are granted. If, two years after an invention is notified to DEBRA, the Recipient has not exploited the invention in the EB Field, DEBRA shall have the right to request assignment or licence (at DEBRA's discretion) of such invention and the Recipient shall, subject to third party rights, do all things necessary to effect such assignment or licence. DEBRA shall have the right to develop and exploit such invention thereafter. Recipient shall introduce DEBRA's assignment or licence rights in any licenses concluded with third parties in order to effectuate such an assignment or licence to DEBRA.
- vii. The Recipient shall not grant to a third party any rights to any Results without first entering into a Revenue Sharing Agreement with DEBRA, under which the Recipient gives to DEBRA a reasonable proportion of any financial benefit received by the Recipient or its affiliates arising from exploitation of the Results.
- viii. DEBRA awards are subject to Revenue Sharing Agreements, the terms of which are specific to the national DEBRA making the Award. The Revenue Sharing Agreement specific to this Award is provided [in Appendix 1] and forms a part of these Terms and Conditions.

## 8. LIABILITY LIMITATION

- i. In no event shall DEBRA be responsible for any liability, financial or otherwise, arising directly or indirectly out of any act or omission of the Recipient, the Grantholder or any other researcher working on the Research Project including, but not limited to, the research conducted under the Grant, the expenditure of the Grant funds, the conduct of the Grantholder and other researchers and the use of the Results.
- ii. The Recipient agrees, during and after the terms of the Grant, to indemnify and keep indemnified DEBRA from and against any and all liability, loss, damage, cost or expenses which may result from the Recipient's, or any of its employees' or licensees', conduct in connection with the Grant except where such liability, loss, damage, cost or expenses are the result of the gross negligence by DEBRA.

## 9. VARIATION OF TERMS

- i. In the extreme cases of contemporaneous research developments negating the meaningful conclusion of the Research Project, or where DEBRA's financial position is such that funding of the Grant cannot be continued for the full term, DEBRA reserves the right to discontinue the Grant by giving three (3) months' notice of the intention to do so. In such circumstances the Recipient and Grantholder shall, from the date that DEBRA notifies them of the decision to terminate the Grant (the "Notification Date"), minimise all expenditure on the

Grant. DEBRA shall, where it is able, reimburse the Recipient for all expenditure committed before the Notification Date which is not cancellable.

- ii. The Grantholder or Recipient, as appropriate, must inform DEBRA as soon as practicable of anything which might delay the start date or completion date of the Research Project, or which might cause divergence from the aims, directions or anticipated outcomes of activities funded by the Grant, or affect the Grantholder's or Recipient's ability to comply with these Terms and Conditions of the Grant.
- iii. DEBRA reserves the right to amend these Terms and Conditions from time to time. If, for any reason during the lifetime of the Grant, such an amendment is made, DEBRA reserves the right to apply the new version of the Terms and Conditions in place of those which were applied at the time of the original award by notification to the Recipient and Grantholder.
- iv. In the event that the provisions of the Award Letter conflict with the provisions of these Terms and Conditions, the Award Letter shall prevail.
- v. The contract between DEBRA, the Recipient and the Grantholder created by the Award Letter, the signed acceptance form (which form part of the Award Letter) and these Terms and Conditions shall continue for the term of the Grant. Any provisions in these Terms and Conditions which are expressed to continue after the term of said contract shall do so.

## **10. GOVERNING LAW, JURISDICTION AND COMPLIANCE**

- i. These Grant Terms and Conditions shall be governed by and construed in accordance with English Law, and subject to the jurisdiction of the English Courts.
- ii. The Recipient and Grantholder must ensure that the activities funded by the Grant are at all times conducted in accordance with all applicable laws and regulations.

## Revenue Sharing Agreement (template)

[Insert Revenue Sharing Agreement of the national funding DEBRA here]