

## A Guide to the Deposit of Cultures for Patent Purposes at NIBSC

### Terms and Conditions

#### 1. Contract Terms and Conditions

The official language of NIBSC is English. Communications in any other language are not accepted.

The NIBSC Patent Deposit Form, which the depositor is required to complete, binds the depositor to:

- provide all necessary information requested by NIBSC;
- provide a completed Biohazard Risk Assessment Form;
- provide material only in the form and quantity required by NIBSC;
- pay all necessary fees, including all charges for the transportation of deposits to NIBSC;
- observe the terms and conditions of the Budapest Treaty;
- accept the terms and conditions for deposit at NIBSC;
- indemnify NIBSC against any claim which may be brought against it as a consequence of the release of samples, unless such claims result from negligence on the part of NIBSC.

#### 2. Requirements for Deposit

Further guidance can be found in the documents produced by the World Intellectual Property Organisation (WIPO) which can be found at [www.wipo.org](http://www.wipo.org).

##### a) *Kinds of Microorganisms that May Be Deposited*

NIBSC accepts the following as Patent deposits under the Budapest Treaty 1977:

- Human cell lines (including embryonic and somatic stem cell lines);
- Animal cell lines;
- Genetically modified animal and human cell lines;

that can be preserved without significant change to or loss of their properties from freezing and/or long-term storage.

Note that:

- No patent deposit should be sent to NIBSC without completed Patent Deposit and Biohazard Risk Assessment Forms having been first received and reviewed by NIBSC. For genetically modified cell lines this will include a formal review by the NIBSC HuMAC Committee. Following a favourable review of the Risk Assessment the customer will be invited to ship the material for deposit. Risk Assessment forms can be accessed from the NIBSC website.
- Processing of material that requires handling at Containment Levels higher than Level 2 may require a longer period to completion depending on the availability of high containment facilities. The price charged for such high containment processing is necessarily higher to reflect the increased cost to NIBSC.

- NIBSC reserves the right to refuse to accept any material for deposit that, in its opinion, presents an unacceptable risk or is technically unsuitable to handle. NIBSC will only accept organisms that do not significantly change after long-term storage at the appropriate storage temperature.

**(b) Technical Requirements and Procedures**

All material submitted to NIBSC for deposit must be in the form of cryopreserved cultures. NIBSC may refuse deposits which have not been packed in a manner capable of maintaining the material in its original cryopreserved state during transit. Deposits are held on condition that they can be preserved without significant change or loss of properties during long term storage.

The minimum number of replicates that must be provided by the depositor for deposit is 12.

(i) Form and Quantity

*Human Cell Cultures (including embryonic and somatic stem cell lines).* Deposits of human cell lines cultured as monolayers or suspension cultures must contain at least  $1 \times 10^6$  cells/ampoule (of viable cells as determined prior to cryopreservation). Deposits of human cell lines, if cultured as colonies from colony fragments, must contain at least 4 colony fragments per ampoule or straw. Where the cell line requires a feeder cell layer to support its growth in culture, a sample of this material must also be provided in a quantity sufficient to support the necessary testing.

Any requests to deposit human embryonic stem cell lines will be subject to current UK regulations and guidelines. Any request to deposit human cell lines other than embryonic stem cell lines must conform to EU regulations and guidelines.

*Animal Cell Cultures.* Cells whose distribution is prohibited under the CITES convention will not be accepted by NIBSC. Deposits of animal cell lines must contain at least  $1 \times 10^6$  cells/ampoule (of viable cells as determined prior to cryopreservation).

(ii) Time Required for Viability Testing

The average length of time required for testing the viability of the various kinds of microorganisms accepted by NIBSC is given below. Depositors should realize that viability testing may, under some circumstances, take significantly longer especially in the case of human embryonic stem cells. Depositors will be advised of this prior to the deposit being accepted.

- |                                  |         |
|----------------------------------|---------|
| • Human embryonic stem cells     | 28 days |
| • Human and animal cell cultures | 14 days |

(iii) Depositor Checks and Renewal of Stocks

NIBSC does not prepare its own batch of the deposited microorganisms. When the stock, originally provided by the depositor, has been depleted through furnishing samples, the depositor will be asked to provide a new deposit. In the case of human stem cell lines deposited in the UK Stem Cell Bank at NIBSC, it may be possible to transfer some of the stock held by the UKSCB to NIBSC patent deposit to provide a new stock of microorganisms. In this case, the depositor will be asked to check samples prepared by the UKSCB for authenticity.

(iv) Import and/or Quarantine Regulations.

Deposits must be covered by the appropriate regulatory documentation before being accepted. In the case of human embryonic stem cell lines this may include application to the UK Steering Committee for the UK Stem Cell Bank and the Use of Human Stem Cell Lines. The depositor will be advised to obtain the regulatory documentation once NIBSC has received a biohazard statement from the customer.

(v) Making the Original Deposit

As well as the NIBSC Deposit Form referred to in (i) above, the depositor must complete a Biohazard Risk Assessment Form and a Shipping and Patent Deposit Order Form.

In the case of human embryonic stem cell lines, the depositor may also be required to complete the applicable form for the UK Steering Committee. The depositor should request information from NIBSC or the UK Stem Cell Bank concerning the appropriate forms.

At least 48 hours before the microorganism is dispatched the depositor must inform NIBSC of the number of ampoules being sent, the method of transportation and the estimated time of arrival. Dispatch must only be handled by couriers approved by NIBSC. If dispatch is by air, NIBSC must be told the flight number and destination, waybill number and handling agent for delivery together with their contact telephone number.

In the event of a later indication or amendment of the scientific description, and/or proposed taxonomic designation or other information supplied to NIBSC, the depositor must complete a revision form indicating the revised information.

(vi) Official Notifications to the Depositor.

The receipt and viability statement are issued on mandatory "international forms" BP/4 and BP/9, respectively, but standard forms are not used for other official notifications.

(vii) Unofficial Notifications to the Depositor.

NIBSC will notify the date of deposit and accession number after the microorganism has been received, but before the official receipt is issued. The result of the viability test will be communicated before the issue of a viability statement only where the viability of the deposit is unacceptably low.

(viii) Supply of Information to a Patent Agent.

NIBSC does not routinely ask the depositor for the name and address of their patent agent. However, if requested, it will send copies of the receipt and viability statement to both the depositor and their patent agent for which a charge will be made.

(ix) Converting a Previous Deposit

Deposits made outside the provisions of the Budapest Treaty may be converted by the original depositor to Budapest Treaty deposits, whether or not they were originally deposited for patent purposes providing an accession number was supplied at the time the original deposit was made. However, any deposits previously made free of charge are subject, on conversion, to the storage fee normally levied for Budapest Treaty deposits. The administrative requirements for conversion are the same as those to be met in respect of an original deposit, except that requirements relating to shipping procedures do not apply.

(x) Making a New Deposit

The depositor is required to complete the NIBSC deposit form and biohazard statement when making a new deposit, to send copies of the relevant documents and declaration (Rule 6.2) and to conform to the procedures mentioned previously in respect of shipping requirements. The receipt and viability statements for any new deposit will also be issued on the "international" forms BP/4 and BP/9, respectively.

**3. Furnishing of Samples****(a) *Requests for Samples***

NIBSC does not advise requesting parties of the correct procedures to follow in order to make a valid request and does not supply copies of request forms in the case of requests requiring proof of entitlement. Such forms must be obtained from the relevant industrial property office.

Notwithstanding any entitlement of third parties to receive samples under patent regulations, NIBSC will withhold samples of potentially hazardous microorganisms until it has confirmed that the requesting party has the appropriate containment facilities to handle such organisms. When responding to requests from overseas, NIBSC assumes that the requesting party has met the import requirements of his own country, and the customer is responsible for provision of the relevant documentation to do so.

**(b) *Notification of the Depositor***

Depositors are notified by letter when samples of their microorganism have been furnished to third parties.

**(c) *Cataloguing of Budapest Treaty Deposits***

NIBSC does not list Budapest Treaty deposits in its published catalogue.

**4. Schedule of Fees**

	<b><u>GBP</u></b>
<b>Cell Lines</b>	
(a) Deposits and storage including provision of certification and viability statements	1000
(b) Issuance of a new (or updated) viability statement	100
(c) Furnishing of a sample (excluding carriage costs)	100
(d) Issuance of (new or updated) certification	50
(e) Administration fee for amendments	50

Fees plus VAT, where applicable are payable to NIBSC.

**5. Address for Correspondence and Shipment**

UK Stem Cell Bank  
National Institute for Biological Standards and Control  
Blanche Lane  
South Mimms  
Potter Bar  
Herts. EN6 3QG  
UK

Telephone: (+44-(0)1223) 1701 641 000

Facsimile: (+44-(0)1223) 1701 646 730

E-Mail: [enquiries@ukstemcellbank.org](mailto:enquiries@ukstemcellbank.org) .uk

Website: <http://www.nibsc.org/ukstemcellbank>

## 6. Step by Step Guide to Making a Patent Deposit

- (i) Contact the UK Stem Cell Bank via the email address given in section 4 above requesting the forms necessary to deposit material under the WIPO patent deposit process.
- (ii) Complete the Patent Deposit and the Biohazard Risk Assessment Forms in full for each deposit and send both forms to NIBSC at the address given on the form. Do **not** ship samples at this stage.
- (iii) Once the forms have been received, reviewed and accepted by NIBSC, you will be issued with a reference number that must be quoted in all correspondence (and on your samples).

**Note:** NIBSC reserves the right to refuse deposits which in its opinion represent unacceptable hazards, significant technical or other difficulties, or where ethical considerations are inconsistent with those applied in the UK.

- (iv) Complete the Shipping and Patent Deposit Order Form and email this to NIBSC as soon as possible after acceptance by NIBSC of your request to deposit. Ensure that you raise a purchase order containing our reference number and send this along with the Order Form. It is only then that NIBSC can receive your sample.
- (v) NIBSC will require a minimum 12 ampoules/straws of the cryopreserved cell line for deposit. NIBSC does not accept growing cultures. Specific technical details can be found in Section 2 above. It is essential for quality control purposes that all ampoules are prepared at the same time.
- (vi) You are required to supply a sufficient quantity of any special growth factors or feeder cells which may be required during culture and quality control procedures for any deposit.
- (vii) It is important to ensure that when you deposit any cell line, the name of the cell line (and if possible the NIBSC reference number) is written in full on the vial. If you have already labelled the vial, then the information provided on the vial **must** match that provided by you in the appropriate section of the Patent Deposit Form. The full name must also be provided in the Identification Section of the Patent Deposit Form. Incomplete or incorrect information may result in the return of your material.
- (viii) You may only use a courier approved by NIBSC and material must be shipped under conditions that maintain the appropriate storage temperature (e.g. a liquid nitrogen dry-shipper for vitrified material). Material received by NIBSC at an inappropriate temperature may not be accepted for deposit and may be returned to the Depositor at their expense.
- (ix) On receipt of the deposit at NIBSC, a provisional Accession Number will be allocated to you. This number remains provisional until the successful completion of the following quality control procedures:
  - Assessment of viability (using an appropriate viability assay)
  - Assessment for mycoplasma contamination
  - Assessment for bacterial and fungal contamination.

Quality control procedures may take between 14 and 28 days to complete or longer in certain circumstances.

**Note:** Deposits are held on condition that they can be preserved without significant

*change or loss of properties during long term storage.*

- (x) The content of at least one ampoule will be examined according to the quality control criteria listed above. Cultures must be replaced by you if consistent low viability or contamination is identified.
- (xi) If any problems arise, you will be informed immediately, and a further course of action discussed and agreed between you and NIBSC.
- (xii) Following successful completion of quality control procedures, NIBSC will confirm the Accession Number and issue a Record of Shipment and Receipt, a Certificate of Viability and a Certificate of Deposition (WIPO Forms BP/4 and BP/9) and issue an invoice for payment. Failure to pay the deposit fees will result in the destruction or return of your patent deposit.
- (xiii) On acceptance of the deposit, NIBSC will hold the deposit under the terms and conditions of the Budapest Treaty, 1977.

## **7. Step by Step Guide to Shipping your Deposit**

- (i) Contact the UK Stem Cell Bank before shipping your deposit
- (ii) Inform NIBSC at least 48 hours before shipping cells.
- (iii) Only use a courier approved by NIBSC. NIBSC approved couriers ship door-to-door.  
**Note:** *NIBSC approved couriers will provide Depositors with the correct packaging and labelling instructions. It is the responsibility of the Depositor to ensure that all national and international regulations have been complied with and all permissions received.*
- (iv) Provide all necessary information to NIBSC (including date and time of arrival, flight information (Airway Bill No. etc) and name of courier).
- (v) Ship cells under conditions that maintain a storage temperature consistent with maintaining the essential properties of the material (e.g. liquid nitrogen dry-shippers for vitrified materials).

**Note:** *Cells received by NIBSC at an inappropriate temperature may not be accepted for deposit and may be returned to the Depositor at their expense.*