



NCRIS ACCESS AND PRICING CODE – RECOMBINANT PROTEINS

Truncated Version

1. DEFINITIONS

1.1 Dictionary

In this Schedule, the following definitions will apply except where the context otherwise requires:

“**ASC**” means the ASC-Recombinant Proteins

“**ASC-Recombinant Proteins**” means the Access and Strategy Committee for the Recombinant Proteins Sub-Project;

“**AusBiotech**” means AusBiotech Limited ABN 87 006 509 726;

“**AusBiotech Board**” means the board of directors of AusBiotech;

“**CEO**” means the Chief Executive Officer of AusBiotech;

“**Code**” means the access and pricing code comprised in this Schedule;

“**Commercial Rate**” means the market rate for the use of a particular NCRIS Facility;

“**Consortium Participants (Recombinant Proteins)**” means the University of Queensland through the Australian Institute for Bioengineering and Nanotechnology, Monash University through the ARC Special Centre for Green Chemistry, Commonwealth Scientific and Industrial Research Organisation through the Division of Molecular and Health Technologies, the University of New South Wales through the School of Biotechnology and Biomolecular Sciences, Hospira Adelaide Pty Ltd, Radpharm Scientific a division of Global Medical Solutions Australia Pty Ltd;

“**Contract Manufacturing Organisation**” or “**CMO**” means an organisation specified as a contract manufacturing organisation under the Funding Agreement and who as at the Commencement Date are Hospira Adelaide Pty Ltd and Radpharm Scientific a division of Global Medical Solutions Australia Pty Ltd;

“**Department**” means the Commonwealth of Australia acting through the Department of Education, Science and Training;

“**Feeder Facilities**” means the individual NCRIS Facilities owned and operated by the University of Queensland through the Australian Institute for Bioengineering and Nanotechnology, the University of New South Wales, CSIRO and Monash University for developing manufacturing processes for and characterisation of protein products in development;

“**Funding Agreement**” means the funding agreement entered between AusBiotech and the Department dated 9 August 2007;



“**GMP**” refers to the code of Good Manufacturing Practice;

“**GMP Facilities**” means the facilities residing in Contract Manufacturing Organisations serving various aspects of GMP production of proteins and peptides and which as at the Commencement Date are the facilities owned by the following Consortium Participants – Hospira Adelaide Pty Ltd and Radpharm Scientific a division of Global Medical Solutions Australia Pty Ltd;

“**Marginal Cost**” means the cost of accommodating the additional user at the NCRIS Facility, including costs such as consumables and any additional support staff . but does not include capital or depreciation expenses;

“**NCRIS Discount Certificate**” means the certificate issued by the Program Manager certifying as to the classification of the researcher under clause 4.1 of this Code and confirming the applicable rate payable by the researcher in respect of the conduct of the relevant project at the Feeder Facility;

“**NCRIS Facility**” means any facility receiving funds from AusBiotech under the NCRIS Funding Subcontract;

“**NCRIS Facility Access Agreement**” means the agreement required to be developed by each NCRIS Facility Owner under clause 1 of this Code;

“**NCRIS Facility Access Application**” means the application by a researcher for access to an NCRIS Facility, available through the NCRIS Project Website;

“**NCRIS Facility Representative**” means the representative of the NCRIS Facility authorised by the NCRIS Facility Owner to negotiate access arrangements with researchers and who will also, unless otherwise notified by the Consortium Participant (Recombinant Proteins)/NCRIS Facility Owner to the chairperson of the ASC-Recombinant Proteins and the Program Manager, be the ASC representative of that Consortium Participant (Recombinant Proteins)/NCRIS Facility Owner appointed under clause 2.6 of this Code;

“**NCRIS Facility Owner**” means the Consortium Participant (Recombinant Proteins) who owns or has responsibility for the management and operation of the relevant NCRIS Facility.

“**NCRIS Funding Subcontract**” means the funding subcontract between AusBiotech and an individual Consortium Participant (Recombinant Proteins) governing the terms on which the funding received by AusBiotech under the Funding Agreement will be provided to that Consortium Participant;

“**NCRIS Principles**” means the key principles forming the basis for the provision of NCRIS funding by the Department;

“**NCRIS Project Website**” means the website containing information on the available NCRIS Facilities, activities which may be undertaken at the NCRIS Facilities, information for researchers about applying for access including a copy of this Code and other information specified in this Schedule;



“NCRIS Research Capability” means the recombinant proteins component of the research capability identified in the NCRIS Roadmap as ‘Biotechnology Products’;

“NCRIS Roadmap” means the ‘Roadmap for the National Collaborative Research Infrastructure Strategy, released in February 2006, which outlines priority areas for investment of NCRIS funds and is available from the Department’s Internet website at the address: http://www.ncris.dest.gov.au/key_documents.htm;

“NCRIS Voucher” means the voucher issued by the ASC-Recombinant Proteins setting out the discounted amount payable by the researcher for access to the relevant GMP Facility;

“NCRIS Voucher System” means the arrangement whereby part of the Funding is applied to subsidise the access costs payable by a researcher for the use of a GMP Facility;

“Program Manager” means the person appointed by AusBiotech to manage AusBiotech’s obligations and responsibilities under the Funding Agreement;

“Recombinant Proteins Sub-Project” means the sub-project to provide for the establishment of the Feeder Facilities for process development for expression and purification of proteins to Australian researchers, along with subsidised access to GMP Facilities for the manufacture of proteins for clinical trialling, more specifically detailed in the project plan annexed to the Funding Agreement;

“Researcher Satisfaction Survey” means the satisfaction survey to be submitted to researchers in the form developed by AusBiotech and provided to the Consortium Participants (Recombinant Proteins) from time to time;

“Tier 1 Researcher” means any Australian higher education institution or public sector research organisation;

“Tier 2 Researcher” means:

- (a) Australian companies with less than 15 equivalent full-time employees;
- (b) collaborations between a Tier 1 Researcher and one or more Tier 3 Researchers; and
- (c) Australian companies owned wholly or in part by a Tier 1 Researcher.

“Tier 3 Researcher” means international companies and all Australian companies not satisfying the criteria for a Tier 2 Researcher;

1.2 Dictionary

Unless otherwise stated to the contrary in this Schedule:

- (a) clause references are to clauses in this Schedule; and
- (b) the definitions in clause 1.1 of this Agreement apply in this Schedule.



2. ESTABLISHMENT AND OPERATION OF ACCESS AND STRATEGY COMMITTEE – RECOMBINANT PROTEINS

2.1 Role of Access and Strategy Committee – Recombinant Proteins

The Access and Strategy Committee for the Recombinant Proteins Sub-Project will:

- (a) Develop, administer and implement access policies and pricing regimes consistent with NCRIS principles; and
- (b) provide advice to the AusBiotech Board, the CEO and the Program Manager relating to the strategic direction of the NCRIS Research Capability.

2.2 Authority of Access and Strategy Committee – Recombinant Proteins

Except as provided in clause 7.2 of this Code, the ASC-Recombinant Proteins is an advisory body only and is not authorised to vary access policies or pricing regimes without the approval of each of AusBiotech, the Consortium Participants (Recombinant Proteins) and the Department.

3. AVAILABLE NCRIS FACILITIES

3.1 Availability of NCRIS Facilities

- (a) The NCRIS Facilities made available under this Code by the Consortium Participants (Recombinant Proteins) are set out in the Project Plan and will be listed on the NCRIS Project Website.
- (b) Policies on access pricing, treatment of intellectual property, compliance with industry standards, insurance, workplace health and safety and associated issues should not substantially deter researchers from gaining access to a particular NCRIS Facility. Nevertheless, it is recognised that researchers will need to comply with reasonable security and access standards where appropriate.

4. SELECTION CRITERIA FOR ACCESS TO NCRIS FACILITIES

4.1 Categories of researchers

Access to NCRIS Facilities will be available to:

- (a) Tier 1 Researchers;
- (b) Tier 2 Researchers;
- (c) Tier 3 Researchers.

Researchers from outside the Consortium Participants (Recombinant Proteins) will be encouraged to apply for access.

4.2 Merit-based access

- (a) Access to NCRIS Facilities will be assessed using a merit-based system using the following criteria:



- (i) feasibility of the project – including consideration of work undertaken to date to progress the research and the benefit to research outcomes if access to the NCRIS Facility is provided;
 - (ii) research experience of the chief investigator;
 - (iii) potential for generation of quality publications in respect of the project or in the research area;
 - (iv) commercialisation potential of the research outcomes;
 - (v) potential benefits of research outcomes; and
 - (vi) speed in which the proposed project can be delivered.
- (b) Other relevant factors in determining access priority will be:
- (i) the potential for projects seeking access to Feeder Facilities to also utilise GMP Facilities ; and
 - (ii) meritorious early career researchers where supported by experienced senior researchers.
 - (iii) Where an NCRIS Facility is approaching maximum capacity in accommodating researchers under this Code, priority may be given to applications from meritorious Tier 1 and Tier 2 Researchers.

5. PROCEDURE FOR ACCESS BY RESEARCHERS TO NCRIS FACILITIES

5.1 Researchers with projects valued at \$100,000 or less and not involving access to GMP Facilities

Researchers with projects valued at \$100,000 or less and who will not require access to GMP Facilities may gain access to Feeder Facilities without formally applying for access to the ASC-Recombinant Proteins or the Program Manager. However the Feeder Facility must submit to the Program Manager, prior to commencement of the project, a completed NCRIS Facility Access Application on behalf of the researcher in order for the utilisation of the Feeder Facilities to be properly accounted in accordance with the requirements of the Department. The completed NCRIS Facility Access Application must indicate the Tier classification and discount for which the researcher will be eligible. It will be the responsibility of the relevant NCRIS Facility Representative to manage these researchers in accordance with requirements described in this Code, the Funding Subcontract and the Funding Agreement.



5.2 **Researchers with projects greater than \$100,000 and Researchers seeking access to GMP Facilities.**

Researchers with projects above \$100,000 in value and researchers at GMP Facilities, must complete and submit an NCRIS Facility Access Application to the Program Manager before gaining access to an NCRIS Facility.

5.3 **Review of initial application**

For research projects to which clause 5.2 applies, on receipt of a properly completed NCRIS Facility Access Application, the Program Manager will, following consultation with the NCRIS Facility Representative/s recommend to the researcher one or more NCRIS Facilities which may meet the researcher's project requirements. The Program Manager's recommendations will be made based on an assessment of the relevant NCRIS Facilities in respect of the following criteria:

- (a) capacity – whether the NCRIS Facility has the necessary expertise;
- (b) availability – whether the NCRIS Facility is available for the proposed project at the time requested by the researcher;
- (c) location – whether the NCRIS Facility is conveniently located to the researcher's site;
- (d) cost – the competitiveness of the cost of using the NCRIS Facility for the researcher's project; and
- (e) NCRIS Facility use – NCRIS Facilities that have not received a significant number of NCRIS research projects, will receive special consideration.

A recommendation by the Program Manager is not confirmation that the researcher will be successful in obtaining access to the chosen NCRIS Facility or that the researcher will qualify for a NCRIS Discount Certificate or NCRIS Voucher to offset the costs of access to the chosen NCRIS Facility.

5.4 **Researcher responsible for choice of NCRIS Facility**

The researcher will be solely responsible for the final choice of NCRIS Facility and neither AusBiotech nor the Program Manager will have any liability to the researcher in relation to the final choice of NCRIS Facility.

5.5 **Negotiation with NCRIS Facility Representative**

- (a) The researcher will contact the relevant NCRIS Facility Representative to discuss specific project requirements, access terms and other relevant considerations including IP ownership. The NCRIS Facility Representative must agree on the terms of the NCRIS Facility Access Agreement to govern the researcher's access to the NCRIS Facility.
- (b) A NCRIS Facility Representative may refuse to grant a researcher access to the NCRIS Facility where:



- (i) the researcher refuses to comply with the NCRIS Facility Owner's reasonable requirements in respect of insurance coverage or workplace health and safety procedures;
- (ii) the researcher and the NCRIS Facility Representative are unable to agree on the terms of the NCRIS Facility Access Agreement; or
- (iii) in the reasonable assessment of the NCRIS Facility Owner in consultation with the chairperson of the ASC, the project, if undertaken, would consume too much of the available time at the NCRIS Facility or conflict with the development of other projects at that NCRIS Facility.
- (iv) the Facility is not fit-for -purpose.

5.6 Submission of Proposal to Program Manager

Once the researcher reaches agreement with the NCRIS Facility Representative on the terms of the NCRIS Facility Access Agreement, the researcher must submit the final (potentially revised) NCRIS Facility Access Application to the Program Manager.

For research projects to which clause 5.1 applies, the NCRIS Facility Owner will determine whether the researcher is a Tier 1, Tier 2 or Tier 3 Researcher according to the established criteria and, based on that classification and the pricing principles set out in this Code, the amount of any discount to apply in respect of the researcher's access to the NCRIS Facility.

As part of the reviews described in 7.1 the Program Manager will audit the NCRIS facilities to ensure that the same standards are used across the Facilities. If there are any discrepancies the Program Manager will bring it to the ASC for review.

The NCRIS Facility Owner must notify the Program Manager of the researchers classification and the level of discount prior to commencement of the project.

For all research projects to which Clause 5.2 applies, the ASC will be responsible for determining both the Tier classification and the level of discount. However, this will also be consistent with the established criteria and, based on the classification and the pricing principles set out in this Code,

For projects to which Clause 5.2 applies the Program Manager will issue an NCRIS Discount Certificate or NCRIS Voucher (as the case may be) to the researcher.

5.7 Review of Classification

Where the NCRIS Facility Owner is uncertain as to the classification to apply to a researcher in respect of a project to which clause 5.1 applies, , or if the researcher disputes the classification determined by the NCRIS Facility Owner under clause 5.6, the Program Manager must be notified and the



proposal must be referred to the chairperson of the ASC-Recombinant Proteins for resolution.

If the ASC is unable to reach a unanimous decision, the issue will be referred to the CEO of AusBiotech whose decision will be final

5.8 **Payment to NCRIS Facility**

For projects to which Clause 5.2 applies researchers must present the NCRIS Discount Certificate or NCRIS Voucher to the NCRIS Facility Owner at the time that payment for access is due under the relevant NCRIS Facility Access Agreement.

6. **PRICING PRINCIPLES**

6.1 **General**

- (a) AusBiotech and the Consortium Participants (Recombinant Proteins) will in determining the pricing principles for the NCRIS Facilities governed by this Code, aim to ensure that the NCRIS Facilities are available to the widest possible pool of researchers and that the pricing principles do not operate to deter any class of researcher from seeking access.

6.2 **NCRIS Facilities (other than GMP Facilities) - Rates**

The rates payable by researchers accessing NCRIS Facilities (other than GMP Facilities) under this Schedule are set out in the table.

| Researcher Classification | Applicable Rate (NCRIS Facilities (other than GMP Facilities)) |
|----------------------------------|---|
| Tier 1 Researcher | Marginal Cost |
| Tier 2 Researcher | Marginal Cost plus 25% |
| Tier 3 Researcher | Commercial Rate (no discount) |

6.3 **GMP Facilities – Rates/NCRIS Voucher System**

The NCRIS Voucher System will operate to provide subsidised access to GMP Facilities by providing a discount on the access fee agreed between the relevant CMO and the researcher. The discounts available to researchers are set out in the table.



| Researcher Classification | Applicable Discount Rate (GMP Facilities) |
|----------------------------------|--|
| Tier 1 Researcher | Maximum discount available |
| Tier 2 Researcher | Intermediate discount |
| Tier 3 Researcher | Commercial Rate (no discount) |

6.4 **Payment of NCRIS Vouchers**

- (a) A CMO receiving a NCRIS Voucher must present same to AusBiotech together with confirmation from the researcher that the services under the terms of the NCRIS Facility Access Agreement have been provided by the CMO.
- (b) On receipt of the NCRIS Voucher and confirmation from the researcher, AusBiotech will either:
 - (i) where Funds have been released to the CMO in advance of the provision of services under the NCRIS Voucher System in accordance with clause 5A.3 of the NCRIS Funding Subcontract, apply the NCRIS Voucher against such advance; or
 - (ii) subject to clause 5.1 of the NCRIS Funding Subcontract, where no advance of Funds has been provided, or any such advance has been fully accounted for through the application of earlier NCRIS Vouchers, pay to the CMO the cash value of the NCRIS Voucher.

7. **REVIEW**

7.1 **Review of Project**

- (a) The Program Manager in consultation with the ASC-Recombinant Proteins and the Consortium Participants (Recombinant Proteins) will undertake a review of the access arrangements established under this Code every 6 months.
- (b) This review will cover the costing of access to NCRIS Facilities, pricing principles and include information gathered from the Researcher Satisfaction Surveys, other reports and data provided under 1 of this Code and the information provided by the Consortium Participants (Recombinant Proteins) under the NCRIS Funding Subcontracts.

7.2 **Review**

- (a) Subject to subclause (b) below, any proposed amendments to this Code will be referred to the ASC-Recombinant Proteins in the first instance and then AusBiotech, the Consortium Participants and the Department for approval.



- (b) If the ASC unanimously approves an amendment to the rates set out in clause 6.2 and/or clause 6.3, subject to approval by the Department, these new rates will take immediate effect and will be deemed to be incorporated into this Code.

8. COMPLAINTS AND GRIEVANCES PROCESS

8.1 Internal escalation process

Without derogating from the dispute resolution process established between AusBiotech and each Consortium Participant (Recombinant Proteins) under their respective NCRIS Funding Subcontracts, all parties will adopt the following escalation process in relation to complaints and grievances under this Code:

- (a) referral to the Program Manager in the first instance,
- (b) if unable to be satisfactorily resolved through discussions with the Program Manager, then the Program Manager will refer the matter on to the chairperson of the ASC-Recombinant Proteins;
- (c) if unable to be satisfactorily resolved by the chairperson, the chairperson will refer the matter to the CEO of AusBiotech;
- (d) if unable to be resolved by the CEO of AusBiotech, the CEO will refer the matter to the Board of AusBiotech.

8.2 External process

If the internal process under clause 8.1 is unsuccessful, the dispute resolution processes under the NCRIS Funding Subcontract (where the issue is between AusBiotech and a Consortium Participant) or the standard access agreement (where the issue is between the NCRIS Facility Owner and the researcher) will apply.