

MEMORANDUM OF UNDERSTANDING

NATIONAL SCREENING SERVICE (NSS)

and

ROTUNDA HOSPITAL

**PROVISION OF COLPOSCOPY AND CERVICAL HISTOPATHOLOGY SERVICES FOR
CERVICALCHECK – THE NATIONAL CERVICAL SCREENING PROGRAMME**

for the period

1 January 2017 – 31 December 2017

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This MEMORANDUM OF UNDERSTANDING (MOU) is made

BETWEEN

1. **NATIONAL SCREENING SERVICE** (the "NSS"), of King's Inns House, 200 Parnell Street, Dublin 1, part of the Health Service Executive (the "Executive"), statutory body, having its principal headquarters at Oak House, Lime Tree Avenue, Millennium Park, Naas, Co. Kildare, details of which are set out in Schedule 1 or any successor body or assigns,
2. **ROTUNDA HOSPITAL, DUBLIN 1**, (the "Hospital"), incorporated under Royal Charter of 1756, whose principal place of business is at Rotunda Hospital, Parnell Street, Dublin 1, details in respect of which are set out in Schedule 1, or any successor body.

BACKGROUND

- (A) The National Screening Service is part of the Health and Wellbeing Division of the Health Service Executive (HSE) and encompasses BreastCheck – The National Breast Screening Programme, CervicalCheck – The National Cervical Screening Programme, BowelScreen – The National Colorectal Screening Programme and Diabetic RetinaScreen – The National Diabetic Retinal Screening Programme.
- (B) The NSS is obliged, *inter alia*, to carry out or arrange to carry out a national cervical screening programme for the early diagnosis of cervical precancerous abnormalities, and arrange for the primary treatment of cervical precancerous abnormalities in women. The NSS requires colposcopy and cervical histopathology services for the purposes of the programme.
- (C) As part of this MOU, the NSS wishes to secure the performance by the Hospital of the Relevant Services on the terms and conditions specified below and the Hospital wishes to perform the Relevant Services.

THE PARTIES AGREE as follows:

1. Definitions and Interpretation

1.1 In this MOU, unless the context requires otherwise:

"Act" has the meaning given in clause 18;

"Additional Services" has the meaning given in clause 5.2 and Schedules 2 and 3;

"Additional Services Addendum" has the meaning given in Schedule 2;

"Authorised Person" has the meaning given in clause 7;

"Business Day" means a day (other than a Saturday or a Sunday) on which banks are open for business in Ireland;

"Claiming party" has the meaning given in clause 14 (Force Majeure);

"Clinical Indemnity Scheme" means the scheme relating to claims alleging medical malpractice or clinical negligence operated by the State Claims Agency;

"Codes of Practice" means the codes of practice produced by the NSS for the provision of the Services as the same may be amended from time to time, and any other guidance, circulars, policies, directions, protocols and any document of a similar nature in each case produced by the NSS and which has issued to the Hospital from time to time;

"Commencement Date" means 1st January 2017;

"DPA" has the meaning given in clause 19;

"Duration of the MOU" means a period commencing on the Commencement Date and continuing until the earlier of the Expiry Date or the date that this MOU is terminated in accordance with clause 17;

"Employee Level" has the meaning given in Schedule 4 (Staffing);

"Executive" means the Health Service Executive;

"Expiry Date" means 31st December 2017;

"Facilitated Referral" means the NSS assists in the referral process to colposcopy clinics;

"Fees" have the meaning given in clause 5 (Fees);

"First Performance Notice" has the meaning given in clause 10.1;

"Force Majeure" has the meaning given in clause 14 (Force Majeure);

"Functions" means the applicable parts of the NSS's National Screening Programme for the early diagnosis of cervical precancerous abnormalities and its arrangements for the primary treatment of cervical precancerous abnormalities in women insofar as those functions relate to colposcopy services;

"MOU" means this MOU and the schedules hereto, together with any amendments thereto agreed in writing between the parties;

"NSS Guidelines for Quality Assurance in Cervical Screening" refers to the revision in force at any time of quality assurance standards and requirements for each step of the cervical screening process, with particular reference to the sections for Colposcopy and Histopathology;

"HPV testing" refers to testing for the Human Papillomavirus;

"Major Incident" means an occurrence causing an unexpected surge in demand for the Services or any aspect of the Services which the Hospital could not reasonably have foreseen or taken steps to avert, with the direct result that the resources of the Hospital (in terms of staff, stock and beds or otherwise) are insufficient to deal fully with that occurrence at the same time as providing the Services in full compliance with this MOU;

"Minister" means the Minister for Health;

"Non-claiming party" has the meaning given in clause 14 (Force Majeure);

"New Referral" means a new episode of care commencing with a referral letter for a woman stating the indication for colposcopy services and including the attendance of the woman at the colposcopy service;

"Relevant Services" means the Services to be delivered at, or by, the Hospital or clinic;

"Review Meetings" means the meetings held pursuant to clause 8.1;

"Second Performance Notice" has the meaning given in clause 10.2;

"Services" means the colposcopy services to be delivered under this MOU and as more particularly described in Schedule 2 (including any "Additional Services" as agreed between the parties in accordance with Schedule 2);

"Service Users" means each person who is referred to the Hospital as part of the provision of the Services;

"Termination Notice" has the meaning given in clause 17.1;

"Unfunded Services" has the meaning given in paragraph 4 of Schedule 3;

"Working Hours" means a Business Day;

"WTE" means Whole Time Equivalent; and

"Year" means a calendar year from 1 January to 31 December.

1.2 In this MOU:

- (a) references to clauses, paragraphs and Schedules are to clauses, paragraphs and Schedules to this MOU.
- (b) references to a "company" shall be construed so as to include any company, corporation or other body corporate, wherever and however incorporated or established;
- (c) references to a "person" shall be construed so as to include any individual, firm, company, government, state or agency of a state, local authority or government body or any joint venture,

association or partnership (whether or not having separate legal personality);

- (d) a reference to any statute or statutory provision shall be construed as a reference to the same as it may have been, or may from time to time be, amended, modified or re-enacted;
- (e) any reference to a "day" or a "Business Day" shall mean a period of twenty-four (24) hours running from midnight to midnight;
- (f) references to times are to time in Ireland;
- (g) references to a "month" shall mean a calendar month;
- (h) a reference to any other document referred to in this MOU is a reference to that other document as amended, varied, novated or supplemented at any time;
- (i) any phrase introduced by the terms "including", "include", "in particular" or other similar expression shall be construed as illustrative and shall not limit the sense or meaning of the words preceding those terms;
- (j) references to the singular include the plural and vice versa; and
- (k) references to the masculine include the feminine and vice versa.

1.3 All headings and titles are inserted for convenience only. They are to be ignored in the interpretation of this MOU.

2. Appointment and Principles

2.1 The NSS hereby appoints the Hospital to perform the Relevant Services subject to the terms and conditions of this MOU, and the Hospital confirms that it is able and willing to perform the Relevant Services and hereby accepts such appointment.

2.2 The parties agree that in carrying out their respective obligations under this MOU, they shall each endeavour, without prejudice to any statutory rights or obligations of the Executive and subject to the Fee, to:

- (a) develop and deliver the Relevant Services to the highest quality using due skill, care and diligence and in a professional manner;
- (b) comply with the Codes of Practice with a view to continuous quality improvement;
- (c) recognise the need to provide the Relevant Services in a cost efficient manner and
- (d) deliver the Relevant Services in accordance with the NCSS Guidelines for Quality Assurance in Cervical Screening in force at

any time – with particular reference to the sections for Colposcopy and Histopathology.

3. Duties of the NSS

3.1 General

The NSS will provide copies of all relevant documents and publications on an ongoing basis to the Hospital in support of the provision of quality-assured services.

3.2 Promotion of and Access to the Services

The NSS will publicise the colposcopy service provided by the Hospital as a NSS CervicalCheck programme colposcopy service:

- (a) Make available publicly and to referring doctors the contact details of the colposcopy service;
- (b) Include the Hospital's colposcopy service in the process of facilitated referrals.

4. Duties of the Hospital

4.1 General

The Hospital shall each perform the Relevant Services in accordance with the specifications outlined in Schedule 2 (Specification) and the Codes of Practice.

4.2 Provision of the Relevant Services

The Hospital shall, within the limits of the Fee to be paid pursuant to clause 5 (Fees) and set out in Schedule 3 (Fees):

- (a) Make available to each Service User those of the Relevant Services that are appropriate to the individual needs of that Service User;
- (b) Carry out all duties and responsibilities which may be required to ensure the provision of the Relevant Services in a timely and efficient manner, to the best of its skill and ability and to a standard which is in all respects in accordance with this MOU; and
- (c) Endeavour to procure that the Relevant Services are provided in accordance with:
 - (i) the NSS's policies and objectives as specified in writing to, and agreed with each Hospital, from time to time;
 - (ii) the relevant policies, objectives and directions of the Minister and/or the Executive; and

- (iii) a spirit of respect for the individuality of the Service User and the principle of promotion of the well-being of each Service User to whom the Services are provided.

4.3 Other Obligations of the Hospital

The Hospital hereby agrees to:

- (a) act in a thoroughly competent and efficient manner so as to give to the NSS the full and complete benefit of that party's knowledge, experience, expertise and competence in performing services such as the Relevant Services;
- (b) comply with all applicable laws and regulations and the procedures and requirements of any relevant governmental bodies and any safety or security requirements of the NSS notified to and agreed with the Hospital from time to time, in providing the Relevant Services (including, without limitation, any statutory safety requirements in force for the time being) and procures that the same are complied with in all respects by that party's officers, employees, agents and sub-contractors;
- (c) obtain and maintain all licences, permits and permissions necessary to provide the Relevant Services in accordance with applicable laws and regulations and notify the NSS immediately in the event that such licences, permits and permissions are not obtained or maintained; and
- (d) as soon as practicable notify the NSS of the occurrence of any significant matters which may affect the delivery, provision or level of the Relevant Services.

5. Fees

- 5.1 In consideration for the performance of the Relevant Services, and upon receipt of confirmation that the Relevant Services have commenced, the NSS shall arrange for payment to the Hospital an amount which shall not exceed the amount specified in Schedule 3 (the "Fee") to an account nominated by the Hospital.
- 5.2 If the NSS is of the opinion that the scope of the Relevant Services performed pursuant to this MOU should be increased and/or extended, under the terms and subject to the conditions of this MOU, the amount and timing of any payment(s) due in respect of and the specification(s) for such additional relevant services (the "Additional Services") will be agreed in advance in writing between the parties prior to the commencement of performance of those services. Once any additional fee has been agreed in respect of any Additional Services, that fee shall be treated as part of the Fee for the purposes of this MOU, and the Additional Services shall be treated as part of the Relevant Services, respectively, for the purposes of this MOU.

5.3 The timing and method of payment by the NSS to the Hospital shall be agreed by the parties and made in accordance with the provisions of Schedule 3.

6. Information Requirements

6.1 Other Information Obligations

The parties will cooperate with each other in their monitoring and audit relationships.

7. Access Rights

7.1 The NSS shall be entitled to inspect and review the performance and provision of the Relevant Services by the Hospital and may arrange for an independent party to inspect and review the same throughout the Duration of this MOU.

7.2 Any person duly authorised by the NSS ("Authorised Person") may visit the relevant premises of the Hospital, as appropriate on reasonable written notice, to carry out an audit and/or inspection of the provision of the Services and/ or the Relevant Services, as appropriate. Such audits and inspection shall include, inter alia, the inspection, monitoring and assessment of the Hospital's premises, facilities, staff, records, equipment and procedures. The Hospital shall give all such assistance and provide all such facilities as the Authorised Person may reasonably require for such audit or inspection.

7.3 Each Authorised Person when accessing the Hospital's premises will comply with the relevant Hospital's policies and procedures and reasonable requirements in relation to such access.

7.4 The NSS shall provide copies of any reports, reviews, inspections, audits or notes arising out of any inspection, review or audit pursuant to clauses 7.1 or 7.2 to the Hospital and shall discuss any concerns arising out of such inspection, review or audit with the Hospital at the earliest opportunity. The NSS shall not disclose any reports, reviews, inspections, audits or notes arising out of any inspection, review or audit pursuant to clauses 7.1 or 7.2 (or the contents thereof) without the written consent of the Hospital.

8. Review Meetings

8.1 Review meetings shall take place between the NSS and the Hospital at least **annually** ("Review Meetings"). The parties will be represented by the "Main contact persons" specified in Schedule 1.

8.2 The provisions of the Schedules to this MOU, and the performance of the Services and implementation of this MOU shall be reviewed at each Review Meeting. In particular, all or any of the following may be considered:

(a) Financial reports and issues arising.

(b) Human Resources and staffing issues.

- (c) Activity Data – summary of Services provided.
- (d) The objectives and actions taken by the Hospital to deliver the Services, or Relevant Services, as appropriate, as specified in Schedule 2 (Specification).
- (e) Review of agreed performance indicators and outcomes (as set out in Schedule 5 (Performance Monitoring)).
- (f) Whether the needs of Service Users are being met.
- (g) Compliance with Services specifications (including Codes of Practice, Schedule 2, etc.)
- (h) Evaluation of information provided pursuant to clause 6 (Information Requirements).
- (i) Any matters notified in writing to the NSS (matters which may affect the delivery, provision or level of the Services or Relevant Services, as appropriate).
- (j) Any reports received by the NSS indicating areas of concern, or serious untoward incidents.

9. Amendment

- 9.1 The MOU shall not be amended, altered or changed other than by the expressed agreement in writing of the parties.
- 9.2 Without prejudice to the foregoing, any amendment, alteration, modification, extension or revocation to the Schedules to this MOU may be made by means of a Contract Change Note set out in Schedule 6 duly completed and signed by the parties.

10. Performance Notices

10.1 First Performance Notice

If as a result of any information received, or inspection undertaken or following a Review Meeting or otherwise, the NSS is of the opinion that the provision of the Relevant Services by the Hospital is not in accordance with this MOU, the NSS shall give notice in writing to the Hospital specifying in reasonable detail the principal reasons why the NSS believes that the Relevant Services are not being provided in accordance with this MOU (the "First Performance Notice") and, without prejudice to any other right or remedy which the NSS may have in respect of such failure, the NSS may request the Hospital to take such reasonable steps as may be necessary to ensure compliance with this MOU within fourteen (14) days of receipt of such notice.

10.2 Second Performance Notice

If the Hospital has not taken steps to ensure compliance with this MOU within fourteen (14) days of receipt of the First Performance Notice, the NSS shall give a second notice to the Hospital in writing (the "Second Performance Notice") and, without prejudice to any other right or remedy which the NSS may have in respect of such further failure, the NSS may request the Hospital to agree with the NSS a plan of action and a timetable for addressing the specified area(s) of non-compliance with this MOU within the 14 days the Hospital shall be entitled, if so wishes, to call a meeting of all parties hereto who are affected by such First Performance Notice, (a "Performance Review Meeting").

At each such performance review meeting the parties will be represented by the "Main contact person" specified in Schedule 1.

10.3 Effect of Non-Compliance

If the Hospital has not carried out the agreed plan of action within the agreed timetable or has failed to engage with the NSS in good faith to agree a plan of action and timetable for implementation, the NSS may by notice in writing to the Hospital issue a termination notice to Hospital in respect of such part of the Relevant Services that are not being provided in accordance with this MOU by the Hospital specifying that if the Hospital does not take action to rectify the breach within four months from the date of the notice that the MOU shall be terminated.

10.4 Allocation of Costs

For the avoidance of doubt, where the NSS takes, or is required to take, steps pursuant to this clause 10 to address any areas of non-compliance arising in respect of Services for which it has responsibility (excluding Relevant Services), and where a Hospital takes, or is required to take, steps pursuant to this clause 10 to address any areas of non-compliance arising in respect of the Relevant Services, then where such failure is due to any act or default of such Hospital, any costs arising there from shall be borne by the Hospital.

11. Insurance

11.1 Throughout the Duration of this MOU, each Hospital shall maintain the insurance which will include an indemnity in favour of the Executive on the public liability, employer's liability and motor insurance policies as set out in Schedule 7 (Insurance) on the terms specified and with insurers regulated by, or authorised to operate on a freedom of services basis by, the Irish Financial Services Regulatory Authority.

11.2 An endorsement in each Hospital's public liability, employer's liability and motor insurance policies in favour of the Executive and in a form reasonably acceptable to the Executive in relation to the relevant aspects of this Clause 11 shall be evidenced to the Executive by a certificate from the relevant insurer(s).

- 11.3 This Clause 11 shall be without prejudice to the operation of the Clinical Indemnity Scheme.
- 11.4 For the avoidance of doubt, each Hospital shall maintain the minimum levels of insurance as outlined in Schedule 7 (Insurance).
- 11.5 At the request of the Executive the Provider shall increase the agreed insurance limits or obtain additional coverage.
- 11.6 Each Hospital shall, if requested by the NSS, provide NSS with copies of its certificates of insurance or certified copies of all policies showing that all insurances required by each Hospital under this MOU are in force for the periods specified. Each Hospital shall notify the NSS immediately in the event that any of such insurances cease to be available.

12. Service User Centred Care

- 12.1 The Hospital will provide the Relevant Services to Service Users without discrimination on account of race, sex, sexual orientation, colour, religion, national origin or age. Except where the medical condition or physical or intellectual needs of the Service User require special or different treatment to be provided, the Hospital will provide the Relevant Services to Service Users without discrimination on account of physical or mental illness, intellectual disability or physical disability.

13. Major Incidents

- 13.1 The Hospital shall report in writing to the NSS, within twenty-four (24) hours of becoming aware of the occurrence, any Major Incidents which may impinge on the delivery of Relevant Services specified by this MOU where such incidents have significant implications for the contractual and service relationship between the parties.
- 13.2 During the period of the Major Incident, the extent to which it impacts upon the Hospital's ability to provide the Relevant Services, including elective activities, under-performance in delivering such activities during a Major Incident will not constitute a matter for which the NSS may issue a Performance Notice.
- 13.3 Where a dispute relating to matters which constitute a Major Incident arises it shall be resolved through the dispute resolution procedures outlined in this MOU.
- 13.4 During the period of a Major Incident the Hospital shall be paid for performance of the Relevant Services, and under-performance as a result of the Major Incident shall not be penalised.

14. Force Majeure

- 14.1 "Force Majeure" means, in relation to a party, a circumstance beyond the control of that party (the "Claiming party") and lock-outs, strikes and other industrial disputes (in each case, whether or not relating to the Claiming party's workforce and whether or not beyond the reasonable control of the

Claiming party). For the avoidance of doubt, Force Majeure does not include Major Incidents which shall be dealt with in accordance with clause 13 of this MOU.

14.2 The Claiming party will not be in breach of this MOU or otherwise liable to the other party or parties (the "Non-claiming party") for any delay in performance or any non-performance of any obligations under this MOU (and the time for performance will be extended accordingly) if and to the extent that the delay or non-performance is owing to Force Majeure. This clause only applies if:

(a) the Claiming party could not have avoided the effect of the Force Majeure by taking precautions which, having regard to all matters known to it before the occurrence of the Force Majeure and all relevant factors, it ought reasonably to have taken but did not take; and

(b) the Claiming party has used reasonable endeavours to mitigate the effect of the Force Majeure and to carry out its obligations under this MOU in any other way that is reasonably practicable.

14.3 The Claiming party will promptly notify the Non-claiming party of the nature and extent of the circumstances giving rise to Force Majeure.

14.4 If the Force Majeure in question prevails for a continuous period in excess of one (1) month after the date on which the Force Majeure begins, the Non-claiming party is then entitled to give notice to the Claiming party to terminate the MOU. The notice to terminate must specify the termination date, which must be not less than four months after the date on which the notice to terminate is given. Once a notice to terminate has been validly given, the MOU will terminate on the termination date set out in the notice.

14.5 No party shall have any liability to the other in respect of termination of this MOU due to Force Majeure, but rights and liabilities which have accrued prior to termination shall subsist.

15. Dispute Resolution

15.1 The parties to this MOU agree to avoid disputes and deal with issues as they arise. It is expected that any disputes in relation to this MOU shall be resolved through direct discussion between representative(s) managing this Arrangement on behalf of the NSS and representative(s) of the Hospital, where appropriate. Such discussions shall take place at the Review Meetings.

15.2 In the event that a dispute is not resolved at a Review Meeting to the satisfaction of a party any party may call an extraordinary meeting of the parties by service of not less than 5 days written notice on the other parties and each party agrees to procure that its "Main contact person", as specified in Schedule 1, shall attend such meetings.

15.3 In the event that any disputes arising out of, or in connection with, the MOU cannot be resolved by discussion between the disputing parties then the parties may agree to refer the dispute for full and final resolution to mediation and/ or arbitration and the mediator and/ or arbitrator shall be nominated by MOU in writing between the parties. In the event that agreement on the appointment of a mediator and/ or arbitrator cannot be reached between the parties within fourteen (14) days of the request to refer the matter to mediation and/ or arbitration (or such other period as is agreed in writing between the parties), then the parties hereby agree that the mediator and/ or arbitrator shall be appointed by the President of the Law Society of Ireland for the time being. The parties agree that

- (a) any arbitration shall be governed by Irish law and by the provisions of the Arbitration Acts 1954 to 1998, and any re-enactment, adaptation, amendment or extension of same for the time-being in force;
- (b) the award of the arbitrator shall be final and binding on both parties;
- (c) the arbitrator shall have power to determine all disputes arising out of or in connection with the Arrangement between the parties;
- (d) the seat of arbitration shall be Dublin, Ireland and the language of the arbitration shall be English.

16. Confidentiality

16.1 Each Party shall comply with and procure that its officers, employees, agents, contractors and advisors (together "Personnel") shall comply with the directions for the time being of any party revealing its own confidential information ("Confidential Information") to another party(s) hereunder regarding such confidential information provided, or obtained in connection with this MOU.

16.2 Each party acknowledges that any Confidential Information obtained from, or relating to another party an/or its patients, servants or agents, and its Personnel in the course of, preparing for, or in connection with the establishment of or the performance of this MOU is and shall remain the property of the disclosing party.

16.3 In further consideration of each party entering into this MOU each party hereby undertakes, with respect to Confidential Information of the other parties that it (and its Personnel):

- (a) shall use Confidential Information only for the purposes of this MOU;
- (b) shall not disclose any Confidential Information to any third party without the consent of the disclosing party; and
- (c) shall take all necessary precautions to ensure that all Confidential Information is held in confidence.

16.4 Each Party who has received (a "Receiving Party") Confidential Information from another party hereunder shall inform the disclosing party in advance of disclosure to any third party, agents or sub-contractors to whom it intends to disclose Confidential Information of the disclosing party and the disclosing party shall have the right to veto the disclosure of such Confidential Information by the Receiving Party to any such persons. In the event of such a veto, no Confidential Information of the disclosing party shall be disclosed by the Receiving party to any such vetoed person.

16.5 Nothing in this Clause 16 shall restrict the disclosure of information which:

- (a) is or becomes public knowledge other than by breach of this clause;
- (b) is in possession of a Receiving Party without restriction in relation to disclosure before the date of receipt from the Disclosing Party;
- (c) is independently developed without access of the information;
- (d) is received from another person who lawfully acquired it and who is under no obligation restricting its disclosure; or
- (e) is required to be disclosed by law.

16.6 The provisions of this Clause 16 shall continue to apply after the expiry or termination of the MOU.

17. Termination

17.1 This MOU, subject to the foregoing, may be terminated in its entirety by any party on the giving of a four (4) month period of notice ("Termination Notice") in writing to the each of the other parties.

17.2 If the NSS exercises its right to terminate this MOU, the NSS will pay to the Hospital reasonable and agreed costs and the relevant proportion of the Fee accrued in respect of the Relevant Services up to the expiry date of the Termination Notice together with any consequential losses or damage that may arise out of termination of this MOU.

17.3 Termination of this MOU for any reason shall be without prejudice to the rights and remedies of any party in relation to any negligence, omission or default of the other party or parties prior to termination.

17.4 In the event of termination of this MOU for any reason, the provisions of this MOU shall continue to bind each party insofar as and for as long as may be necessary to give effect to their respective rights and obligations.

18. Freedom of Information

18.1 The NSS and the Hospital hereby acknowledges that the Freedom of Information Acts 1997, 2003 and 2014 (the "Act") applies to the Executive.

- 18.2 In the event that any information or materials held or prepared by the NSS or the Hospital are the subject of a request for information under the Act, the NSS or the Hospital, as appropriate, will procure that any such materials are supplied promptly to the Executive for disclosure.
- 18.3 The Act offers certain procedural protection for some categories of information and the NSS and the Hospital hereby agree to clearly identify any information or records which it considers to fall within such categories at the time of provision to the Executive, stating the relevant category and the reason why it is believed that the document or information falls within that category.
- 18.4 Notwithstanding clause 18.3, the NSS and the Hospital hereby acknowledge that the categorisation of the information by the NSS or the Hospital shall not be final or binding on the Executive and that disclosure may be permitted by law notwithstanding such categorisation.
- 18.5 Unless stated otherwise by the NSS or the Hospital when the relevant document or information is provided to the Executive, it will be assumed that such document or information is eligible for disclosure under the Act.
- 18.6 The Executive shall have no liability for any disclosure made by it in accordance with the requirements of the Act.

19. Data

Data Protection

- 19.1 The parties shall have regard to their statutory obligations under the Data Protection Acts 1988 and 2003 ("DPA").
- 19.2 The NSS undertakes to ensure that it has all consents, authorisations and permissions necessary to enable the NSS to access and disclose any personal data of a Service User, to the extent that the NSS may require access to or the ability to disclose such data in the lawful performance of its functions.
- 19.3 Each Party hereby undertakes to comply with their respective obligations under the DPA and to indemnify the other parties against any loss, compensation, damages, expenses and costs which become payable or are incurred by the other parties in respect of or as a result of a breach by the breaching party of this clause 19 or a breach of the DPA.
- 19.4 Where personal data regarding Service Users is given by a party to another for the purpose of this MOU, it shall be used solely and exclusively for the purposes for which it is expressly provided and for other purposes permitted by law.
- 19.5 In particular, insofar as a party collects or obtains personal data ("Data") from patients, the Parties shall
- (a) not process (including obtain, retain, disclose or transfer) any Data, other than in accordance with the DPA; and

- (b) in accordance with Section 2(1)d and 2C of the DPA, apply appropriate technical and security measures to protect any data against unauthorised or unlawful processing (including obtaining, retaining, disclosing or transferring) and against accidental loss, destruction or damage.

Data / Information requirements

- 19.6 All patient information exchanged between the Hospital and the NSS must accurately identify the patient, including programme generated identifier, full name, address, date of birth and medical record number.
- 19.7 Detailed documentation of activity will be recorded in each Hospital so that clinical and administrative audit can be undertaken.
- 19.8 The Hospital will continue to provide the extraction of information from the colposcopy computer system databases to the NSS, to facilitate reporting on Key Performance Indicators (KPIs). NSS will provide a report regarding KPIs to the Hospital.

20. Representations and Warranties of the Parties

The parties represent and warrant to each other that:

- 20.1 it has all necessary power and authority to execute, deliver and perform its obligations under this MOU;
- 20.2 the execution, delivery and performance by it of this MOU has been authorised by all necessary action on its part; and
- 20.3 each of the obligations of the parties under this MOU constitutes a legally binding obligation.

21. General

21.1 Notices

(a) Requirement for Writing

Wherever in this MOU provision is made for the giving or issuing of any notice, submission, endorsement, consent, approval, acknowledgement, certificate or determination by any person (a Notice), unless otherwise specified such Notice shall be in writing and the words **notify, endorsed, consent, approval, acknowledged, certify or determined** shall be construed accordingly.

(b) Addresses

Any Notice shall be duly given if signed by or on behalf of a duly authorised officer of the person giving the Notice and left at or sent by registered post or email transmission to the names and addresses contained in Schedule 1.

(c) Changes

Any party may change its address for Notice to another address in Ireland by prior notice to the other party. That notification shall only be effective on:

- (i) any effective date specified in the notification; or
- (ii) if no effective date is specified, or the effective date specified is less than 5 Business Days after the date when notice is received, the date falling 5 Business Days after the notification has first been received by a party.

(d) Receipt

Save where otherwise provided in this MOU, any Notice shall be addressed as provided in clause 21.1(b) and shall be, in the absence of earlier receipt, deemed to have been given or made:

- if sent by hand, when delivered at the address of the relevant party; or
- if sent by prepaid post, 2 (two) Business Days after posting; or
- if sent by email, at the time of transmission.

21.2 Remedies and Waivers

- (a) No delay or omission by any party to this MOU in exercising any right, power or remedy provided by law or under this MOU shall:
 - (i) affect that right, power or remedy; or
 - (ii) operate as a waiver of it.
- (b) The exercise or partial exercise of any right, power or remedy provided by law or under this MOU shall not preclude any other or further exercise of it or the exercise of any other right, power or remedy.
- (c) The rights, powers and remedies provided in this MOU are cumulative and not exclusive of any rights, powers and remedies provided by law.

21.3 Severability

If at any time any provision of this MOU is or becomes illegal, invalid or unenforceable in any respect under the law of any jurisdiction that shall not affect or impair:

- (a) the legality, validity or enforceability in that jurisdiction of any other provision of this MOU; or
- (b) the legality, validity or enforceability under the law of any other jurisdiction of that or any other provision of this MOU.

21.4 No Partnership and No Agency

- (a) Nothing in this MOU and no action taken by the parties pursuant to this MOU shall constitute, or be deemed to constitute, a partnership, association, joint venture or other co-operative entity between any of the parties.
- (b) Nothing in this MOU and no action taken by the parties pursuant to this MOU shall constitute, or be deemed to constitute, any party the agent of any other party for any purpose. Neither party has, pursuant to this MOU, any authority or power to bind or to contract in the name of the other party to this MOU.

21.5 Further Assurance

Each and any party shall, from time to time on request, do or procure the doing of all acts and/or the execution of all documents in a form satisfactory to any other party which any other party may reasonably consider necessary for giving full effect to this MOU and securing to the other party the full benefit of the rights, powers and remedies conferred upon it in or by this MOU.

21.6 Entire MOU

This MOU constitutes the whole MOU and understanding of the parties as to the subject matter hereof and there are no prior or contemporaneous MOUs (whether or not in writing) between the parties with respect thereto. No party has relied on any representation except as expressly set out in this MOU.

21.7 Prior Obligations of the NSS

Nothing in this MOU shall prevent or restrict the HSE NSS from performing or omitting any act or thing which it is required to perform or omit pursuant to a statutory right or obligation or an order or written direction (whether general or specific) of the Minister for Health.

21.8 Costs and Expenses

Each party shall pay its own costs and expenses in relation to the negotiation, preparation, execution, implementation and interpretation of this MOU.

21.9 Counterparts

- (a) This MOU may be executed in any number of counterparts, and by the parties on separate counterparts but shall not be effective until each party has executed at least one counterpart.
- (b) Each counterpart shall constitute an original of this MOU, but all the counterparts shall together constitute but one and the same instrument.

21.10 Assignment

It is hereby expressly stated that the Hospital may not assign (in whole or in part) the benefit and burden of this MOU and arrange for the performance of the Relevant Services in whole or in part, without the prior written consent of the NSS.

21.11 Governing Law

This MOU shall be governed by and construed in accordance with the laws of Ireland.

SCHEDULE 1

Contact Details

Part A – The HSE NSS

Name: HSE National Screening Service

Address: Kings Inn House, 200 Parnell Street, Dublin 1

Legal status: Statutory body

Registered charity status: N/A

Tax clearance number: 09592374-28218C

Main contact person: Ms Linda Maher, Colposcopy Coordinator

Head of Screening: Mr Charles O'Hanlon, Assistant National Director

Authorised signatory: Mr Charles O'Hanlon

Telephone number: 01-8659300

Fax number: 01-8659333

E-mail for contact person linda.maher@screeningservice.ie

Part B – The Hospital

Name: Rotunda Hospital

Address: Parnell Street, Dublin 1

Legal status: Charter Corporation

Registered charity status: Registered Charity Number: CHY 240

Tax clearance number: 0045082-28925W

Main contact person: Prof Fergal Malone

Master / General Manager: Prof Fergal Malone

Authorised signatory: Prof Fergal Malone

Telephone number: 01 817 1700

Fax number: 01 872 6523

Premises (where the Service operates from): Rotunda Hospital, Parnell Street, Dublin 1

SCHEDULE 2

Service specifications

1. Purpose of this Schedule

This Schedule is intended to specify the manner in which the Hospital will perform the Relevant Services in consideration for the Fee (as set out in Schedule 3 (Fees)). The performance of the Relevant Services will be monitored as set out in Schedule 5 (Performance Monitoring).

2. Broad Principles of Service Provision

In providing the Services the parties should be guided by the following principles:

- (a) Improving health and patient care;
- (b) Providing Service User centred care in accordance with the Department of Health Statement of Strategy 2015 – 2017 (including Healthy Ireland - A Framework for Improved Health and Wellbeing 2013 – 2025) and other policies as determined by the Executive and others;
- (c) Planning services to take cognisance of patient/user requirements at the pre-treatment, treatment, recovery, discharge and follow-up stages of the patient journey;
- (d) Compliance with legal responsibilities and obligations including the Health Acts 1947 to 2008 including Health act 2007 Revised, updated to 26 July 2016, the Medical Practitioners Act 2007 including the Medical Practitioners Act 2007 Revised Updated to 14 October 2014, Nurses and Midwives Act 2011, Health and Social Care Professionals Act 2012 and the Pharmacy Act 2007;
- (e) Delivering high quality care through effective clinical governance;
- (f) Providing cost effective services and value for money;
- (g) Equity of access to services;
- (h) Interdisciplinary cross sector working and appropriate interfaces with primary, community and continuing care delivery system;
- (i) Delivering services in accordance with health and safety laws and best practice and;
- (j) Providing information and evidence of implementation of these principles.

3. Provision of colposcopy services

The anticipated demand for the Relevant Services and the available capacity of the Hospital have been analysed to determine the appropriate type, range and volume of the Relevant Services provided by the Hospital under this MOU.

- (a) Provide Colposcopy Services for women who are new referrals:

Hospital	New Referrals – projected number per annum (capacity)
Rotunda Hospital	2,000

- (b) Provide Colposcopy Services for women – follow up, as defined by the Codes of Practice and Quality Assurance requirements and standards.
- (c) Establish and maintain secure electronic connection between the Hospital and the NSS for the transmission and receipt of files in NSS-specified formats.
- (d) Provide IT support for the installation and continuous operation of Colposcopy Computer Systems for use by staff of the Colposcopy Service.
- (e) Provide the colposcopy services in accordance with the relevant sections of the current revision of the NSS Guidelines for Quality Assurance in Cervical Screening (NSS/PUB/Q-1) and in line with the Organisational and Clinical Guidance for Quality Assured Colposcopy Services (CS/PUB/CLP-7).
- (f) Implement revisions in management and organisational protocols, and policy changes, based upon updated guidance issued by NSS from time to time.
- (g) Meet the Key Performance Indicators (KPIs) as defined in the NSS Guidelines for Quality Assurance in Cervical Screening: Colposcopy (latest edition in force).
- (h) Organise and manage CPC / MDT meetings for the care planning of women with frequency, participation and protocols in accordance with best practice guidelines.
- (i) Provide colposcopy reporting metrics to the NSS in an agreed format (Colp 1 reporting form) on a monthly, quarterly and annual basis.
- (j) Ensure that all colposcopist staff members (doctors and nurses) are facilitated to ensure continuing accreditation by the British Society or Colposcopy and Cervical Pathology (BSCCP).
- (k) Ensure the necessary capital and current spending for the maintenance and renewal of equipment required in order for the colposcopy service to perform the Relevant Services to the required standards.

4. Provision of cervical histopathology services in support of colposcopy services

Histopathology services comprise the acceptance, processing, and reporting of cervical biopsies taken in the colposcopy service.

- (a) Provide best practice histopathology services in laboratory facilities accredited to ISO 15189 or equivalent;
- (b) Provide consultant histopathologist participation in CPC / MDT meetings organised by the colposcopy service(s) served by the histology laboratory;
- (c) Apply SNOMED coding to histology results;
- (d) Provide histology data for women who have consented to participate in the CervicalCheck programme from the histopathology laboratory information system, at least monthly in arrears, and to work with the NSS to determine if this frequency may be increased in time;
- (e) Provide cervical histopathology services in accordance with the NSS Guidelines for Quality Assurance in Cervical Screening: Histopathology (latest edition in force).
- (f) Provide histology reporting metrics to the NSS in an agreed format (CS-F-LAB-11 Histo 1) on a quarterly basis.
- (g) Ensure the necessary capital and current spending for the maintenance and renewal of equipment required in order for the histopathology service to perform the Relevant Services to the required standards.

5. Laboratory services - cytology screening and HPV testing

The Hospital will ensure that the Colposcopy Service uses NSS-designated laboratories for the provision of cytology screening and HPV testing services.

6. Cases of invasive cervical cancer

- a) The Hospital will include notification of women identified with new diagnoses of cervical cancer, as part of the monthly colposcopy metrics returns.
- b) The Hospital will implement NSS policy/guidance in informing women who have been diagnosed with invasive cervical cancer of the presence, purpose and possible outcome of the cervical cancer audit process.
- c) Where requested by the NSS, the colposcopy service will review specifically identified cases of invasive cervical cancer at a CPC/MDT meeting, and report the outcome of any discussions to the NSS.
- d) Where requested by the NSS, the histopathology service will review slides and/or tissue samples related to specifically identified cases of invasive cervical cancer, and report the review completion and outcome to the NSS. Where requested, the histopathology service will provide slides and/or tissue samples for review by an independent laboratory designated by the NSS.

- e) Where the NSS conducts a review of a case of invasive cervical cancer and communicates the outcomes of that review to a consultant doctor engaged by the Hospital, the Hospital will comply with NSS guidance in ensuring, where appropriate, a discussion and disclosure of the review findings with the woman concerned takes place.

7. Facilitated referrals

NSS CervicalCheck operates a facilitated referral process, advising women and referring doctors of colposcopy services that offer appointments within target waiting times. In the event that the Colposcopy Service has reached capacity, is unable to provide appointments to new referrals within the guidelines and wishes to request that the CervicalCheck programme refrain from making any new referrals to the service for a short period of time until congestion at the service has eased, then the "Facilitated Referral – Colposcopy Service 'Re-direct Referrals'/'Red Flag' Notification Form should be used. CS/F/CLP-9 Facilitated Referral – Colposcopy Service 'Redirect Referrals'/Redflag Notification Form". All sections should be filled and the form is to be signed by the Lead Clinician and Hospital Manager.

8. Additional Services

- (a) Where the parties agree in writing to perform Additional Services, a detailed specification for the Additional Services must be agreed in writing between the relevant parties to this MOU prior to any Additional Services being performed by the Hospital including the range, type, and volumes of Relevant Services, together with the amount and timing of payments due in respect of the Additional Services (the "Additional Services Addendum").
- (b) The Additional Services Addendum shall be appended to this MOU and the terms thereof shall be incorporated into this Schedule (and Schedule 3, in the case of the Fee for the Additional Services) at the next Review Meeting.

9. Complaints handling

The Hospital must be compliant with Part 9 of the Health Act 2004, Health Act 2004 (Complaints) Regulations 2006 (S.I. 652 of 2006) and the Health Service Executive policy and procedures on complaints (Your Service, Your Say) or equivalent.

The Hospital will manage all complaints received from Service Users concerning the provision of the Relevant Services covered in this MOU.

Such complaints, and any actions thereof, must be communicated to the NSS on a monthly basis (as part of the monthly colposcopy returns – Appendix 1).

10. Review

This Schedule should be reviewed at a Review Meeting and may be amended, if necessary, to reflect and address any issues arising during the Year. If any changes are made to the Schedule following the review, a Contract Change Note pursuant to Schedule 6 and the revised Schedule should be signed and dated by the parties.

11. Policies, Procedures and Protocols

- (a) The Hospital shall have policies, procedures and protocols in place in line with best practice for the services being provided.
- (b) The Hospital shall provide the NSS with a copy of any policy, procedure or protocol which is relevant to this MOU currently operated by the Hospital, respectively, upon receipt of a written request from the NSS.
- (c) The Hospital shall endeavour not to cancel Service User appointments unnecessarily and will notify the Service User of the cancellation at the earliest practicable date.

12. Referenced documents

- CS/F/PM-13 Colp1 Reporting Form
- CS/F/LAB-11 Histo1 Reporting Form
- CS/F/CLP-9 Colposcopy Service 'Over-subscribed'/Ref Flag Notification Form – Facilitated Referrals

SCHEDULE 3

Fees

1. Colposcopy Services

The Fee (inclusive of all duties, taxes, expenses and other costs associated with or incurred in the performance of the Relevant Services) to be paid / transferred to the Hospital in consideration for the performance of the Colposcopy Service in accordance with the terms of this MOU, shall be:

Hospital	New Referrals - projected number p.a.	Fee per new referral attended	Total annual funding for projected numbers
Rotunda Hospital	2,000	€ 287.00	€ 574,000.00

The relevant funding is payable for the performance of the Relevant Services (as specified in Schedule 2) only.

Additional new referrals: Where the NSS and the Hospital agree that a colposcopy service is permitted to take on additional referrals and exceed their annual agreed capacity, the clinic will be compensated at a rate of €287.00 for each new referral attended above the agreed projected annual number.

2. Histopathology support for colposcopy services

Provided that the colposcopy services are provided in accordance with the service specifications (Schedule 2), the NSS will provide a funding contribution towards the histopathology services (cervical biopsies) provided by the hospital to support the colposcopy service(s).

Hospital	Annual contribution to cervical histopathology services
Rotunda Hospital	€ 99,080

3. Payment of the Fees

- (a) The Fees in respect of the Relevant Services shall be payable by / transferable from the HSE NSS to an account designated by the Hospital.
- (b) In the event that the Relevant Services are not being provided each quarter as per the service specification (Schedule 2), the HSE NSS reserves the right to withhold, delay or retract payment of part or all of the Fees.

- (c) Where the performance of Additional Services is agreed by the parties pursuant to clause 5.2, the amount and timing of payments due in respect of the Additional Services, and the specifications for those Additional Services shall be agreed in writing pursuant to clause 5.2 and paragraph 9 of Schedule 2.

4. **Unfunded Services**

The Fee is payable for the provision of the Relevant Services (as specified in Schedule 2) only. Any other services provided by a Hospital that have not been authorised in advance in writing by the NSS shall be outside the scope of this MOU ("Unfunded Services") and the costs of the Unfunded Services and all responsibilities, obligations and liabilities relating to or arising in connection with the Unfunded Services shall be the sole responsibility of the Hospital.

SCHEDULE 4

Staffing

1. Staffing

- (a) The Hospital is required to maintain employment numbers as set out in paragraph (b) of this clause.
- (b) The employment numbers shall be:

Colposcopy Clinic WTE 2017						
Hospital	Lead Colposcopist annual sessions in place	Clinical Colposcopist weekly sessions in place	Clinical Colposcopist annual sessions in place	Nurse WTE in place	Clerical administration WTE in place	Health Care Assistant WTE in place
Rotunda Hospital	48	5.00	240.00	3.00	3.50	1

- (c) As agreed the necessary Employees must be in place in order to adhere to the NSS Guidelines for Quality Assurance in Cervical Screening (edition in force).
- (d) If the staffing level is not being met, the Hospital must set out a plan to re-establish the agreed numbers for the colposcopy service.

2. Employment Monitoring Reports

The Hospital shall complete the monthly Employment Monitoring Return template (the "EMR") indicating the number of staff employed by the Hospital for the provision of these Relevant Services, and submit the EMR to the NSS *on the dates/within the periods* of the timetable below.

Timetable for return of the EMR Report

Due Date	Date Received	Comment
7 th January		
7 th February		
7 th March		
7 th April		
7 th My		
7 th June		
7 th July		
7 th August		
7 th September		
7 th October		
7 th November		
7 th December		

SCHEDULE 5

Performance Monitoring

1. Performance Monitoring

Each Hospital shall participate in the data collection programme run by the NSS using the Colposcopy Computer System.

The Colposcopy Service will use the Colposcopy Computer System to generate the Colp 1 reporting document and the monthly Colposcopy activity statistics, and provide these to the NSS as required. The NSS retains the right to modify these documents and the associated required data elements. In addition, the NSS retains the right to access any programme related data directly from the Colposcopy Computer Systems.

2. Service levels and Outcomes

Service levels and employment ceilings will be monitored, and will be reviewed at the Review Meetings. Where variances have occurred the NSS will request the Hospital to take such actions desirable to bring activity, service levels and employment numbers back in line with Schedule 2, the overall terms of the MOU, and the quality assurance guidelines.

3. Performance Indicators

The Hospital will continue to provide the extraction of information from the colposcopy computer system databases to the NSS, to facilitate reporting on Key Performance Indicators (KPIs).

NSS will provide a report regarding KPIs to the Hospital.

A discussion will take place between the parties to effect any adjustments which may be required to facilitate the service provision by the Hospital to meet its KPIs.

SCHEDULE 6

Change Control

Contract Change Note

All requests for a variation to the MOU schedules should be accompanied by a completed and signed copy of the Contract Change Note below.

Contract Change Note

Reference Number:

WHEREAS the parties entered into a Memorandum of Understanding in respect of the Services dated [] (the "Original MOU") and now wish to amend the Original MOU.

IT IS AGREED as follows:

1. With effect from [] the Original MOU shall be amended as set out in this Contract Change Note:

[Full details of any amendments to the Original MOU should be inserted here.]

2. Save as herein amended all other terms and conditions of the Original MOU shall remain in full force and effect.

Signed for and on behalf of the HSE NSS by

Name Title Date

Signed for and on behalf of the Hospital by

Name Title Date

SCHEDULE 7

Insurance

1. Each Hospital shall take out policies for the provision of the following insurances:
 - (a) Public Liability insurance with a limit of indemnity of €6,400,000 (6.4 million euros) any one occurrence, arising from the provision of the Relevant Services, which insurance will also cover claims arising from the activities of any sub-contractor engaged by the Hospital.
 - (b) Employers Liability insurance with a limit of indemnity of €12,700,000 (€12.7 million euros) any one occurrence, arising from the provision of the Relevant Services.
 - (c) Motor Insurance (if the Relevant Services involves use of motor vehicle by the Hospital in respect of its obligations under this MOU) with a third party property damage limit of €2,600,000 (€2.6 million euros) any one occurrence arising from the use of motor vehicle in the provision of the Relevant Services.

2. Professional Indemnity
 - (a) Where appropriate, each Hospital must apply for professional indemnity coverage under the Clinical Indemnity Scheme.
 - (b) To the extent professional service is provided and not otherwise covered, each Hospital must have Professional Indemnity in accordance with the following thresholds or such other thresholds as may be specified by the Executive from time to time:
 - (i) Low Risk: Professional Indemnity with a limit of indemnity of €2,600,000 (2.6 million euros) any one occurrence;
 - (ii) Medium Risk: Professional Indemnity with a limit of indemnity of €4,000,000 (4 million euros) any one occurrence; and
 - (iii) High Risk: Professional Indemnity with a limit of indemnity of €6,400,000 (6.4 million euros) any one occurrence.

(This would not apply to those bodies which have the protection of the Enterprise Liability – Clinical Indemnity Scheme)

3. Review

This Schedule should be reviewed at the Review Meetings and may be amended, if necessary, to reflect and address any issues arising during the Year. If any changes are made to the Schedule following the review, the revised Schedule should be signed and dated by the parties.

SIGNATURE PAGE

IN WITNESS WHEREOF this MOU is executed by the parties as follows:-

Signed by

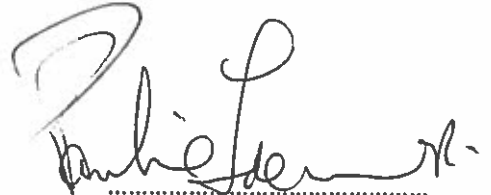


Mr Charles O'Hanlon
for and on behalf of the
NATIONAL SCREENING SERVICE

Date

19.12.16

Signed by



Sec. Gen. Mgt.

Professor Fergal Malone
for and on behalf of
ROTUNDA HOSPITAL

Date

28th Feb 2017