



## New Premises Inspection Report

Centre Name	Bristol Centre for Reproductive Medicine (BCRM)
Centre Number	0295 (Number assigned in advance of Licence Committee)
Name of PR	Mr Peter Wardle
Name of Inspectors	Tony Knox
	Chris O'Toole
Date of Visit	3 <sup>rd</sup> December 2007
Focus	New premises inspection

With notice	<b>X</b>
Short Notice	
Unannounced	

## Purpose of Visit

- Initial visit following first licence (within 3 months of starting)
- Applications to vary a condition of the licence e.g. PDG
- Follow up visit following concerns, actions needed etc.
- Change in existing premises e.g. following refurbishment
- X Advisory Visit
- Any other circumstances resulting in a visit other than new application, investigation and renewal interim inspection

### *Reasons for visit*

The purpose of this visit was to ascertain the progress being made on the new fertility unit premises at Southmead Hospital. These premises will house the new fertility unit in Bristol combining the equipment and resources from both centre 0024 (CRM Bristol) and centre 0032 (Southmead Fertility Unit).

## Points Covered

- The building structure is completed and internal works are nearing a state of completion.
- The centre have been given a handover date from the building contractors of the 17<sup>th</sup> December. It is requested that the centre is awarded a storage licence from this date in order to transfer all cryo-dewars from centre 0024 along with the patients' notes. It was explained to the PR that provision would only be considered upon receipt of a letter indicating that the security system for the cryostore along with the alarms systems, had been successfully installed and tested. These assurances must be received by the HFEA prior to recommendation being made to the Licence Committee on 17<sup>th</sup> December 2007.
- The Licence for Centre 0032 will not expire until 2009.
- The licence for Centre 0024 will expire In December 2007 and will not be renewed.
- Centre 0024 conducted their last licensed treatment cycle on 30<sup>th</sup> November 2007. Work has now commenced in decommissioning of equipment in preparation for moving it to the new premises.
- The inspectors were given a guided tour of the building. It was explained that the design and layout of the unit has been developed with the input of a patient working group. At each stage of the process, the needs and requirements of the patients' have therefore been considered.
- The unit consists of two floors. The ground floor houses all patient treatment areas including: -
  - Five laboratory areas, (egg preparation lab, media preparation lab, ICSI laboratory, Freezing laboratory and diagnostic semen laboratory) and a large dewar store.
    - Both the diagnostic semen laboratory and the media preparation laboratory have hatch access to a vestibule area outside the semen producing rooms. It was explained that the latter will ensure that men with poor quality semen needing to produce their samples into media can collect their sample pots from this hatch prior to producing their samples.
    - The ICSI laboratory has hatched access to the egg preparation laboratory on one side, the diagnostic semen laboratory on the other side and to operating theatre two where eventually all replacements will be performed.
    - The egg collection laboratory has hatch access to operating theatre one where it is intended all egg collections will be performed. It was explained that all egg collections will be performed using IV sedation in the presence of an anaesthetist.
    - A large dewar storage area has been provided. Although none of the services were in place at the time of the inspection, it was noted that provision of air extraction had been provided at ground level. It was explained by the Mr Wardle that a liquid nitrogen storage facility will be housed outside of the unit and will be pumped into the area.
    - A separate freezing room, next to the dewar storage facility has been provided.
  - A clinical laboratory waste area (separate from theatre waste) with secured access proximity door access to outside where the clinical waste will be stored prior to its' collection. It was noted that the internal door leading from the waste area into the laboratory section of the building is secured by key lock. It is recommended that a procedure be put in place to ensure all staff are aware that this door must remain

- locked except when placing items for collection within the area.
- A laboratory office (which will also contain refreshment facilities). Access to this area will be provided into the main operating theatre corridor, close to the staff entrance into the facility. Access to this area will be provided by the use of access proximity passes which will be programmed to ensure that staff have access only to areas they are authorised to have access to.
- A laboratory changing room and shower facility.
- Two operating theatres each with hand washing facilities and an area where instruments can be prepared prior to a procedure commencing.
- Sluice room with secured access to outside where clinical waste will be stored prior to its collection.
- Three semen producing rooms, one of which has been designed to provide disabled access with its own toilet. All patients producing samples will be escorted to the rooms by a member of the nursing staff from the main waiting area through access controlled doors. Each room is equipped with a patient alarm system which can be activated by the patient should emergency assistance be required.
- Nurse changing room and shower.
- A six bedded recovery area. This area has been designed to ensure that each bay is visible to the nursing station which will be manned at all times this area is in use. It was explained that one of the bays will be equipped for intensive recovery requirements should this be required. This area also has a separate room where patients can be taken to discuss their treatment privately, and a second waiting room for the partners of the patients undergoing treatment.
- The main waiting room/reception area is located at the main entrance to the unit. All patients will be required to register at the reception desk upon arrival. This area will contain refreshment facilities for patient use, which will also contain all patient literature.
- Within the waiting area is a room that will be used by the independent counsellor.
- A corridor leading off the reception area contains five consulting rooms, each to be equipped with a scan machine, one nurse scan room and a nurse treatment room. It was explained that the nurse treatment room would be used to take measurements of height, weight, blood tests etc.
- Off another corridor from the reception area are a further three nurse scan rooms and a further quiet room that patients can be taken to discuss any matters privately such as invoice/payment queries etc.
- It was noted that there were sufficient and adequate provision for toilets and storage throughout the ground floor.
- The first floor provides: -
  - A large plant room.
  - A small meeting/conference room for staff.
  - A large open plan office. This area will contain a staff refreshment area and storage facility for patient notes. It was explained that notes stored within this area will be for patients who have completed their current treatment cycle. It was explained that this would act as a holding area for between 6 months to two years potentially before moving to an archive notes facility. It was explained that the remainder of the area would contain desking for approximately 22 staff.
  - A large nursing office and notes storage for patients currently undergoing treatment.

- Mr Wardle explained that an area within the existing fertility unit (Centre 0032) would be retained for all archive storage. It was further explained that archived patient notes from centre 0024 which are currently housed in off site storage, would eventually be transferred to this area also.
- All policies and procedures to be used in the new unit have been adapted where necessary or transferred directly from both Centre 0024 and Centre 0032.
- All patient information has been adapted from existing literature from Centres 0024 and 0032.
- The unit will operate using staff currently employed at both Centre 0024 and Centre 0032.
- The application for licence notes the intention to offer the following treatments within the new unit: -
  - Storage of patient and donor eggs
  - Storage of patient and donor sperm
  - Storage of patient embryos
  - Donor insemination
  - IVF (Including with donor eggs and sperm)
  - ICSI (including with donor eggs and sperm)
  - Laser assisted hatching.
- The application notes that there will be no transport or satellite services and that both private and NHS patients will be treated within the facility.
- Mr Peter Wardle, (current PR at centre 0032) will act as the PR at the new unit and as the accredited consultant. He has worked at the centre 0032 since 1999, and has completed his PR Entry Program assessments.
- Mrs Gillian Ryan (currently in post as Nominal Licensee at Centre 0024) will hold the position of Nominal Licensee at the new unit. She has held the post of Nominal Licensee at Centre 0024 since 1<sup>st</sup> May 2006 and is also qualified as a solicitor.
- Patients who have material stored at either Centre 0032 or Centre 0024 have been informed of the impending move to new facilities. This has included the fact that unless otherwise notified, storage of their samples and notes will be transferred securely to the unit once authorisation to do so is granted by a Licence Committee.
- It was explained that once licensed treatments have been ceased in November, emphasis will be made on ensuring all registration forms are up to date through the EDI system, that information is validated through the same system and that all possible outcomes are registered for both Centre 0024 and Centre 0032. Staff from centre 0024 and centre 0032 have been in communication with the IT Department at the HFEA to ensure that following the transition to the new site, provision will still be available to staff to continue the validation process of data entry for the other two sites from within the new building.
- It was requested that a new centre number be allocated for the new unit as soon as possible. In this way, all documentation currently in preparation phase can include the new number. It was estimated that the installation (pending Trust approval) could be installed within the new unit any time after Monday 17<sup>th</sup> December 2007. This date is to be confirmed.
- It was explained that verification must be received from the new centre that all equipment to be used had been appropriately validated, installed, maintained, serviced and calibrated prior to commencement of licensed treatments commencing. It is anticipated that licensed treatments within the new unit (upon being granted a licence by the Licence Committee), will commence late January 2008

- It was explained that verification of the air quality within the new centre must be forwarded to the HFEA prior to commencing licensed treatments in the new centre.

Complete the box below only if outcomes / actions have been agreed

Agreed outcomes / actions to be taken	To be completed by (where applicable)
<ul style="list-style-type: none"> <li>• The centre number assigned (0295) to be confirmed upon being granted a treatment and storage licence by the Licence Committee.</li> <li>• Confirmation that security and room alarms have been successfully installed and tested within the cryostore prior to Licence Committee sitting on 17<sup>th</sup> December 2007 when a decision will be requested for the storage of the cryo-dewars.</li> <li>• Verification must be received at the HFEA from the new centre that all equipment to be used had been appropriately validated, installed, maintained, serviced and calibrated prior to commencement of licensed treatments commencing.</li> <li>• Verification of the air quality within the new centre must be forwarded to the HFEA prior to commencing licensed treatments in the new centre.</li> <li>• Ongoing dialogue between the HFEA IT and Registration Departments and the new centre are continued regarding the installation of the required EID system and ongoing registration and validation processes required through the EDI system for centre 0024 and centre 0032 data.</li> </ul>	<ul style="list-style-type: none"> <li>• Licence Committee</li> <li>• PR (Mr Peter Wardle)</li> </ul>

Complete the box below only if conditions will need to be imposed, varied or removed

As a result of this visit the following recommendations are made:

Pending successful completion of the points raised above, and notification received in writing from the PR to this effect, application to Licence Committee for the provision of a treatment licence will be made on 17<sup>th</sup> December 2007.

Date (where applicable)

Before 17<sup>th</sup> December 2007.

**Next action**

Presentation to licence Committee 17<sup>th</sup> December 2007.

**Report completed by**

**Signed** \_\_\_\_\_

**Name:** TONY KNOX

**Designation:** INSPECTOR

**Date:** 3<sup>rd</sup> December 2007