New Premises Site Visit Report

Name of Applicant	Cardiff Assisted Reproduction Unit; Centre 0049
Address of Proposed Premises	First Floor, University Hospital of Wales, Heath Park Cardiff, Wales, CF14 4XW
Has the applicant been licensed before	YES; The licence under which Centre 0049 operates is on-going as the new premises are within the curtellage, the centre having moved from the ground floor to the first floor
If yes: Centre Number and Address of previous premises	Cardiff Assisted Reproduction Unit; Centre 0049. Ground floor, University Hospital of Wales, Heath Park Cardiff, Wales, CF14 4XW
Inspector(s)	Dr Andy Leonard
	Mr Tony Knox
Date of visit	19th September 2007
Date of any previous visits to these premises	None; Old Ground Floor premises were inspected on 15th February 2007 for renewal of treatment and storage licence

About the Site Visit

The purpose of the site visit report is to confirm to the PR the findings of the inspection highlighting areas of firm compliance and good practice, as well as areas where further improvement is required. The report may be shared with other regulators on a need to know basis, such as the HC and HTA.

Brief Description of the Centre

The Cardiff Assisted Reproduction Unit (CARU) is part of the Cardiff and Vale NHS Trust and has been licensed by the HFEA since 1992. Fertility treatment services include donor insemination (DI), in vitro fertilisation (IVF) and intracytoplasmic sperm injection (ICSI). Sperm and oocyte freezing and storage is also performed. Five hundred cycles of IVF and ICSI for 459 patients were performed from February 2006 to February 2007, mainly to NHS funded patients. The centre's activities have not changed since the renewal inspection on February 15th 2007, except for the break during the move to the new premises.

The centre is part of the Division of Women's and Children's Health, University Hospital of Wales, Cardiff. Redevelopment of the Division has led to centre 0049 moving from the ground to the first floor of the hospital, within the curtellage, thus not necessitating licence variation. The centre will now be completely housed in renovated facilities on the first floor, comprising one secure (ie no public access) corridor for clinical treatment, recovery, laboratory facilities and administration, and a second perpendicular corridor in which the outpatients clinic is based. The outpatient corridor is open to the public at present. The outpatient clinic is scheduled to be relocated to a secure corridor on the upper ground floor of the hospital in February 2010 as the final stage in the divisional redevelopment programme. The Person Responsible (PR) has been in position since 1992 and is based at the centre full time.

The lead inspector of the renewal inspection team which visited the centre 15th February, 2007, noted in his report to Licence Committee that all recommendations made to the centre had been complied with.

Summing up meeting notes

1. The centre wish to change their name to IVF Wales as part of a re-branding exercise within the business plan, and asked the inspection team to verify the necessary procedure. This request is being actioned.
2. Due to the open public access on outpatients' corridor, the Centre should risk assess the corridor's security and ensure that doors to consultation/scan rooms on it are locked when left empty if patient records are within the rooms.
3. The lack of signage on laboratory doors was not appropriate for these rooms. The centre should arrange for the Trust Health and Safety team to re-visit the centre to advise regarding appropriate signage.
4. The low oxygen alarms in the dewar store and the freezing lab are connected to fan driven extractor systems however it was noted that clean air entry into the rooms was not facilitated, which would limit the air cleansing rate if a low oxygen alarm was activated. Measures should be taken to ensure clean air flow into the rooms when staff are working within them.
5. It was noted that the air ventilation flap between treatment room 1 and the corridor may well be incorrectly adjusted. This should be checked by the air conditioning engineers.
6. Air quality monitoring and result recording protocols need to be developed for the

treatment rooms and laboratories, as at present air monitoring/recording results is done on a less rigorous basis.

7. The inspectorate advises that the centre mail all their patients and other interested parties with their new location and ensure that effective signage is in place to guide patients from the old unit to the new.
8. It was noted that several activities needed to be risk assessed due to the layout of the new premises, these being:

   a) Transfer of frozen samples from the freezing laboratory to the sperm dewar store room, which necessitates passage through several doors and across a corridor with a transfer dewar.
   b) Working with liquid nitrogen in the dewar storage and the freezing room, to take into account the requirement for ventiliation and for two persons to be present at all times while such work progresses.

1. **Organisation**

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of findings from inspection
Evidence of: *(Delete areas not reporting on)*

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident Management
- Contingency arrangements
- Business planning
- Clinical governance
- Knowledge of the legal requirements and COP

Summary of Findings
Organisation, leadership and management are unchanged since the last renewal inspection when no improvements were required. The centre have responded rapidly and comprehensively to requests for information about the new premises, and the local NHS Trust Planning and Facilities resources have been fully integrated in the project planning and execution. The centre's new premises have been inspected and cleared for clinical work by the local NHS Trust Health and Safety and Clinical Governance teams and by Fire Safety inspectors. A coherent business plan is in place for the centre's activities and redevelopment within the Division of Women's and Children's Health. There is potential for expanding the service through increasing the self funded treatment area (NHS funding is for one full treatment cycle and one subsequent embryo transfer only). The centre have room to accommodate this plan and would assess staffing levels as the treatment load increases. The centre wish to change their name to IVF Wales as part of a re-branding exercise within the business plan, and asked the inspection team to verify the necessary procedure. Evidence indicates the centre is well integrated within the operational structure of the host hospital. The Person Responsible (PR) has been in position since 1992 and is based at the centre full time. The PR and Head Embryologist have an effective knowledge of the Code of Practice, 7th Edition, as evidenced by the centre's activities in the past and at present, and through discussions with the inspectorate. Risk management - *Not checked at this inspection, appropriate at last.* Incident Management - *Not checked at this inspection, appropriate at last.* Contingency arrangements - *Not checked at this inspection, appropriate at last.*
Areas for improvement
NONE
Points to consider/action for next inspection
NONE

2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of findings from inspection: *(Delete areas not being reported on)*

- Live birth rates
- 'Welfare of the Child' arrangements
- Confidentiality (including safe storage of patients' records)
- Choice of treatments
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services
- Donor selection
- Egg sharing and surrogacy
- Protection of children arrangements (for patients under 18yrs)

Summary of Findings
Live birth rates – *Not checked at this inspection, appropriate at last.* Patient feedback and satisfaction – *Not checked at this inspection, appropriate at last.* Counselling facilities and services – *Not checked at this inspection, appropriate at last.* Donor selection – *Not checked at this inspection, appropriate at last.* Egg sharing and surrogacy – *Not checked at this inspection, appropriate at last.* Protection of children – *Not checked at this inspection, appropriate at last.* 'Welfare of the Child'– *unchanged since last renewal inspection when appropriate* Choice of treatments – *unchanged since last renewal inspection when appropriate* Complaint handling – *unchanged since last renewal inspection when appropriate. Appropriate information about the Complaints process was seen in the outpatient clinic waiting room* Confidentiality – *in general unchanged since last renewal inspection; patients' records were seen to be safely stored except when on desks in consultation/scanning rooms and an office in the new outpatient's clinic corridor. These rooms had dead locks only and had no door closures, thus could be easily left open by a clinician leaving the room. The clinic corridor is open to the public at both ends so this presents a risk to patient confidentiality.* Privacy and dignity of patients – *Unlocked consultation rooms could theoretically pose a threat to patient privacy, however the PR stated that examinations are normally performed in the scanning rooms. These are locked from the inside as standard procedure when examinations are taking place*.
Areas for improvement
Centre should risk assess the security of the outpatients corridor and ensure that doors to consultation/scan rooms on it are locked when left empty if notes are within the rooms.
Points to consider/action for next inspection
Verify a risk assessment of the security of the outpatients corridor has been made and steps taken to ensure that doors to consultation/scan rooms are locked

3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of findings from inspection: *(Delete areas not being reported on)*

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/ accidents

Summary of Findings
The new premises were, in general, considered fit for purpose by the inspection team. Rooms inspected on the laboratory/treatment room corridor comprised on the right hand side from the entrance: two male production rooms; patient toilets; staff changing rooms and toilets; Admin Office/reception desk; 2 Anterooms for blood sampling/sedation and patient/staff discussions; wash-up room; dirty andrology lab; storage lab for sperm storage tanks; clean andrology lab with lobby; embryology office (4 staff); and on the left hand side: Disposal hold and stock room; 6 bed recovery room; treatment room 1; lab suite (IVF lab; freezing lab with embryo storage; ICSI lab; with lobby/change room); treatment room 2 (simple procedures); plant room for air conditioning and filtration equipment. Rooms inspected on the outpatients clinic corridor comprised on the left hand side from the entrance: Nurse's cloakrooms with WC; Office; Scan room; Office also consulting room; blood sampling room; CSSD store room; and on the right hand side: counselling room; consultation rooms x3; patient waiting room with reception; kitchen store room. Patient toilets and staff changing rooms and toilets were fit for purpose. The Admin/reception office, wash-up room and 2 anterooms were fit for purpose. Each of the two laboratories contained 2 incubators, 1 37℃ oven, and a Class II air flow cabinet as basic equipment. Carbon dioxide cylinders to feed the incubators are stored in a secure cabinet on the ground floor with an automatic changeover device and low pressure alarms, the latter duplicated in the laboratory. There was an issue with the alarm in the laboratory as it kept sounding despite the gas levels being optimal and the alarm on the ground floor not being activated. This needed to be remedied as soon as possible, indeed the Head Embryologist said it was being dealt with on the day of inspection and a technician was observed working on the unit later in the day. Cylinder pressure levels are checked daily by the Head Embryologist and cylinders replaced when pressurised to 2 Bar or less. All essential laboratory equipment are on a protected hospital circuit with generator back-up. All incubators and fridge/freezers are temperature monitored and connected to the CARU alarm system for call out in the event of failure; a procedure is in place for this Between the two embryology labs there is a small freezing laboratory, in which sperm and embryo samples are frozen and two embryo storage dewars are located. These are alarmed for low nitrogen on the CARU alarm system and there is a low oxygen alarm in the room connected to a fan driven extractor system. Air flow into the room needs to be assured when people are working within it to allow rapid movement of nitrogen out of the room in case of liquid nitrogen spillage. There is also a small class II air cabinet in this room which can be

used for clean sperm preparations and, if required, may be used for sperm preparations from viral infected donors with appropriate measures being taken for sterilization thereafter. A procedure is written for this alternative use but has yet to be used.

Sperm storage dewars in the main dewar storage room are fitted with a low nitrogen monitors, also connected to the CARU alarm system, and there is a wall mounted low oxygen monitor which sounds in the laboratory. Hand-held oxygen monitoring units are also used throughout the laboratories, to double check for oxygen levels. SOPs are in place for responding to low oxygen and low nitrogen alarms, and for filling the dewars (weekly) via a large transport dewar bought up from the ground floor via a lift. It is anticipated that next year, the liquid nitrogen supply will be upgraded to allow it to be piped into the laboratories from the storage vessel on the ground floor. The inspectorate was assured by the Head Embryologist that the SOP for moving the large liquid nitrogen transport dewar to the first floor was Health and Safety compliant. The low oxygen alarm in the dewar store is connected to a fan driven extractor system. It was noted however that clean air entry into the room was not facilitated, which would limit the air cleansing rate if the low oxygen alarm was activated. Adjacent to the dewar room was an andrology laboratory with a class II cabinet which appeared fit for purpose. Note that the main dewar storage room and the freezing lab are on different sides of the corridor. This issue is discussed in Section 5, Laboratory and Clinical Practice, below.

It was noted that signage on all laboratory doors was not compliant with Health and Safety regulations. It was suggested that the Trust Health and Safety team should re-visit the facility to advise regarding appropriate signage.

Both treatment rooms are virtually identical and were considered fit for purpose by the clinical inspector. They each have hatch access to their adjacent embryology labs, with a hotblock on the lab side of the hatch. Treatment room 1 is between the recovery room and IVF lab and will be used for egg collection and embryo transfers, while treatment room 2 is between the ICSI lab and plant room and will be used for embryo transfers and IUI. This work distribution can easily change if the work load increases. All procedures are carried out under conscious sedation, which is administered to patients in anterooms 1 or 2 across the corridor, where the patients wait until the treatment rooms are free. It was noted that the air ventilation flap between treatment room 1 and the corridor may well have been incorrectly adjusted. This was bought to the attention of the Head Embryologist.

Gas supplies in laboratories and treatment rooms have all been verified for pressure and cleanliness and a gas supply panel is present in the lab corridor for rapid cut-off. Electrical circuits have all been verified throughout the corridor.

The 6 bed recovery facility, 2 anterooms, wash-up room and admin/receptionist office were all considered fit for purpose

A filtered air supply system has been installed in the plant room to feed Grade C or better air to the laboratories and treatment rooms. This system is functioning effectively according to air monitoring tests which have been performed while it is in operation. Class II cabinets all contain Grade A quality air flow as assessed by air monitoring. Air monitoring is performed using a hand held monitor purchased by the centre. Standard air monitoring protocols need to be developed when the system is up and running.

Access to the outpatients' clinic corridor is open to the public at both ends of the corridor, one end connects to a lobby with lift and stairwell which are well used, the other end to a lift lobby area which also accesses a cardiology ward which is currently closed for renovation at some time in the future. The security issues related to this open access have been discussed in Section 2, confidentiality, above.

On the outpatients clinic corridor, the patient reception and waiting room are fit for purpose, though the waiting room is somewhat small. Patient information and a complaints procedure are displayed. A locked notes storage room was observed off of the waiting room.

3 consulting rooms were observed, one containing an examination couch. Doors to these rooms had deadlocks and no door closures so could easily be left open. They also contained filing cabinets, though these were empty and not used for patient records, as well as chairs and a desk. 2 scanning rooms were observed and were well equipped and fit for purpose. Scanning couches had curtains for patient privacy and windows had blinds to prevent observation from a hospital wing built perpendicular to the outpatients corridor. Scanning room doors also contained deadlocks only and no door closures, however the PR stated it was standard procedure to lock the doors when scanning, and a key was noted in the back of a scanning room door to allow this.

Areas for improvement

1) The laboratory doors were not marked with any Health and Safety signage. The centre should arrange for the Trust Health and Safety team to re-visit the centre to advise regarding appropriate signage.
2) The low oxygen alarms in the dewar store and the freezing lab are connected to fan driven extractor systems however it was noted that clean air entry into the rooms was not facilitated, which would limit the air cleansing rate if a low oxygen alarm was activated. Measures should be taken to ensure clean air flow into the rooms when staff are working within them.
3) It was noted that the air ventilation flap between treatment room 1 and the corridor may well be incorrectly adjusted. This should be checked by the air conditioning engineers.
4) Air quality monitoring and result recording protocols need to be developed for the treatment rooms and laboratories, as at present air monitoring/recording results is done on a less rigorous basis.

Points to consider/action for next inspection

Verify issues above have been acted upon

The standard of the premises and equipment

The standard of this centre renovation in terms of the premises and equipment was, in general, considered to be very good. Considerable thought, time and effort has been expended in its planning and execution.

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and to the HFEA

Summary of findings from inspection: *(Delete areas not being reported on)*

- Information management
- Information to patients and donors
- Information to the HFEA
- Protocols
- Record keeping (including consents)

Summary of Findings	
Information management -	*Records kept securely except for security issues of on outpatient clinic corridor*
Information to patients and donors-	*Not checked at this inspection, appropriate at last.*
Information to the HFEA-	*Not checked at this inspection, appropriate at last.*
Protocols-	*Not checked at this inspection, appropriate at last.*
Record keeping (including consents)-	*Not checked at this inspection, appropriate at last.*

Outcome of audit of records
Not checked at this inspection, appropriate outcome at last.

Highlighted areas of firm compliance
N/A

Areas for improvement
NONE

Points to consider/action for next inspection
The inspectorate advises that the centre mail all their patients and other interested parties with their new location and ensures that effective signage is in place to guide patients from the old unit to the new.

The standard of information provided
Not assessed at this inspection

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection: *(Delete areas not being reported on)*

- Assessment of patients and donors
- Safe handling systems
- Laboratory processes and practice
- Clinical practice
- PGD/ PGS
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

Summary of Findings	
Assessment of patients and donors-	*Not checked at this inspection, appropriate at last.*
PGD/ PGS-	*Not performed at this centre*
Recruitment and retention of staff-	*Not checked at this inspection, appropriate at last.*
Staff competence, training and CPD-	*Not checked at this inspection, appropriate at last.*

Clinical practices- *Not all checked at this inspection, found appropriate at last inspection. It was noted on this inspection that the centre planned that the recovery room would be staffed by one nurse to the six beds therein. This nurse will also be required to ferry sperm samples from the men's production rooms nearby, to the andrology laboratories. The inspectorate question whether this will allow adequate monitoring of recovering patients.*

Safe handling systems- *Class II cabinets are used for all gamete and embryo work. Cabinets are checked, usually daily, with a hand held air quality monitor, as is the room air. The monitoring process and its results are not recorded however, though in future the Head Embryologist says that results will be downloaded from the monitor to a computer, stored and analysed. Incubators are also independently temperature and carbon dioxide (pH) monitored daily. Volatile organic compound monitoring is also performed. All critical equipment seemed well maintained under third party agreements and service records were available.*

Laboratory processes and practice - *Not all checked at this inspection, appropriate at last. On this inspection it was noted that several activities needed to be risk assessed due to the layout of the new premises, these being: 1) Transfer of frozen samples from the freezing laboratory to the dewar store, which necessitates passage through several doors and across a corridor with a transfer dewar. 2) Working with liquid nitrogen in the dewar storage and the freezing room, to take into account the requirement for ventiliation, perhaps from adjacent laboratories in the short term and from new air ducting in the long term, and for two persons to be present at all times while such work progresses.*

Areas for improvement
1) The centre plan that the recovery room will be staffed by one nurse to the six beds therein. This nurse will also ferry sperm samples from the men's production rooms to the andrology laboratories. Given the recovering status of the patients in this room, the inspectorate suggest that the centre risk assess this staff deployment if they consider putting it into place.

2) An air monitoring protocol for the laboratories and treatment room needs to be developed
3) Several activities needed to be risk assessed due to the layout of the new premises:
   a) Transfer of frozen samples from the freezing laboratory to the sperm dewar store room, necessitating passage through doors and across a corridor with a transfer dewar.
   b) Working with liquid nitrogen in the dewar storage and the freezing room, to take into account the requirement for ventiliation, perhaps from adjacent laboratories in the short term and from new air ducting in the long term, and for two persons to be present at all times while such work progresses.

Points to consider/action for next inspection
Attention to areas of improvement above

The provision and quality of staff
Excellent

Topic 1

The applicant meets the requirements for **organisation**

Topic 2

(b) The following actions need to be taken by the date shown before the applicant meets the requirements for **quality**

Action needed:	To be completed by:
1) Centre should risk assess the security of the outpatients corridor and ensure that doors to consultation/scan rooms on it are locked when left empty	31st October 2007
The following conditions apply:	

(c) The applicant does not yet meet the requirements for **quality** for the following reasons:

1) Patients' records on desks in consultation/scanning rooms and an office in the new outpatient's clinic corridor may not be secure. These rooms have dead locks only and no door closures, thus could be easily left open by staff leaving the room. The clinic corridor is open to the public at both ends so there is a risk to patient confidentiality.

Topic 3

(b) The following actions need to be taken by the date shown before the applicant meets the requirements for **premises**

Action needed:	To be completed by:
1) The centre should arrange for the Trust Health and Safety team to re-visit the centre to advise regarding appropriate signage on laboratory doors.	31st October 2007
2) The centre should develop measures to ensure adequate ventilation in rooms in which liquid nitrogen is used.	31st October 2007
3) The air ventilation flap between treatment room 1 and the corridor should be checked by the air conditioning engineers.	31st October 2007
4) Air quality monitoring and result recording protocols need to be developed for the treatment rooms and laboratories.	31st October 2007
The following conditions apply: NONE	

(c) The applicant does not yet meet the requirements for **premises** for the following reasons:

1) The laboratory doors were not marked with any Health and Safety signage.
2) The low oxygen alarms in the dewar store and the freezing lab are connected to fan driven extractor systems however it was noted that clean air entry into the rooms was not facilitated.

3) It was noted that the air ventilation flap between treatment room 1 and the corridor may well be incorrectly adjusted.
4) Air quality monitoring and result recording protocols need to be developed for the treatment rooms and laboratories, as at present air monitoring/recording results is done on a less rigorous basis.

Topic 4

(a) The applicant meets the requirements for **information**

Topic 5

(b) The following actions need to be taken by the date shown before the applicant meets the requirements for **laboratory and clinical practices**

Action needed:	To be completed by:
1) The centre risk assess the nurse in the recovery room also having responsibility for ferry sperm samples between the production rooms and the andrology labs.	31st October 2007
2) Write and instigate an air monitoring protocol for the laboratories and treatment room	31st October 2007
3) Risk assess the movement of frozen samples in a transfer dewar between the freezing laboratory and the dewar.	31st October 2007
4) Risk assess working with liquid nitrogen in the dewar store and the freezing room, to take into account the requirement for ventiliation and for two persons to be present while such work progresses.	31st October 2007
The following conditions apply:	

(c) The applicant does not yet meet the requirements for **laboratory and clinical practices** for the following reasons

1) The centre plan that the recovery room will be staffed by one nurse to the six beds therein. This nurse will also ferry sperm samples from the men's production rooms to the andrology laboratories. The inspectorate question whether this will allow adequate monitoring of recovering patients.
2) An air monitoring protocol for the laboratories and treatment room needs to be developed
3) Several activities needed to be risk assessed due to the layout of the new premises:
 a) Transfer of frozen samples from the freezing laboratory to the sperm dewar store room, necessitating passage through doors and across a corridor with a transfer dewar.
 b) Working with liquid nitrogen in the dewar storage and the freezing room, to take into account the requirement for ventilation and for two persons to be present at all times while such work progresses.

Next Action

I will verify that the centre have acted on the action points defined above after the appropriate time periods.

Summary of findings for Licence Committee
(If final visit before Application considered by LC)

This report is for centre 0049 and for filing in centre records at HFEA. The new premises are within the curtellage and therefore this report does not need to be presented to Licence Committee.

Appendix A: The inspection team and staff interviewed

The inspection team

Andy Leonard	Chair, Inspector, HFEA
Tony Knox	Inspector, HFEA
	Inspector HFEA

Report compiled by_____ Andy Leonard _____

Signed_____

Designation_____Inspector, HFEA_____

Date_____28/9/07_____

RESPONSE OF PERSON RESPONSIBLE TO THE SITE VISIT

Centre Number……..….

Name of PR……..…....

Date of Inspection…….…....

Date of Response……..….....

Please state any actions you have taken or are planning to take following the inspection with time scales

I have read the inspection report and agree to meet the requirements of the report.

Signed……..…

Name……..….

Date…….....

2. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

We also welcome comments about the inspection on the inspection feedback form, a copy of which should have been handed out at the inspection. If you require a copy of the feedback form, please let us know.

Please return this section of the report to:
Dr Stephanie Sullivan
Head of Inspection, HFEA
21 Bloomsbury Street
London
WC1B 3HF