

We are the regulator: Our job is to check whether hospitals, care homes and care services are meeting essential standards.

Synexus Thames Valley Clinical Research Centre

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We followed up on our inspection of 17 March 2014 to check that action had been taken to meet the following standard(s). We have not revisited Synexus Thames Valley Clinical Research Centre as part of this review because Synexus Thames Valley Clinical Research Centre were able to demonstrate that they were meeting the standards without the need for a visit. This is what we found:

Requirements relating to workers

✓ Met this standard

Details about this location

Registered Provider	Synexus Limited
Registered Manager	Mrs Angela Harnick
Overview of the service	Synexus Thames Valley Clinical Research Centre recruits individuals to take part in clinical trials, run at it's own dedicated research centre. A DEXA (Dual Energy X-ray Absorptiometry) scanning service is offered at this centre to people either before and during clinical trials, or following a direct GP referral.
Type of service	Diagnostic and/or screening service
Regulated activity	Diagnostic and screening procedures

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Summary of this follow up review

Why we carried out this review

We carried out an inspection on 17 March 2014 and published a report setting out our judgements. We asked the provider to send us a report of the changes they would make to comply with the standards they were not meeting.

We have followed up to make sure that the necessary changes have been made and found the provider is now meeting the standard(s) included within this report. This report should be read in conjunction with the full inspection report.

We have not revisited Synexus Thames Valley Clinical Research Centre as part of this review because Synexus Thames Valley Clinical Research Centre were able to demonstrate that they were meeting the standards without the need for a visit.

How we carried out this review

We reviewed information given to us by the provider.

Spoke with staff from Human Resources

We have not revisited Synexus Thames Valley Clinical Research Centre as part of this review.

What we found about the standards we followed up

We had previously inspected this service on 17 March 2014. The provider has now provided evidence to demonstrate that recruitment processes have improved and people were now cared for, or supported by, suitably qualified, skilled and experienced staff.

You can see our judgements on the front page of this report.

More information about the provider

Please see our website www.cqc.org.uk for more information, including our most recent judgements against the essential standards. You can contact us using the telephone number on the back of the report if you have additional questions.

There is a glossary at the back of this report which has definitions for words and phrases we use in the report.

Our judgements for each standard reviewed

Requirements relating to workers

✓ Met this standard

People should be cared for by staff who are properly qualified and able to do their job

Our judgement

The provider was meeting this standard.

The provider was meeting this standard.

People were cared for, or supported by, suitably qualified, skilled and experienced staff.

Reasons for our judgement

When we carried out our initial compliance inspection in March 2014, we had minor concerns relating to this standard. During that inspection, we found that all the required information checks were in place prior to the employment of staff with the exception of satisfactory evidence of conduct in previous employment concerned with the provision of services relating to health or social care employers. We carried out a desk based review inspection to check whether improvements had been made.

We spoke with the human resources (HR) business partner. They told us that since the previous inspection, all existing and new staff had undergone Disclosure and Barring Service (DBS) checks. The HR business partner confirmed that newly recruited staff did not commence employment until HR had completed the relevant checks.

We reviewed the recruitment records of newly appointed staff and the existing staff to corroborate this information. This showed that the following pre-employment checks were carried out: proof of identity, recent photographs, Disclosure and Barring Service (DBS) criminal history checks and a full employment history. Other pre-employment checks included the right to work in the United Kingdom and confirmation of qualifications and experience and references from the previous employment. Checks had been completed to ensure that people were registered with their relevant professional body, such as the Nursing and Midwifery Council, Health Professions Council and General Medical Council. The HR business partner assured us they would carry out a risk assessment to determine if a person reported to have a prior conviction was suitable for employment at the research centre.

About CQC inspections

We are the regulator of health and social care in England.

All providers of regulated health and social care services have a legal responsibility to make sure they are meeting essential standards of quality and safety. These are the standards everyone should be able to expect when they receive care.

The essential standards are described in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009. We regulate against these standards, which we sometimes describe as "government standards".

We carry out unannounced inspections of all care homes, acute hospitals and domiciliary care services in England at least once a year to judge whether or not the essential standards are being met. We carry out inspections of other services less often. All of our inspections are unannounced unless there is a good reason to let the provider know we are coming.

There are 16 essential standards that relate most directly to the quality and safety of care and these are grouped into five key areas. When we inspect we could check all or part of any of the 16 standards at any time depending on the individual circumstances of the service. Because of this we often check different standards at different times.

When we inspect, we always visit and we do things like observe how people are cared for, and we talk to people who use the service, to their carers and to staff. We also review information we have gathered about the provider, check the service's records and check whether the right systems and processes are in place.

We focus on whether or not the provider is meeting the standards and we are guided by whether people are experiencing the outcomes they should be able to expect when the standards are being met. By outcomes we mean the impact care has on the health, safety and welfare of people who use the service, and the experience they have whilst receiving it.

Our inspectors judge if any action is required by the provider of the service to improve the standard of care being provided. Where providers are non-compliant with the regulations, we take enforcement action against them. If we require a service to take action, or if we take enforcement action, we re-inspect it before its next routine inspection was due. This could mean we re-inspect a service several times in one year. We also might decide to re-inspect a service if new concerns emerge about it before the next routine inspection.

In between inspections we continually monitor information we have about providers. The information comes from the public, the provider, other organisations, and from care workers.

You can tell us about your experience of this provider on our website.

How we define our judgements

The following pages show our findings and regulatory judgement for each essential standard or part of the standard that we inspected. Our judgements are based on the ongoing review and analysis of the information gathered by CQC about this provider and the evidence collected during this inspection.

We reach one of the following judgements for each essential standard inspected.

 **Met this standard** This means that the standard was being met in that the provider was compliant with the regulation. If we find that standards were met, we take no regulatory action but we may make comments that may be useful to the provider and to the public about minor improvements that could be made.

 **Action needed** This means that the standard was not being met in that the provider was non-compliant with the regulation. We may have set a compliance action requiring the provider to produce a report setting out how and by when changes will be made to make sure they comply with the standard. We monitor the implementation of action plans in these reports and, if necessary, take further action. We may have identified a breach of a regulation which is more serious, and we will make sure action is taken. We will report on this when it is complete.

 **Enforcement action taken** If the breach of the regulation was more serious, or there have been several or continual breaches, we have a range of actions we take using the criminal and/or civil procedures in the Health and Social Care Act 2008 and relevant regulations. These enforcement powers include issuing a warning notice; restricting or suspending the services a provider can offer, or the number of people it can care for; issuing fines and formal cautions; in extreme cases, cancelling a provider or managers registration or prosecuting a manager or provider. These enforcement powers are set out in law and mean that we can take swift, targeted action where services are failing people.

How we define our judgements (continued)

Where we find non-compliance with a regulation (or part of a regulation), we state which part of the regulation has been breached. Only where there is non compliance with one or more of Regulations 9-24 of the Regulated Activity Regulations, will our report include a judgement about the level of impact on people who use the service (and others, if appropriate to the regulation). This could be a minor, moderate or major impact.

Minor impact - people who use the service experienced poor care that had an impact on their health, safety or welfare or there was a risk of this happening. The impact was not significant and the matter could be managed or resolved quickly.

Moderate impact - people who use the service experienced poor care that had a significant effect on their health, safety or welfare or there was a risk of this happening. The matter may need to be resolved quickly.

Major impact - people who use the service experienced poor care that had a serious current or long term impact on their health, safety and welfare, or there was a risk of this happening. The matter needs to be resolved quickly

We decide the most appropriate action to take to ensure that the necessary changes are made. We always follow up to check whether action has been taken to meet the standards.

Glossary of terms we use in this report

Essential standard

The essential standards of quality and safety are described in our *Guidance about compliance: Essential standards of quality and safety*. They consist of a significant number of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009. These regulations describe the essential standards of quality and safety that people who use health and adult social care services have a right to expect. A full list of the standards can be found within the *Guidance about compliance*. The 16 essential standards are:

Respecting and involving people who use services - Outcome 1 (Regulation 17)

Consent to care and treatment - Outcome 2 (Regulation 18)

Care and welfare of people who use services - Outcome 4 (Regulation 9)

Meeting Nutritional Needs - Outcome 5 (Regulation 14)

Cooperating with other providers - Outcome 6 (Regulation 24)

Safeguarding people who use services from abuse - Outcome 7 (Regulation 11)

Cleanliness and infection control - Outcome 8 (Regulation 12)

Management of medicines - Outcome 9 (Regulation 13)

Safety and suitability of premises - Outcome 10 (Regulation 15)

Safety, availability and suitability of equipment - Outcome 11 (Regulation 16)

Requirements relating to workers - Outcome 12 (Regulation 21)

Staffing - Outcome 13 (Regulation 22)

Supporting Staff - Outcome 14 (Regulation 23)

Assessing and monitoring the quality of service provision - Outcome 16 (Regulation 10)

Complaints - Outcome 17 (Regulation 19)

Records - Outcome 21 (Regulation 20)

Regulated activity

These are prescribed activities related to care and treatment that require registration with CQC. These are set out in legislation, and reflect the services provided.

Glossary of terms we use in this report (continued)

(Registered) Provider

There are several legal terms relating to the providers of services. These include registered person, service provider and registered manager. The term 'provider' means anyone with a legal responsibility for ensuring that the requirements of the law are carried out. On our website we often refer to providers as a 'service'.

Regulations

We regulate against the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009.

Responsive inspection

This is carried out at any time in relation to identified concerns.

Routine inspection

This is planned and could occur at any time. We sometimes describe this as a scheduled inspection.

Themed inspection

This is targeted to look at specific standards, sectors or types of care.

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