Inspection Report

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

Sarah Cannon Research UK

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Tel: 02032195200

Date of Inspection: 01 May 2013

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We inspected the following standards as part of a routine inspection. This is what we found:

Consent to care and treatment	✓ Met this standard
Care and welfare of people who use services	✓ Met this standard
Cleanliness and infection control	✓ Met this standard
Assessing and monitoring the quality of service provision	✓ Met this standard
Complaints	✓ Met this standard

Details about this location

Registered Provider	Sarah Cannon Research UK Limited
Registered Manager	Mr. Rocky Lee Billups
Overview of the service	Sarah Cannon Research UK is the one registered location of the provider Sarah Cannon Research UK Limited. This location is a research facility conducting clinical studies of new cancer drugs for adults only. People attend this service with a referral from their own doctor or specialist and this includes NHS patients. The location is a suite of rooms, on several floors, in Harley Street in central London.
Type of service	Acute services without overnight beds / listed acute services with or without overnight beds
Regulated activity	Treatment of disease, disorder or injury

Contents

When you read this report, you may find it useful to read the sections towards the back called 'About CQC inspections' and 'How we define our judgements'.

Summary of this inspection

Why we carried out this inspection

This was a routine inspection to check that essential standards of quality and safety referred to on the front page were being met. We sometimes describe this as a scheduled inspection.

This was an unannounced inspection.

How we carried out this inspection

We looked at the personal care or treatment records of people who use the service, carried out a visit on 1 May 2013, talked with people who use the service and talked with carers and / or family members. We talked with staff and reviewed information given to us by the provider.

What people told us and what we found

We spoke with two people who were participating in clinical trials. They told us that they had received sufficient information to give their consent to the trial and understood about the limits of a clinical trial. One person said they were "extremely well looked after" and could find no "significant faults" with the whole process to date.

People were assessed and screened prior to commencing a trial and this included tests and consultation about suitability. They saw a doctor at every visit to the centre and their progress and response to the trial was monitored.

There were effective systems in place to reduce the risk of infection. The centre was clean and well maintained and staff had received infection control training.

People were made aware of how to complain about any aspect of the service, however there had been no complaints in the last 12 months. People said that they would tell staff if they had a concern and had always received prompt responses.

There were detailed systems for reviewing the quality and safety of each clinical trial and these included quality assurance reviews, audit and inspection by the trial sponsors.

In this report the name of a registered manager appears who was not in post and not managing the regulatory activities at this location at the time of the inspection. Their name appears because they were still a registered manager on our register at the time.

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 inspected

Consent to care and treatment ✓ Met this standard

Before people are given any examination, care, treatment or support, they should be asked if they agree to it

Our judgement

The provider was meeting this standard.

Before people received any treatment they were asked for their consent and the provider acted in accordance with their wishes.

Reasons for our judgement

Before people received any treatment they were asked for their consent and the provider acted in accordance with their wishes. We spoke with two people and reviewed their medical records. They had both received very detailed patient information about their clinical trial following consultation with one of the doctors. They had taken this away so that they had the opportunity to discuss and think about whether they wished to participate in a clinical trial. They had had continuing opportunities to ask more questions and seek more information whenever they wished.

The medical records contained the signed patient information sheet and consent forms. Staff told us that if the clinical trial protocols were changed then there would be a new consent process and people confirmed that this was what they had experienced. People also said that the information was presented in a way that they understood.

The information sheet detailed that people could drop out of the trial at any time and people were well aware of this. All the people recruited for the trials had capacity so that they were able to give informed consent.

The provider had undertaken an audit of consent for one of the clinical trials in March 2013. This involved 59 people all of whom had consented using the correct version of the consent form. One finding was that the informed consent process was "very well documented" in patient notes. In addition every clinical trial had strict protocols, agreed by an Ethics Committee, that were reviewed by the trial sponsors and these required informed consent as part of the trial process.

Care and welfare of people who use services ✓ Met this standard

People should get safe and appropriate care that meets their needs and supports their rights

Our judgement

The provider was meeting this standard.

People experienced care, treatment and support that met their needs and protected their rights.

Reasons for our judgement

People's needs were assessed and treatment was planned and delivered in line with their individual clinical trial plan. Ethical approval for clinical trials included the design and rationale of the trial, patient information, contracts and pre-clinical information about the drugs used. Each person was individually risk assessed for their suitability for each clinical trial. People continued to attend appointments with their original referring specialists and were seen by a doctor at every appointment at Sarah Cannon. We saw that updates were sent between the medical teams looking after people so that those involved had the most up to date information about people.

There were arrangements to deal with foreseeable medical emergencies and staff confirmed that all staff had had appropriate training in resuscitation. We saw the resuscitation equipment on each clinical floor of the centre. This was checked daily and the records were up to date. Each person was closely monitored during their appointment to ensure that there were no ill effects from the drugs used. In the event of a person becoming unwell there were transfer arrangements with a nearby hospital. The centre also had plans for other emergencies which would affect the running of the service and these included the use of nearby registered facilities.

People told us that they were very well looked after at the centre. One person said that they were "extremely well looked after". Another said that staff phoned with test results and they felt very involved with the treatment plans. Family members also told us that they were happy with the centre's care, responsiveness to questions and concern for their relative.

Cleanliness and infection control ✓ Met this standard

People should be cared for in a clean environment and protected from the risk of infection

Our judgement

The provider was meeting this standard.

People were protected from the risk of infection because appropriate guidance had been followed. People were cared for in a clean, hygienic environment.

Reasons for our judgement

People told us that the staff were careful to wash their hands prior to care and that the centre was clean. There were protocols for staff to follow if a person had an infection.

There were effective systems in place to reduce the risk and spread of infection. Infection control policies and procedures were available on the provider's intranet to guide staff. Expert infection control advice was available from specialists at the nearby Harley Street Clinic. Clinical staff confirmed that they had received infection control training.

The provider had contracts for the appropriate disposal of clinical waste and sharp items. We saw that clinical waste was stored and disposed of safely. Each clinical area had a cleaning schedule and practitioners were responsible for maintaining clean and hygienic surfaces and equipment. The centre was cleaned daily. We saw that the centre was clean and well maintained on the day of our visit.

All instruments used in the centre were single use and were not reused so that no decontamination of instruments was required. We saw that staff wore appropriate protective items, such as gloves and aprons, when needed. There were hand washing facilities in each clinical area.

Assessing and monitoring the quality of service provision ✓ Met this standard

The service should have quality checking systems to manage risks and assure the health, welfare and safety of people who receive care

Our judgement

The provider was meeting this standard.

The provider had an effective system to regularly assess and monitor the quality of service that people receive. The provider had an effective system in place to identify, assess and manage risks to the health, safety and welfare of people who use the service and others.

Reasons for our judgement

People who use the service were asked for their views about their care and treatment and these were acted on. We saw that people could give comments on a daily basis when they attended this location as well as in a formal annual survey of all the people who have used the service. This feedback was monitored and reviewed at the Integrated Governance Committee which met monthly and reported to the Medical Advisory Committee.

The Integrated Governance Committee was the means by which the service monitored incidents, complaints and risk as well as people's satisfaction. Decisions about care and treatment were made by the appropriate staff at the appropriate level in consultation with people who were participating in the clinical trials.

Sarah Cannon Research UK was also monitored by the sponsors of the clinical trials so that the trials were conducted to the protocols that had been agreed. Drugs used in the trials were approved for use by the Medicines and Healthcare Regulatory Agency (MHRA). We saw that there was an internal quality assurance process for each clinical trial that included audits of consent and adherence to the trial protocols.

In addition Sarah Cannon was accredited by CHKS (Comparative Health Knowledge System) who reviewed the service's compliance against oncology care standards in the autumn of 2012. This combined data analysis with site assessment to benchmark care standards against national quality standards and identify areas of good practice and opportunities for improvement.

Complaints ✓ Met this standard

People should have their complaints listened to and acted on properly

Our judgement

The provider was meeting this standard.

There was an effective complaints system available. Comments people made were responded to appropriately.

Reasons for our judgement

People were made aware of the complaints system in the patient information they received. They told us they were able to discuss any concerns whenever they attended the centre and had their comments listened to and answered promptly. There was a comment card which people were encouraged to use, "how did we do today", and the comments were collated into a report by the governance lead.

The provider kept a log of complaints but we were told that there had been no complaints in the last 12 months. Any complaints would be reviewed by the management team and the provider's integrated governance system.

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.

Contact us

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