healthcare.

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Your quarterly news update from Sintons
NHS Trust pays the price for failing to comply with a patient’s living will

An out of court settlement of £45,000 was recently agreed in a claim for damages brought against The George Eliot Hospital NHS Trust arising from a failure to comply with a patient’s advance decision (commonly known as a ‘living will’).

The claim was brought by the family of Brenda Grant, an 81 year old woman who was admitted to George Eliot Hospital in Nuneaton in 2012 following a catastrophic stroke. Prior to the stroke, Mrs Grant had drawn up an advance decision refusing life sustaining treatment in the specific circumstance she should lose capacity in the future to make decisions about her medical treatment. It was said that she feared degradation and indignity more than death, having seen her own mother lose independence through dementia. Unfortunately Mrs Grant did not notify her family about the existence of her advance decision, although her GP was aware and her local hospital, George Eliot, had been supplied with a copy.

Following the stroke in 2012 which left her unable to walk, talk or swallow, Mrs Grant was admitted to George Eliot Hospital. Although a copy of her advance decision was contained within her hospital records, over the subsequent months it was misplaced and was consequently overlooked by treating healthcare professionals. After three months in hospital, Mrs Grant was fitted with a PEG to enable her to be fed directly into her stomach, before being discharged to a nursing home. Family members were unaware of the existence of the advance decision until they were alerted by Mrs Grant’s GP shortly before her readmission to hospital. The family then requested that the hospital respect Mrs Grant’s advance decision and withdraw life sustaining treatment. By this time, Mrs Grant had been kept alive by artificial nutrition and hydration for nearly two years in direct contravention of the wishes set out in her advance decision. The hospital agreed to the family’s request and treatment was withdrawn. Mrs Grant died on 4 August 2014. This is thought to be the first case in which a claim for negligence has been brought against a Trust for failing to follow an advance decision. The case highlights the importance of NHS Trusts and other health and social care providers having robust record keeping systems in place to ensure that advance decisions are properly documented in patient records in a manner which is readily visible to treating health professionals.

Following Mrs Grant’s death, George Eliot Hospital introduced a new system whereby the existence of an advance decision is now documented on the front page of patient notes. This case also highlights the importance of a person who has made an advance decision bringing it to the attention of family members. Had Mrs Grant’s family been aware of her advance decision they could have ensured that the hospital acted in accordance with her wishes from the outset.
The importance of An IP strategy when developing diagnostic tests and devices for patient benefit

Sintons LLP were delighted to have sponsored the Diagnostics North East Conference 2018 in March this year. Members of our healthcare team also attended the two day conference at the Centre for Life in Newcastle Upon Tyne.

There were some excellent and thought provoking presentations about the innovative work going on in this sector which is offering great benefit to patients.

One of the consistent themes running through the conference was the importance of Intellectual Property (IP) management when developing such diagnostic tests and devices in order to maximise opportunities for industry, academia and the NHS.

Protection of any IP created needs to be seen as an integral part of any new development or testing from the outset.

There are some practical steps that researchers and developers can take to ensure their IP is protected for potential future commercialisation:

**CONFIDENTIALITY**
Checking that all members of staff and third party consultants or contractors have appropriate contractual confidentiality obligations in place, which cover the scope of the development project being undertaken and ensuring that such staff and third parties are aware of their obligations.

Asking everyone working on the project (including any new starters) to sign a short form confidentiality undertaking can help reinforce the message about protecting the confidential nature of the work.

**OWNERSHIP**
It is vital that the ownership of any IP created as part of the development is clear and that you have the right to use all IP created. Joint ownership of IP can be problematic where the development involves the collaboration of a number of parties.

It is usually more beneficial for future exploitation for all the IP created to have a single owner but this will depend on the nature of the collaboration.

**IDENTIFY ANY POTENTIAL IP RIGHTS THAT MAY APPLY**
When developing a particular device, there may be more than one IP right that applies to different elements of the device, so it is important to have an overarching view of the potential IP rights that could apply.

**IDENTITY**
Certain materials created during the development (such as design drawings and specifications) may have copyright protection depending on the author. As copyright arises automatically, it is important that there is an appropriate record kept of all such work created so that the author of the work and the date created is clear. This is a good discipline to maintain from the start of any development project.

**DESIGN RIGHTS**
Design rights apply to the shape and configuration of a device and can apply to purely functional products. As with copyright, it is important to ensure that you have a record of who created the design and when it was created.

You may also like to consider registering any novel designs at the Intellectual Property Office.

**PATENTS**
If the development leads to an invention, patent protection may be possible although it is worth noting that a method of medical treatment or diagnosis is not patentable.

Applying for patent protection can be difficult to obtain and is costly but it is vital to protect future commercialisation so it can be worth the upfront investment.

**TRADEMARKS**
If the project is successful, the development of a distinctive trademark for the marketing of the device may be required. Registration of any trademark is necessary in order to ensure protection.

If you are involved in a new diagnostic development project, we would recommend obtaining some initial IP advice at the outset.

Having an IP strategy in place from the start and reviewing it at regular intervals will greatly assist you in ensuring that any IP is appropriately protected if the project is ultimately successful.
GDPR

When is a public authority not a public authority?

Ready or not, the General Data Protection Regulation (2016/679) (the “Regulation”) is here after many months of publicity, analysis and some scare mongering about what will happen post 25 May 2018.

It will be interesting to see how things develop in the next few months and what comes to be considered “market” and best practice when demonstrating compliance with the legislation.

Under Article 6(6) of the Regulation, one of the lawful bases for processing personal data is where processing is necessary for the purposes of legitimate interests pursued by the data controller or a third party (“Legitimate Interests”).

These Legitimate Interests need to be weighed against the interests or fundamental rights and freedoms of the data subject and such fundamental rights and freedoms can override the Legitimate Interests of the data controller or third party so a controller may not always be able to rely on Legitimate Interests as the basis for processing.

Legitimate Interests cannot be claimed for processing carried out by a public authority in the performance of their tasks. The idea being that there is a specific lawful basis for such processing under Article 6(e) of the Regulation where the processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller (“Public Interest/Official Authority”).

This has led many to believe that there is a blanket prohibition on public authorities relying on Legitimate Interests for the purposes of processing personal data. However, the wording of Article 6 requires further consideration in light of the Data Protection Act 2018 (the “Act”).

The Act supplements the Regulation and provides that for the purposes of the Regulation, a public authority as defined by the Freedom of Information Act 2000 is a “public authority” for the purposes of GDPR. NHS trusts, NHS Foundation Trusts and certain other NHS bodies will be well aware of their status as public authorities from a Freedom of Information point of view. They are therefore considered to be a public authority from a GDPR point of view also. However, section 7(2) of the Act provides that a public authority is only a public authority when performing a task carried out in the public interest or in the exercise of official authority vested in it.

Section 8 of the Act further provides that for the purposes of Article 6(e) of the Regulation (Public Interest/Official Authority), the performance of a task in the public interest or in the exercise of official authority vested in the controller essentially means the exercise of any statutory function.

So when is a public authority not a public authority? When it is not performing a statutory function.

There are many activities that NHS trusts, NHSFTs and other NHS bodies undertake in addition to their statutory functions.

In such circumstances, they may not be able to rely on Article 6(e) (Public Interest/Official Authority) as the basis for processing personal data.

They will need to consider another basis for processing such personal data, which can include Legitimate Interests.

Whether or not a public authority can rely on Article 6(e) (Public Interest/Official Authority) for processing personal data will require an analysis of the statutory functions of the relevant public authority in each case as the statutory functions of NHS Trusts, NHS Foundation Trusts and other NHS bodies are all different.

NHS bodies need to be mindful of this when considering the lawful basis for processing personal data.

If you require any further information or advice on GDPR, please contact the GDPR team.

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Dilapidations
Prepare Your Exit Plan

What is the issue?
On a basic level, dilapidations are items of disrepair that are caused by the tenant's repairing covenants in a lease.

What are dilapidations?
Dilapidations are relevant throughout the term of a lease. They will be brought into sharp focus when the lease ends and the end of the term will often act as a trigger for the parties to consider dilapidations issues.

Generally, a tenant's failure to comply with its repairing covenants entitles the landlord to claim damages.

This will be subject to some statutory restrictions.

The starting point for a measure of damages payable to a landlord for dilapidations following the end of a lease term will be the reasonable cost of doing the works plus loss of rent for the period until the works have been completed, where appropriate.

TENANT'S CONSIDERATIONS
Prior to the end of a lease, whether due to expiry of the contractual term, exercise of a break or surrender, it is imperative that a tenant considers its position in relation to any possible dilapidations at the property.

The tenant should review the terms of its lease, any licences to alter, deeds of variation and schedules of condition to double check its obligations to repair, decorate, reinstate and yield up and take advice as to the extent of those obligations if necessary.

Once the extent of those obligations have been established, the tenant will need to consider whether any works are required in order to ensure compliance at the end of the term. If works are required and the tenant wishes to carry out those works, it will want to ensure that it has sufficient time within which to do so.

The tenant will have no rights of access to the property following the end of the term and it would need to agree separate or additional arrangements with the landlord for access, for instance by entering into an additional licence or tenancy at will, which could come with a cost.

Any break option available to the tenant may be conditional on the tenant having complied with its covenants. Dilapidations may mean that it is unable to comply with those conditions and therefore unable to exercise the break option.

PRACTICAL STEPS TO BE PREPARED
Well in advance of the expiry date (or indeed the date for service of a break notice), the tenant should consider each of the following factors:

1. **Instruct a surveyor** - it is advisable for the tenant to instruct a surveyor for advice on the works needed in order to comply with the terms of its lease.

   If a schedule of dilapidations is served by the landlord in respect of the premises, the tenant should always obtain advice from its surveyor on the contents of the schedule.

2. **Does the tenant wish to carry out the works** - fundamentally, the tenant will need to decide whether it wishes to carry out any required works itself.

   It is important that the tenant obtains legal advice before moving ahead with any works as this could affect the tenant's position in respect of any damages due to the landlord.

   It may wish to yield up the premises in breach of the repair and yield up covenants in the lease and to deal with the landlord's claim for dilapidations afterwards.

   One major influencing factor here is that carrying out the works itself will give the tenant significant control over the level of expenditure incurred.

3. **Establish the landlord's plans** - what are the landlord's plans for the premises?

   The landlord's plans for the premises will affect the value of the landlord's claim in respect of the tenant's liability for dilapidations.

   If the landlord plans to demolish the premises, or where structural alterations are to be carried out at the end of or shortly after the end of the term to the extent that any repairs would be rendered valueless, generally no damages will be available to the landlord.

   This will only relate to a breach of the tenant's obligation to repair.

   It will be a question of fact and the burden of proof in relation to the landlord's intention will be on the tenant.

   This is not easy to establish and a tenant will almost certainly need to take specific legal advice if it wishes to rely upon this principle.

   It is important to note that if the landlord only plans to do the work because of the dilapidated state of the premises, then damages may still be recoverable.

4. **Valuation advice** - the tenant should take expert valuation advice on the effect of the disrepair on the value of the landlord's reversionary interest as it may be less than the cost of doing the works, depending on the market and the landlord's plans for the premises.

5. **Schedule of condition** - the tenant should take a schedule evidencing the state of repair of the premises on the date that it yields up. This is probably best done by way of a photographic schedule of condition.

Take advice early
Dilapidations are a complex area and are only summarised here. Establishing a tenant's exact liability is not straightforward and there are a number of legal considerations to take into account when assessing liability.

A tenant should always take advice from its solicitor and surveyor in plenty of time before the end of the term.

Where a tenant is intending to exercise a break option, it should ensure that such advice is obtained well ahead of the date for service of the break notice (particularly where works may be required).
What is an advance decision?

• The legal concept of an advance decision (often referred to as a living will) was introduced by the Mental Capacity Act 2005.
• It is an advance statement of instructions by a capacitated adult about what medical treatment they do not want to receive in the future, in the event of them losing capacity to make such decisions.
• It only takes effect when the person who made it has lost capacity to consent to or refuse the specified medical treatment.
• It can be verbal or in writing although an advance decision to refuse life-sustaining treatment must be in writing, signed and witnessed and must clearly state that the decision is to apply even if life is at risk.
• A valid and applicable advance decision to refuse treatment has the same legal status as a decision to refuse treatment made by a person with capacity at the time of that treatment. It is legally binding and must be respected.
• Healthcare professionals must follow an advance decision if they are satisfied that it is valid and is applicable to the patient’s circumstances. Failure to follow an advance decision in this situation could lead to a civil claim for damages for battery or a criminal charge of assault.
• Healthcare professionals will be protected from liability if, prior to treating the patient, they take all practical and appropriate steps to find out if the person has made an advance decision, and either do not know or are not satisfied that a valid and applicable advance decision exists.
• Emergency treatment must not be delayed in order to search for an advance decision where there is no clear indication that one exists. Where it is clear that a patient has made an advance decision that is likely to be relevant, healthcare professionals should assess its validity and applicability as soon as possible although sometimes the urgency of treatment decisions will make this difficult.
• Where there is genuine doubt or disagreement about the existence, validity or applicability of an advance decision the Court or Protection has the power to decide.