



HOW ACHIEVER MEDICAL HELPS YOU COMPLY WITH THE HUMAN TISSUE ACT (HTA)

Introduction

If you are based in the UK and store or handle human tissue you must comply with the regulations of the Human Tissue Act (HTA). If you work with such tissues you must have a licence. Compliance with the act has been a legal requirement in the UK since 2005. The Act covers England, Wales and Northern Ireland. There's also an equivalent act in Scotland, which has similar requirements. The Act is regulated by the Human Tissue Authority, which carries out periodic audits to assess your compliance under your licence.

Complying with the HTA means that both your institute, and you personally, have a legal duty to track the physical location of all human tissue. It can be challenging to manage this without it impacting on your day job. Especially if you don't have software systems in place to help you.

For more than 15 years our sample management system, Achiever Medical, has been helping labs and Biobanks successfully comply with the Human Tissue Act (HTA) while improving their lab and sample processes. During that time, we have also introduced new features to make sure you have the tools you need as the legislation evolves. Plus, we have had first-hand experience of attending audits alongside our customers to make sure our software continues to meet your requirements. Achiever Medical's standard, in-built functionality enables you to:

- Know where your samples are right now
- Know where your samples have been and what has been done to them
- Understand your samples' informed consent and how you can use them
- Track each sample's chain of custody
- Manage your Standard Operating Procedures (SOPs)
- Carry out your own internal, proactive audits
- Analyse the quality of your lab and sample processes



Leeds Teaching Hospitals Trust passed our HTA inspections in 2013 and 2017 and it was commented in the final report that the Achiever Medical system enables good practice for tissue tracking. Removing manual audit tasks and the automation of repetitive data entry in Achiever Medical has created time for both clinicians and laboratory workers. This allows for more research and less concern about legislative compliance.

- Chris Chambers, IT Systems Officer, Leeds Teaching Hospitals Trust

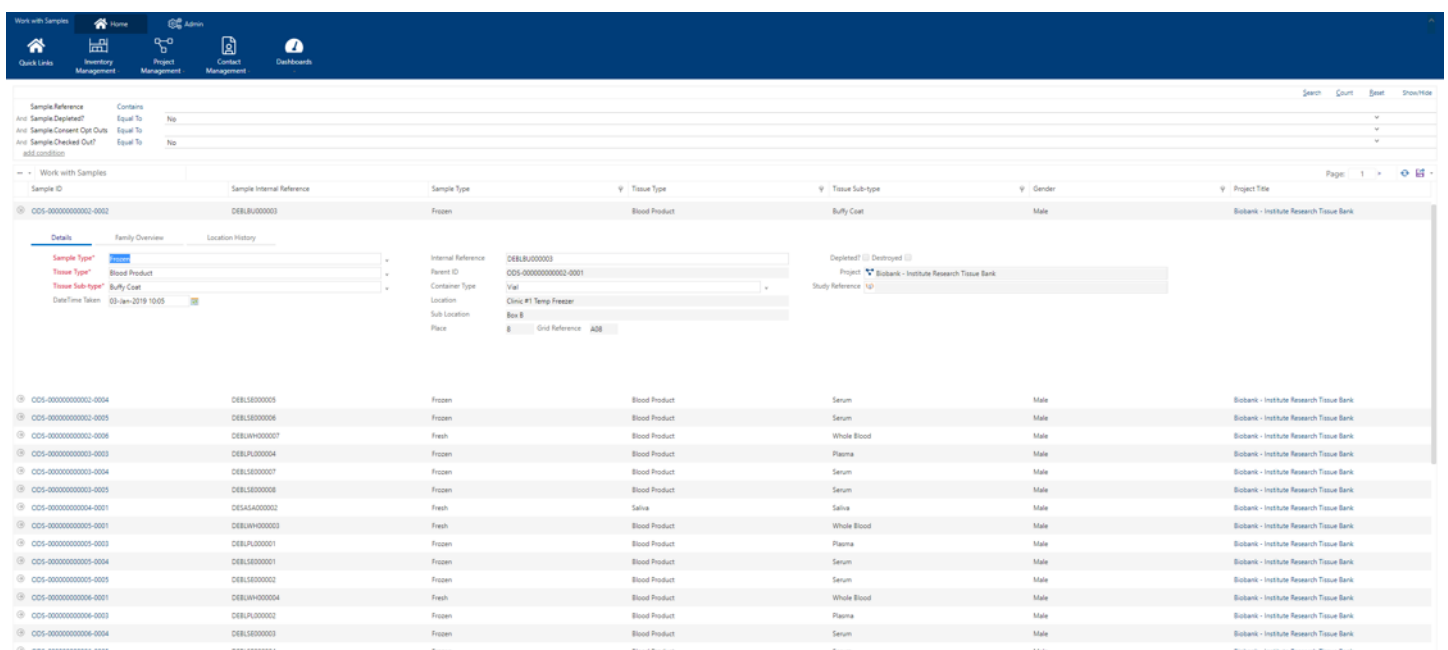
Know where your tissue samples are right now

You may be storing or working with thousands – possibly millions - of biological samples. Knowing where every one of them is, at any time, is impossible without a computerised system. However, your most immediate challenge is knowing where a given sample is right now.

Many labs still use spreadsheets to maintain manually a list of samples and their current location. However, if you are using several spreadsheets and your data is not captured consistently, finding a sample can be like trying to find a needle in a haystack. Achiever Medical's extensive searching facilities allow you to quickly find your sample using different data values and by scanning barcodes.

Plus, using spreadsheets comes with a very high risk of human error when you start updating your records. Just think about moving a 96-well plate between shelves in a freezer. That's 96 manual updates to your list. The more samples you move at a time, the less likely you'll record the changes correctly, and consistently.

This is where Achiever Medical also helps. If you want to move a set of samples, you just select the ones you're moving and the new location. The system updates them all in a single step – and with the same information. You might be checking them out of storage, moving them into storage or even moving them around within storage. That might be one, 96 or any number. Using Achiever Medical it's simple, quick and, importantly, consistent.



Sample ID	Sample Internal Reference	Sample Type	Tissue Type	Tissue Sub-type	Gender	Project Title
005-0000000000-0002	DEBLJ000003	Frozen	Blood Product	Buffy Coat	Male	Biobank - Institute Research Tissue Bank
005-0000000000-0004	DEBLJ000005	Frozen	Blood Product	Serum	Male	Biobank - Institute Research Tissue Bank
005-0000000000-0005	DEBLJ000006	Frozen	Blood Product	Serum	Male	Biobank - Institute Research Tissue Bank
005-0000000000-0006	DEBLJ000007	Fresh	Blood Product	Whole Blood	Male	Biobank - Institute Research Tissue Bank
005-0000000000-0003	DEBLJ000004	Frozen	Blood Product	Plasma	Male	Biobank - Institute Research Tissue Bank
005-0000000000-0004	DEBLJ000007	Frozen	Blood Product	Serum	Male	Biobank - Institute Research Tissue Bank
005-0000000000-0005	DEBLJ000008	Frozen	Blood Product	Serum	Male	Biobank - Institute Research Tissue Bank
005-0000000000-0001	DEBLJ000002	Fresh	Saliva	Saliva	Male	Biobank - Institute Research Tissue Bank
005-0000000000-0001	DEBLJ000003	Fresh	Blood Product	Whole Blood	Male	Biobank - Institute Research Tissue Bank
005-0000000000-0003	DEBLJ000001	Frozen	Blood Product	Plasma	Male	Biobank - Institute Research Tissue Bank
005-0000000000-0005	DEBLJ000001	Frozen	Blood Product	Serum	Male	Biobank - Institute Research Tissue Bank
005-0000000000-0005	DEBLJ000002	Frozen	Blood Product	Serum	Male	Biobank - Institute Research Tissue Bank
005-0000000000-0001	DEBLJ000004	Fresh	Blood Product	Whole Blood	Male	Biobank - Institute Research Tissue Bank
005-0000000000-0003	DEBLJ000002	Frozen	Blood Product	Plasma	Male	Biobank - Institute Research Tissue Bank
005-0000000000-0004	DEBLJ000003	Frozen	Blood Product	Serum	Male	Biobank - Institute Research Tissue Bank
005-0000000000-0005	DEBLJ000003	Frozen	Blood Product	Serum	Male	Biobank - Institute Research Tissue Bank
005-0000000000-0001	DEBLJ000004	Fresh	Blood Product	Whole Blood	Male	Biobank - Institute Research Tissue Bank

Sample search with storage location details displayed



Know where your samples have been and what has been done to them

To be HTA compliant you don't just need to know where a sample is right now but also where it has been since it was donated. That's much more of a headache if your system doesn't log that data automatically. Achiever Medical does this as standard.

Automated auditing of location history

Every sample has its own storage location history and whenever you move the sample this history is updated automatically. You might move a sample on its own or in a group. You might want to move an entire box or rack of samples. Whatever you need to do, the location history of your samples is automatically updated in the background – so that's one less thing for you to think about.

Also, when you move an entire storage sub location, either temporarily or permanently, you have the comfort of knowing the location history is being automatically maintained – and is consistent. In fact, all processes, such as dispatching a set of samples or checking samples out for colleagues in a different department automatically maintain the location history.

The result is a comprehensive location history audit of where your sample has been since donation. That's not just great evidence to show an HTA auditor but it's a goldmine for evidencing the viability of samples for research.

Aliquots and derivatives inherit their parent sample's history on creation

Achiever Medical's location history audit is so comprehensive it's also updated whenever a sample is split, depleted, destroyed, and when consent is withdrawn.

When a sample is split into child aliquots or derivatives, each of those newly created samples share the same location history prior to the split. Achiever Medical automatically clones the location history of the parent onto each of the child aliquots as well as recording details of the split. The result is a comprehensive timeline for each individual aliquot and best of all, it all happens without any extra effort from you.

Check outs with reservations

In addition, Achiever Medical allows you to check out a sample from a position in storage and automatically reserve that spot. This means that when you return the sample it is returned into its same position. Achiever Medical automatically locates the sample reservation, updates the sample's location history and quietly removes the reservation, all in a single step.

Audit your high risk processes

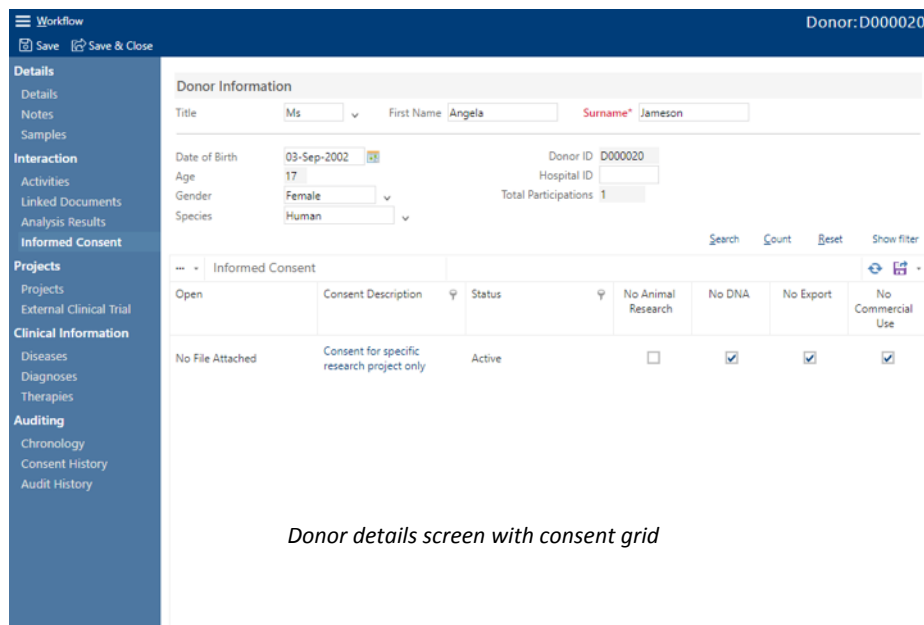
For some of your lab processes, such as emergency freezer moves and consent withdrawal, accurately capturing the sample's location history is critical. These processes may also carry a high risk of human error. Achiever Medical helps you manage these processes and minimise these risks.

The alarm warning of a freezer going out of temperature is a dread known across the industry. Inevitably it will be 3am and you'll be the team member who's on call. When you get into the lab you need to pull racks of samples and move them rapidly into your backup freezer. You really don't want to spend ages updating the location history on 80,000 samples, especially when you know that once Maintenance have fixed the freezer, they will all be going right back again. Achiever Medical allows you to multi-select the boxes you need to move and simply move them temporarily to the backup freezer. The system does all the hard work of auditing 80,000 samples for you and remembers where every one of them was moved from. Once the freezer has been brought back to temperature you can return the boxes to their previous location. Achiever Medical then quietly audits all 80,000 samples and puts each of them right back where they came from.

Understand your samples' informed consent and how you can use them

Your HTA licence requires that you record informed consent and process samples in compliance with it. However, tracking the signed paperwork for every donor can be difficult especially when donors want to influence how their tissue samples are used in research.

Achiever Medical enables you to capture informed consent information against your donors whether that's in the system itself, pointing to a URL or entering the physical location.



The screenshot shows the 'Donor details screen with consent grid' in the Achiever Medical system. The interface is divided into a left sidebar with navigation links and a main content area for donor information and consent management.

Donor Information:

- Title: Ms
- First Name: Angela
- Surname: Jameson
- Date of Birth: 03-Sep-2002
- Age: 17
- Gender: Female
- Species: Human
- Donor ID: D000020
- Hospital ID: [Empty]
- Total Participations: 1

Informed Consent Grid:

Open	Consent Description	Status	No Animal Research	No DNA	No Export	No Commercial Use
No File Attached	Consent for specific research project only	Active	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

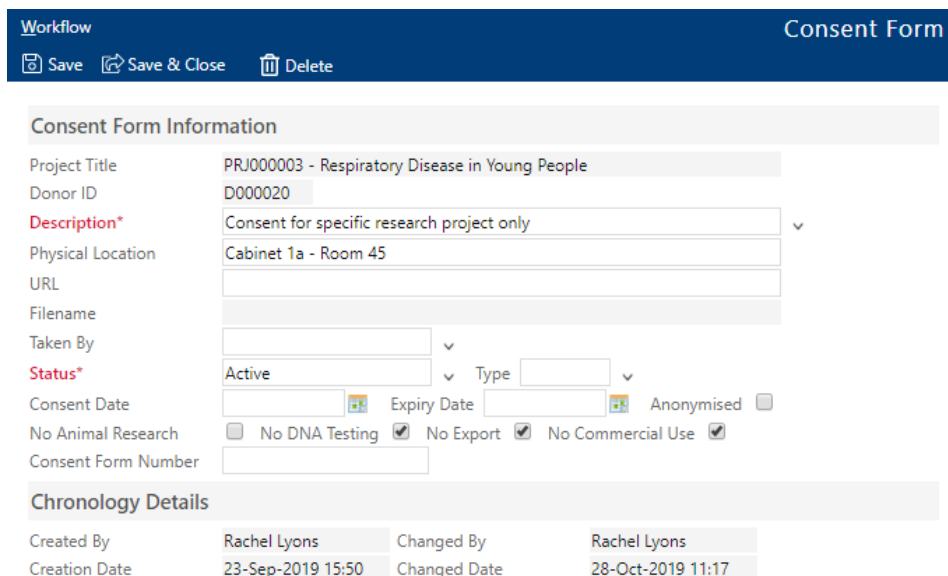
Donor details screen with consent grid

Scan your consent forms and store them electronically in the database

Achiever Medical allows you to scan consent and save it in the database alongside the tissue samples that are processed in accordance with it. The system automatically protects the identity of the donor from users who don't need that knowledge.

Record donor preferences

You can record donor preferences as opt-outs specified on the consent form. Such preferences are visible anonymously with a single click from any sample against that donor. This makes it easy when looking to build a cohort of samples for research.



Workflow **Consent Form**

Save Save & Close Delete

Consent Form Information

Project Title PRJ000003 - Respiratory Disease in Young People

Donor ID D000020

Description* Consent for specific research project only

Physical Location Cabinet 1a - Room 45

URL

Filename

Taken By

Status* Active Type

Consent Date Expiry Date Anonymised

No Animal Research No DNA Testing No Export No Commercial Use

Consent Form Number

Chronology Details

Created By Rachel Lyons Changed By Rachel Lyons

Creation Date 23-Sep-2019 15:50 Changed Date 28-Oct-2019 11:17

Donor consent screen with opt outs

Manage the withdrawal of consent process

When informed consent is withdrawn Achiever Medical automatically produces a list of all existent samples from that donor and shows you exactly where each of them is stored. You don't need to track them down before processing them according to your Standard Operating Procedures (SOPs). They'll even be displayed if they've been checked out to an external institute or included in a composite sample such as a Tissue Micro-Array.



Since using Achiever Medical we are more compliant with different legislation and our quality control processes have improved significantly.

- Biobank Manager at a leading UK University

Track each sample's chain of custody

The HTA mandates that you record a chain of custody for each sample. At any time, you need to be able to show not just where a sample is but also who is legally responsible for it. Achiever Medical tracks the transfer of custody and records it in each sample's location history audit.

Manage tissue transfers between departments

A transfer of samples to someone in another department can be easily logged as a dispatch. The process is so quick that some Achiever Medical customers use it even if the samples are moving into the next room. This means that all tracking "paperwork" is electronic and that an SOP for internal and external transfers can be as similar and simple as possible.

Send your samples out to external institutes

Transferring your tissue samples to external institutes requires more information, but in Achiever Medical the process is basically the same as transferring between departments. You may want to record further details such as the courier used, consignment numbers, QC checks about the paperwork and the shipping protocol.

You may also want to record who acknowledged receipt once it reaches the addressee. If the recipient has their own HTA licence, your legal responsibility stops there. It only starts up again if those samples are returned and, of course, Achiever Medical can set up reminders for when the sample is due for return.

Manage your current SOPs

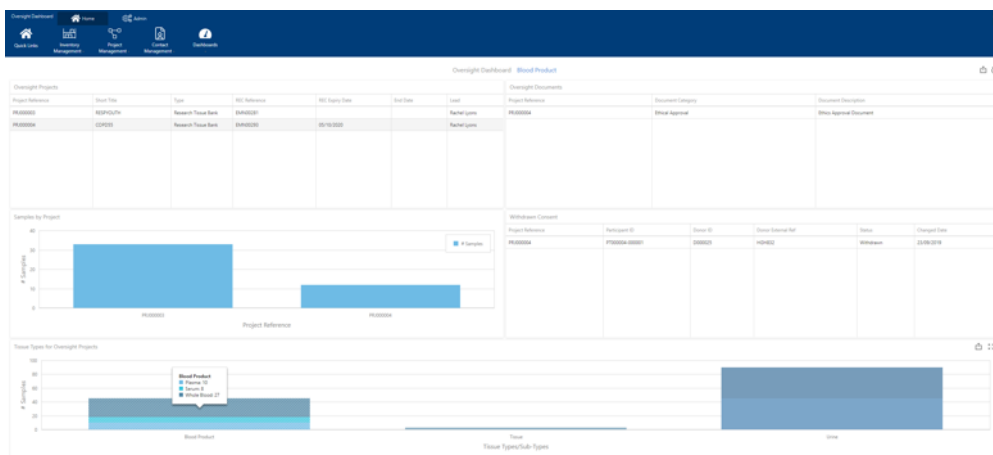
Standard Operating Procedures underpin all your HTA-related work, and you may have these detailed in several different documents and diagrams. Trying to dig all these out, especially when an HTA auditor wants to inspect them and quiz your team on its compliance, can be tricky. It's easiest to store your current SOPs in the system to which they relate, alongside the samples. Achiever Medical allows you to do just that and keep the back-catalogue of prior versions and the dates that they were operable. That way, when an HTA auditor asks one of your staff "Where is your current SOP" they can point at the computer and confidently say "in Achiever Medical, alongside the project to which it relates".

Carry out your own proactive, internal audits

Familiarity breeds confidence and Achiever Medical's proactive auditing features allow you to schedule your own internal audits. Carrying these out periodically means that they become part of your team's every day processes and no longer seen as something to fear. In addition, you also build a body of compliance evidence that gives confidence to management and auditors. Plus, you are instilling quality and efficiency in your processing by spotting and fixing issues before they become costly.

Analyse the quality of your lab and tissue sample processes

For you to effectively manage your HTA compliance you need to have oversight of your samples, storage, consent and processes. Achiever Medical includes several real-time, interactive dashboards so you can see at a glance what samples you have, where they all are, how your processes are running and what issues are being raised/fixed. This helps you to comply easily with the Human Tissue Act while still focusing on your day-to-day operations.



Oversight officer interactive dashboard

ABOUT INTERACTIVE SOFTWARE

At Interactive Software, we have over 25 years' experience in helping transform lab processes and provide greater transparency and insight into data using our innovative Laboratory Sample Management Software, Achiever Medical.

Assisting you to comply with the Human Tissue Act (HTA) and improving your standard operating procedures are integral to our Achiever Medical implementations. We have experienced HTA audits first-hand; aiding our customers through the process and ensuring our Achiever Medical software continues to deliver functionality to support compliance.

Our experienced business analysts ensure that you gain maximum benefit from Achiever Medical's in-built processes to manage your standard operating procedures and meet your compliance and quality requirements. We work closely with you to identify any process gaps by delving into critical business objectives and goals to ensure any required changes deliver the required outcome.

For more advice on how we can help you with your compliance and accreditation goals, contact us:

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