

Tips for Human Tissue Authority Inspections

The Human Tissue Authority (HTA) have begun Inspecting licensed premises. If they intend to visit your Unit, they will inform you, and will provide you with a document detailing the proposed Inspection date, the objectives of the Inspection, the accommodation they will require, and how they intend to conduct the Inspection.

They will Inspect against the information you provided in the Compliance Report and any conditions imposed on your licence.

The Regulatory Support Centre, in conjunction with an MRC Unit that has been Inspected, have prepared this brief document to outline what Units should expect from an Inspection, and to provide you with some pointers as to how best to prepare yourself and your Unit.

- You should expect the Inspection team to be very thorough. The Inspection team will be composed of one or two HTA employees and a specialist assessor.
- Be open and honest, you have nothing to hide.
- The HTA will give you few weeks notice of an imminent Inspection. However, they may give you only few days to collate requested documentation and become fully 'Inspection ready'.
- Make sure that all the people the Inspectors wish to speak to are available and fully briefed. You should warn them that the Inspection time-table may be subject to last minute changes.
- It is likely that the Inspectors will want to talk to the DI, all Persons Designated, members of senior management and possibly some senior Investigators (they can ask to speak to absolutely anyone within the Unit).
- Ensure all the paperwork requested is available; if it is not possible to present all requested documents then tell the Inspectors. If possible, present all the requested documentation in a folder (or series of folders) to be made available to the team.
- If you have any additional documents which you feel would give the Inspectors a better feel for how you work, have these available also (e.g. minutes from relevant meetings, related policy documents).
- If you use the intranet / internet to disseminate information on tissue governance, ensure that this is available and can be easily accessed by the Inspection team. This includes access to MRC guidance and policies (on the MRC Corporate website) and to information on RCIAS (internal audit).
- Make sure that other relevant functions within your Unit are aware of the imminent Inspection and that they are able to provide you with copies of, for example, Health and Safety documentation, asset register information and equipment service records etc.
- Inspectors are likely to want to know how you manage all tissue samples within your Unit, including the systems you have in place to identify and trace non-human animal tissue or other material not covered under your licence.
- Other issues the Inspectors may be interested in are how you: monitor when research ethics committee approval has lapsed for specific samples, record the disposal of tissue and ensure that you comply with donors' wishes. As

- many of you are aware the RSC is currently working with Units to ensure appropriate IT infrastructure is in place to support adequate sample tracking.
- Initial Inspections are likely to centre on identifying policies and processes, examining documentation and methods of disseminating these. Full process audit (i.e. testing if these policies and processes are fully implemented) may become more dominant in the future.
 - Be aware of the conditions to your licence, both statutory and additional: have them at your finger tips.
 - Inspectors will spend a lot of time with DIs. Part of the scope of the Inspection is likely to be ensuring that the DI is able to fulfil their role on the licence (see below for more details).
 - The spirit in which Inspections are being conducted is that of that of offering advice on how licensed premises can become fully compliant with the conditions of their licence; the HTA Inspectorate is working with the community to support implementation.

In short, **be prepared, open and honest**. If you hear that your Unit is to be subject to Inspection by the HTA, please feel free to contact the MRC Regulatory Support Centre. We will offer you all the support we can.

What characteristics should a Designated Individual exhibit?

This is by no means an official, nor an exhaustive list of things to consider when accepting the role of DI. Rather it is a suggestion of some of the practical aspects of being an effective DI.

Delegation - Choosing the right team of Persons Designated is critical. You must involve them as much as possible in all policy and process developments and delegate tasks to them.

Communication – Not only do you need good personal communication skills, but also you must communicate effectively with Health and Safety staff, governance structures and senior management within of your organisation. A large part of your job will be to coordinate activities and ensure that the governance of human tissue remains high on the agenda of your organisation.

Flexibility – You must be willing and able to work flexibly; there will be times when your role as DI will get in the way of you doing ‘your day job’. It is important that your managers are aware of this and allow you the flexibility to manage what could be a complex set of changing priorities.

Time – Being the DI on a licence is not a trivial task, nor does it come to an end once you have submitted your Compliance Report. Depending on the size of your organisation, your role as DI may well amount to an average of 1 day per week, in particular over these initial years of implementation. You should consider discussing with your line manager whether your role as DI should be specified in your job description.

Training – Identify your own training needs and those of your Persons Designated. Ensure that they can be met and keep training logs. The HTA provide training for

DIs, which we would encourage you to attend. If you have difficulty finding appropriate training, contact the Regulatory Support Centre for help. We will work with you to either to find any available training or will endeavour to provide you with appropriate training to support you in your role.