**Guidance on retention period for study documentation**

1. **CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS (CTIMPS)**
   1. The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 makes the archiving of clinical trial documentation a legal requirement. The ICH GCP (Good Clinical Practice) Guidelines define and list all of the documents that are essential for the conduct of a clinical trial.
   2. EC Directive 2003/63/EC requires that essential documents be retained for at least fifteen years after completion or discontinuation of the trial or for at least two years after the last approval of a marketing application in the region.
   3. The Medicines for Human Use (Clinical Trials) Regulations require that the essential documents and medical files of trial subjects are retained for at least 5 yearsafter completion of the trial.
   4. For practical purposes, commercial trial documents are usually archived for a period of 15 years. The cost of archiving commercial studies should be recovered by UHBW and the archiving fees specified in the agreement between UHBW and the Sponsor.
   5. Where UHBW is the Sponsor, clinical trial documentation for CTIMPs will be retained for 15 years.
   6. The MHRA has no specific additional requirements for CTIMP trials in paediatric patients.  UHBW Health Records policy should be followed for the retention of medical records of paediatric patients, including records of the patient’s participation in the trial. The Records Management Code of Practice for Health and Social Care 2016 states that children’s records should be retained until the patient’s 25th birthday or, if the patient was 17 at the conclusion of treatment, until their 26th birthday.
2. **IMP FOR ADVANCED THERAPIES**

EU Guidance on GCP for Advanced Therapy Medicinal Products 2009 requires that study documentation must be kept for 30 years after the expiry date of the product, or longer if required by the MHRA.

1. **ARCHIVING – PROJECTS OTHER THAN CLINICAL TRIALS OF CTIMPs (NON-CTIMPs)**
   1. There is no legal requirement to archive documentation for non-CTIMPs. The Medical Devices Regulations 2002 do not include any express legal requirement to archive trial data gathered from clinical investigations of Medical Devices (ciMDs).
   2. However the ICH GCP Guidelines state that the same principles for CTIMPs *“may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects.”* The Guidelines state that *“the Sponsor or owners of the data should retain all of the Sponsor-specific essential documents pertaining to the trial.”* Joint guidance issued by the Department of Health and the MRC (Medical Research Council) recommends 5 years.
   3. In view of the above, it is therefore good practice to archive research documentation for all non-CTIMP studies.
   4. Where UHBW is the Sponsor of a non-CTIMP project, documentation should be retained for a period of 5 years following completion of the project, unless otherwise stated in essential trial documents. For some studies, a longer retention period may be required (e.g. clinical genetic studies or some interventional studies involving children). In such circumstances, the appropriate retention period should be determined on a case by case basis.