Archiving	Reporting results, peer review & Knowledge utilization - Archiving & Open data	
	VERSION	4.0

Aim
The correct archiving of research materials after a study has been completed, enabling reproduction and replication of the research and/or future use of research data

Responsibilities
Executing researcher:
- Should provide documents required for archiving

Project leaders:
- Ultimately responsible for correct archiving of the project*

Research assistant:
- Should provide documents required for archiving

** For longitudinal projects (with the exception of large longitudinal studies, such as LASA, Hoorn and AGGO), the project leader and executing researchers are jointly responsible for archiving extensive documentation to enable new researchers to continue the project (and reproduce previous results where applicable).*

Requirements
- At the end of a study, the executing researcher should provide the project leader with all the information required for archiving (see How To) and update the Data Management Plan accordingly.
- At the end of a study, the project leader needs to ensure the Data management department is consulted regarding filing and documentation policies. For WMO-studies the Clinical Montoring Center (at the location where the Principal Investigator is contracted) should be contacted (via intranet and/or Monitor on the study) regarding adequate storage of paper (including 'wet ink' signatures in) data files and documentation.
- No confidential, privacy sensitive information should be stored in the archived data. Stored information should not be directly traceable to individual people within a dataset, therefore a Subject ID log should be stored separate from the collected data (see SOP RDM001). Informed consent forms are allowed in the archive, after removal of the study number. Consent forms must be destroyed 5-30 years after the closure of the study, in consultation with the Data Protection Officer (DPO). The retention period may vary per type of research and should in general be kept for the same duration as main storage requirement for the type of study (nWMO: 5-15 years, WMO: 15-30 years depending on MDR/GCP/ATMP involvement). Contact the DPO (Functionaris Gegevensbescherming) for advice on storing or deleting privacy sensitive information, as both fall under data processing under the AVG/GDPR (AMC: Marleen Inge – fg@amc.nl; VUmc: Michel Paardekooper – privacy@vumc.nl).
- The storage of key files (Subject ID log) according to the different laws and regulations (see below).

- Internal Amsterdam UMC guidelines require , in line with NFU (Richtlijn Kwaliteitsborging mensgebonden onderzoek/ Guideline Quality Assurance for research involving human subjects), a storage duration for research data of at least:
    - 5-15 years for nWMO studies (to be determined in consultation with the DPO)
    - 15 years for other WMO studies
    - 25 years for research under GCP (investigational medicinal products)
    - 30 years for advanced therapeutic medicinal products
    - 15-X years for Medical Devices (depending on many factors, contact the MDR experts)

How To
What should be archived:

- One folder per project in general and subfolder for each (published) paper with: 1) final version of paper, 2) final dataset, 3) final syntax, any other information required to get from study set-up to results that were published, also called a 'replication package';
- Such (sub)folders should include all relevant:
- logbooks of the analyses;
- raw data in digital format
- relevant e-mail correspondence (including phone number and letter correspondence); This is easily achieved in Outlook by creating a separate personal file;
- all other relevant documentation for reproduction of your results.

WMO and WMO-GCP studies have to follow the archiving regulations that are obligatory for WMO and WMO-GCP studies.

Other documentation, and the electronic version of articles/reports, should be handed over to the project leader. Don't forget to also archive relevant e-mail correspondence. For Amsterdam UMC researchers: The Research Data Management Servicedesk and Clinical Monitoring Center can be consulted for proper storage of all data described in the SOP RDM001 and related Data Management Plan (Phase 5).

Key Files
A key file/ Subject ID log is a list coupling a code (study number, participant number, etc.) with the name and contact details of the study participant. The storage of key files is subjected to different regulations see comments for storage duration above.

- Consult with DPO/RDM/CMC regarding limiting risks of keeping such sensitive data. One protective measure can be: As soon as it is expected that the participants do not need to be approached for the aim of the study, only the digital version of the key file is destroyed, and a paper version is archived (locked cabinet). After approval of the DPO.

Non digital materials that need to be archived: Consult with CMC and/or RDM colleagues at your institute
The (encoded) original (raw) data recorded in a physical form.
Examples: Questionnaires transcripts, lab results and paper logbooks. If there are electronic versions of the original data, i.e. scanned questionnaires (images), then the paper versions should not be stored in the physical archive (unless specifically stated otherwise).

Storage period in physical archive
The standard storage period is 5 years from the moment the material is stored into the archive. Longer storage periods will require permission from the division, privacy-officer, RDM. Examples of

this would include longitudinal cohort studies and other studies which may be (potentially) followed up.

- More information Data Management VUmc can be found here (intranet)
- Research Data Management AMC (intranet)
- Website VUnet about datamanagement

Audit questions

1. Are any potential logbooks of the analyses, other documentation, and the electronic version of articles/reports in the project leader's possession?
2. Have the right materials been archived?
3. Is the guideline/SOP followed and is this documented and relevant info and access handed over to the project leader?
4. Has, if a report of the research results has not been completed in full, all the material relevant to the report been transferred (with handover meeting/documentation) to the project leader or another associated researcher?
5. Have the completed questionnaires been stored in the archive room?
6. Has the documentation for the longitudinal projects been handed over to the right person to enable a continuation of the project?

LINKS

	Link
NFU Richtlijnkwaliteitsborging	https://www.nfu.nl/themas/randvoorwaarden-wetenschappelijk-onderzoek/klinisch-onderzoek
AMC How to archive?	http://intranet.amc.nl/web/organisatie/domeinen/research/clinical-research-unit-cru/stappenplan/archivering.htm
VUmc archiving	https://intranet.vumc.nl/afdelingen-themas-1/clinical-monitoring-center/stappenplan-klinisch-onderzoek/afronding/5.-archivering.htm
VU Archiving	https://stsfed.login.vu.nl/adfs/ls?wa=wsignin1.0&wtrealm=https%3a%2f%2fvunet.login.vu.nl&wctx=https%3a%2f%2fvunet.login.vu.nl%2fServices%2f_layouts%2fAuthenticate.aspx%3fSource%3d%252Fservices%252Fpages%252Fpracticalinformation%252Easpx%253Fcid%253Dtcm%25253a164%252D414365%252D16
VU rules on archiving non-digital materials	https://stsfed.login.vu.nl/adfs/ls?wa=wsignin1.0&wtrealm=https%3a%2f%2fvunet.login.vu.nl&wctx=https%3a%2f%2fvunet.login.vu.nl%2fThemes%2f_layouts%2fAuthenticate.aspx%3fSource%3d%252Fthemes%252Fpages%252Fstandaard%252Easpx%253Fcid%253Dtcm%25253a164%252D414220%252D16
VUmc Data Management	https://intranet.vumc.nl/afdelingen-themas-1/datamanagement.htm
VUnet Data Management	https://stsfed.login.vu.nl/adfs/ls?wa=wsignin1.0&wtrealm=https%3a%2f%2fvunet.login.vu.nl&wctx=https%3a%2f%2fvunet.login.vu.nl%2fServices%2f_layouts%2fAuthenticate.aspx%3fSource%3d%252Fservices%252Fpages%252Fpracticalinformation%252Easpx%253Fcid%253Dtcm%25253a164%252D412089%252D16

Amsterdam Public Health

Amsterdam UMC University Medical Centers | VU Vrije Universiteit Amsterdam | University of Amsterdam

AMC Data Management Helpdesk	http://intranet.amc.nl/web/organisatie/domeinen/research/research-life-cycle/rdm-helpdeks.htm
AMC CRU SOPs	https://intranet.amc.nl/web/organisatie/domeinen/research/clinical-research-unit-cru/cru-home/sops-dm.htm
Eudralex GCP	https://ec.europa.eu/health/documents/eudralex/vol-10_en
Archiveren: van onderzoeksgegevens en van fysieke informatie - procedure VUmc	https://amsterdamumc.iprova.nl/iDocument/Viewers/Frameworks/ViewDocument.aspx?documentid=b792456b-b287-4856-aaaa-2a495b8a07f4&customcss=&HyperlinkID=441accb1-aa35-443b-9a60-adaea0ca719d&FromLogin=1

DOCUMENT HISTORY

Version	Status	Date	Name
4.0	Revision	11NOV2020	Amber Boots, Elize Vlainic
3.3	Links updated, AMC links added, GDPR added	31JUL2018	APH
3.2	Minor text adjustment; link to VU guidelines added	17OCT2016	EMGO
3.1	Minor text adjustments, addition handling key files	01APR2016	EMGO
3.0	Guideline rewritten; revision format	19JUN2015	EMGO
2.2	Addition reminder sending report to METc, revised opinion on storage of informed consents	31OCT2013	EMGO
2.1	English translation	01JAN2010	EMGO
2.0	Name of transfer modified in transfer and archiving. New rules for archiving, storage period from 10 to 5 years	04OCT2007	EMGO
1.1	Privacy added	31OCT2005	EMGO

DOCUMENT APPROVAL

Role	Name	Date
Project Leader	Dr. Seta Jahfari	21MAY2021