



# Five Safes RO-Crate: FAIR Digital Objects for Trusted Research Environments

## Document Version

Submitted manuscript

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## Citation for published version (APA):

Soiland-Reyes, S., Wheeler, S., Giles, T., Goble, C., & Quinlan, P. (2024). Five Safes RO-Crate: FAIR Digital Objects for Trusted Research Environments. Manuscript submitted for publication. In *International FAIR Digital Objects Implementation Summit 2024* TIB Open Publishing.

## Published in:

International FAIR Digital Objects Implementation Summit 2024

## Citing this paper

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# Five Safes RO-Crate: FAIR Digital Objects for Trusted Research Environments for Health Data Research

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Trusted Research Environments (TREs) are secure locations in which data are placed for researchers to analyse. TREs can be set up to host administrative data, hospital data or any other data that needs to remain securely isolated. It is hard for a researcher to perform an analysis across multiple TREs, requesting and gathering the data needed from each one. Federated analysis widens the scope of research and makes more effective use of data, but that data needs to be analysed across geographical or governance boundaries, for example in devolved healthcare in the UK and across national borders in Europe.

A federated infrastructure makes it much easier for analysis tools to access multiple TREs. Health Data Research UK (HDR UK) (<https://www.hdruk.ac.uk/>) is developing a blueprint for TRE federation [1] and tools for federated data discovery. There are different ways of implementing the well-established TREs, and many popular analysis tools already in widespread use, so solutions need to be readily adoptable by existing systems. Moreover, the infrastructure needs to work within the “Five Safes” framework [2] that aims to protect data and enable data services to provide safe research access to data.

RO-Crate [3] is a community effort to establish a lightweight, native approach to packaging research data with their metadata. It has become a widely adopted framework for inter-service exchange, resource archiving, and reproducible reporting, used by digital research infrastructures and their services. It is an implementation of the FDO Forum’s FAIR Digital Objects.

The HDR UK, through TRE-FX project (<https://trefx.uk/>), has developed the “Five Safes RO-Crate” [4] as a new way of packaging up the digital objects needed for research requests and results with the information needed for the tools and TRE providers. Five Safes RO-Crates enable the exchange of query requests and results between analysis clients and TREs while ensuring that the access is safe and the process transparent. Included within its specification are eight steps that ensure that the RO-Crate’s metadata for safe data, safe people, safe projects, safe settings and safe outputs are reviewed according to Five Safes principles. The Five Safes RO-Crate Profile builds on the Workflow-Run-RO-Crate (<https://www.researchobject.org/workflow-run-crate/>), first developed in the EU EOSC-Life project, effectively making them a representation of trusted workflow provenance.

The approach has been piloted with TREs from Scotland, Wales and England and implemented by two widely used analysis toolkits (DataSHIELD, BitFount). Five Safes RO-Crates will be a pillar of HDR UK’s ongoing Federated Analytics development.

## References

- [1] DARE UK, “Federated Architecture Blueprint”, 2023, <https://dareuk.org.uk/our-work/federated-architecture-blueprint/>
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