#InvestEUresearch

Horizon 2020 Work Programme for Research & Innovation 2018-2020

Horizon 2020 'Health, demographic change and wellbeing'

Open Research Data Pilot

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Research and Innovation

Introduced with H2020 as part of Open Science and Open Access policies

Open access to research data: right to access and re-use research data

Opening up research data has the potential to

- improve the quality of scientific results
- avoid unnecessary duplications
- involve societal actors
- and significantly contribute to economic growth (through open innovation)

The H2020 ORD pilot aims to improve and maximise access to and re-use of research data generated by Horizon 2020 projects

The ORDP takes into account the need to balance openness and protection of scientific information, commercialisation and IPR, privacy concerns, security as well as data management and preservation questions.

As of 01 January 2017 the ORDP is applicable by default to Health research H2020 funded projects

European Commission

Legal basis: Art. 29.3 of the H2020 MGA

Art. 29.3 – extract

[OPTION 1a for actions participating in the Open Research Data Pilot: Regarding the digital research data generated in the action ('data'), the beneficiaries must:
(a) ***deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user*** *— the following:*
(i) the ***data, including associated metadata, needed to validate the results presented in scientific publications****, as soon as possible;*
[…]
(iii) ***other data, including associated metadata, as specified and within the deadlines laid down in the 'data management plan'*** *(see Annex 1);*
(b) ***provide information — via the repository — about tools and instruments*** *at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves)*

Legal basis: Art. 29.3 of the H2020 MGA – PHEs (1)

Recent change to this Article (18/10/2017): *'Open access to research data' to provide for third party access to research data in health actions in cases of* ***public health emergencies****"*

[…] (ii) [OPTION A for ***health actions that participate in the Open Research Data Pilot, if foreseen in the work programme****:* ***data which is relevant for addressing a public health emergency****, if specifically requested by the [Commission][Agency] and within the deadline specified in the request][OPTION B: not applicable];*

Legal basis: Art. 29.3 of the H2020 MGA – PHEs (1)

Rationale: acquire and share relevant research data as rapidly as possible for the most adequate and timely public health response.

Only for health-related research projects identified as generating relevant data for addressing a PHE, the European Commission may request the Consortium

- the timely open access or, exceptionally,
- the granting of special access rights to third parties who need the data for addressing the emergency

In health-related research projects targeting PHEs, the beneficiaries must provide open access to the relevant research data

- at the latest within 30 days after they have been generated or, exceptionally,
- the European Commission may agree on the granting of special access rights to third parties who need the data for addressing the emergency

Case-by-case assessments between the European Commission and the Consortium will be carried out in order to identify specific conditions (e.g. substituting open access obligation with special access rights for third parties, identification of data relevant to address the PHE, identification of third parties needing the data, etc.).

European Commission

ORDP: which data is concerned

The following data is concerned

- Data **underlying scientific publications** unless appropriately **anonymised** and complying with **data protection rules**
- Additional data **defined and agreed by the consortium in the data management plan (DMP)** (avoiding potential IP and confidentiality infringements)

The following data is not concerned

- Any type of **data prior to publication** (unless otherwise agreed upon by the consortium)
- **Raw/individual patient data (IPD)** unless appropriately anonymised and compliant with data protection rules

Data Management Plans (DMPs) (1)

Participation in the ORD pilot is **not part of the evaluation of proposals**

"[…] However, good research data management as such should be addressed under the impact criterion, as relevant to the project"

A DMP should include information on

- the handling of research data during and after the end of the project
- what data will be collected, processed and/or generated which methodology and standards will be applied
- whether data will be shared/made open access and
- how data will be curated and preserved (including after the end of the project)

Data Management Plans (DMPs) (2)

DMP template: provided in Annex I [of the H2020 FAIR Data Guidelines]

DMP - a 'living' document "[…] *Since participation in the ORD pilot is not an evaluation criterion, the proposal is not expected to contain a fully developed DMP"*

Costs related to ORDP are eligible for reimbursement (Article 6 and Article 6.2.D.3, but also other articles relevant for the cost category chosen)

Guidelines on FAIR Data Management in Horizon 2020

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/open-access-data-management/data-management_en.htm

Annotations specific for health research projects will be available in the H2020 Participant Portal

'As open as possible, as closed as necessary' (1)

Art. 29.3: *"As an exception,* ***the beneficiaries do not have to ensure open access to specific parts of their research data*** *under Point (a)(i) and (iii), if the achievement of the action's main objective (as described in Annex 1) would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access."*

Opt-out possibilities

- during the application phase
- during the grant agreement preparation (GAP) phase and
- after the signature of the grant agreement

Reasons for opting out

- Obligation to protect results
- Security obligations
- Protection of personal data
- Project does not collect/generate data
- Other legitimate reasons

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'As open as possible, as closed as necessary' (2)

Opting out is possible for concrete and well-justified reasons

BUT

- It concerns data underlying publications => results need to be protected *before* publication => generally no conflict with obligation to protect results
- It does not concern non-anonymised patient data => generally no conflict with data protection rules

THEREFORE

- **for SC1 projects generally no reason to opt-out**
- *If* there is a reason to opt-out this must be specifically explained and not just refer to the obligation to protection personal data or results

Thank you!

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