

Output Review Process v2.1

	Role	Date
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Reviews	Reviewers from SAIL, Aridhia, HDR UK, ICODA, BMGF	v1.3 – v1.8 from July-Sept
Final review & publication		v2.0
ICODA review and publication		v.2.1 March 2022

ICODA has committed to the 'Five Safes' Framework



Safe projects

Is the use of data appropriate?



Safe data

Is the risk of disclosure in the data minimised?



Safe people

Can users be trusted to use the data in an appropriate manner?



Safe settings

Can data be accessed in a Trusted Research Environment?



Safe outputs

Are there disclosure risks from reported results?

Purpose of the Output Review Process

ICODA expects a high standard of accountability from researchers, and the Output Review process is part of this expectation

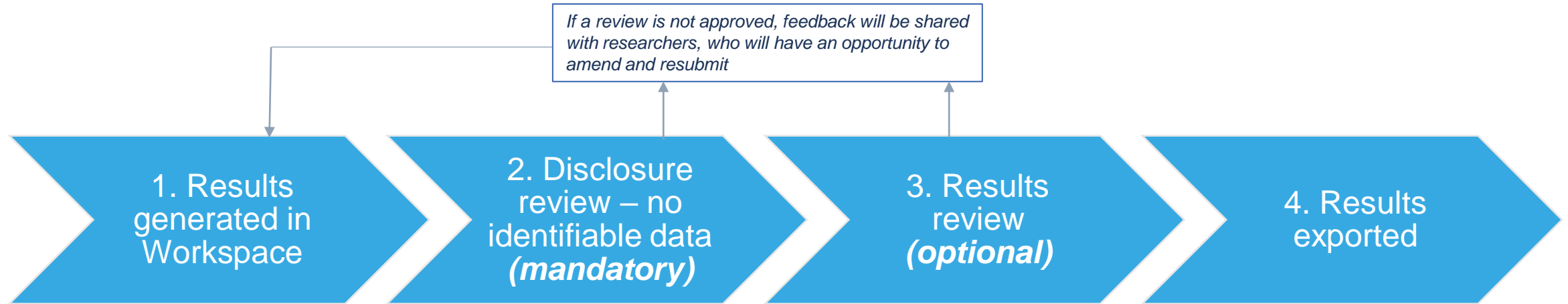
Purpose:

1. To ensure Safe Outputs, i.e. ensure there are no disclosure risks from output generated and exported from the Workbench
 2. To validate scientific integrity of results (as required)
- This document outlines the different levels of output review, review elements and who is responsible

Output review comprises two components:

- **Disclosure review** – review and remediate potentially identifiable information - conducted in researcher's Workspace
- **Results review** – ensure scientific integrity and reassure data contributors – potentially conducted in separate Workspace/s

Output Review Process



Responsible

Researchers

Mandatory:
PI / Workspace Admin*
If required:
**ICODA/
 Stats Expert Group**

**Stats Expert Group/
 External Reviewers/
 Community Reviewers/
 Data contributors**

- No individuals identifiable in results (e.g. no names, DOBs, addresses, telephones, email addresses, patient identifiers or other unique identifiers)
 - Should consider any linkage that may be possible from results with other data sets
- *PI to submit measures undertaken to minimise disclosure to ICODEA*

- Check results are sound (no unexplained anomalies)
 - Under exceptional circumstances:
 - Recreate Workspace with data, models & tools
 - Re-run analysis
 - Check results match those awaiting output
- Irrespective of whether this step is requested, the PI retains responsibility for scientific integrity of results*

2 weeks for Disclosure review; 2 further weeks if Results review required

2. Worked example for Disclosure Review only



The following steps are envisaged:

- Researcher requests Workbench airlock
- PI / Workspace admin does disclosure review check and, if satisfactory, informs ICODA
- If required, PI / Workspace admin requests further external disclosure check by ICODA or SEG member
 - ICODA identifies and designates appropriate ICODA or SEG team member to perform the external disclosure review
 - ICODA informs PI / Workspace admin who to invite into the Workspace airlock
 - External disclosure review is performed by responsible ICODA or SEG member
- If no identifiable elements are found
 - Review is completed and logged [see chart 13]
 - Reviewer informs ICODA that review is complete with no issue
 - ICODA authorises PI / Workspace admin to allow airlock export
- If identifiable elements are found:
 - Review is completed and logged [see chart 13]
 - Reviewer informs ICODA
 - Research team informed of issues by ICODA and asked to remediate
 - Process repeats

**In a Federated analysis scenario, additional Disclosure checks may be performed by the Data custodian before analysis results are returned*

When is an external Disclosure Review required?

- The Disclosure Review step is undertaken to ensure Safe Outputs, i.e. ensure there are no disclosure risks from output generated and exported from the Workbench
- The PI Research Lead/Workspace admin is responsible for Disclosure review in most cases
- The external Disclosure Review step is taken when:
 - Mandated by the Data Contributor
 - Recommended by the Expert Review Panel who reviewed original project proposal, due to:
 - Access to sensitive / controversial data
 - Sample size, rarity of events, geographic area, availability of other data than could be linked to re-identify individuals etc
 - Requested by the PI / Research Lead, with rationale

Who performs an external Disclosure Review?

- The external Disclosure Review step may involve one or more, or combinations of:
 - ICODA personnel
 - Stats Expert Group reviewer(s)

3. Worked example for Results Review



As per 2. Disclosure review, then additionally, the following steps are envisaged:

- ICODA/PI identifies Results review is necessary* or has been requested
- If required, PI adds external reviewers to the existing Workspace.
- If results recreation required (extremely exceptional):
 - ICODA informs Aridhia Results review is necessary, specifying Workspace(s) required for the review & their members*
 - Aridhia arranges provisioning of review Workspace(s), transfer of data and methods to review Workspace(s) working with PI
 - Reviewer(s) invited to review Workspace(s)
- Results Review performed by Reviewer(s)
- If results are acceptable
 - Review is completed and logged [template issued on request]
 - Reviewer(s) inform ICODA
 - ICODA authorises Aridhia to allow airlock export
- If adjustments are required
 - Review is completed and logged [template issued on request]
 - Reviewer(s) inform ICODA
 - Research team informed and asked to make changes
 - Process repeats

*See chart 8

When is a Results Review required?

- The Results Review step is undertaken to ensure research is robust and high quality
- The PI Research Lead is responsible for reviewing their own results in most cases
- The Results Review step is taken when:
 - Mandated by the Data Contributor
 - Recommended by the Expert Review Panel who reviewed original project proposal, due to:
 - Access to sensitive / controversial data
 - Sample size, rarity of events, geographic area, availability of other data than could be linked to re-identify individuals etc
 - Potential to generate controversial results
 - Requested by the PI / Research Lead, with rationale

Who performs a Results Review?

- The Results Review step may involve one or more, or combinations of:
 - Data Contributor reviewer(s)
 - Stats Expert Group reviewer(s)
 - External reviewer(s)
 - Open Community Reviewer(s)

Guidance

Standards for Researchers

ICODA expects a high standard of accountability from researchers, and the output review process is in addition to this expectation

- Researchers are responsible for safe outputs
- Researchers must be ICODA accredited and have completed their onboarding training
- Researchers must check data and outputs to ensure they are safe and in line with project approval
- Researchers must provide documentation for reviewers to understand outputs
- Researchers should minimise Results Review requests
- Researchers are responsible for ensuring they follow any requirements Data Contributors have set when access was granted to the Data.

Instructions for PIs/Workspace admins performing Disclosure Reviews

Send an email to: international.alliance@hdruk.ac.uk

Email Title: Disclosure review – Output

Please include in the email:

- Your Project Name:
- Your Project Lead:
- Date of review:
- Who performed the review:
- Please detail the checks undertaken:
- Any concerns or comments:
- Please confirm that the output contains no identifiable data: Yes/No

[See slide 13 for more details](#)

Output Review Standards for Reviewers

- Reviewers are responsible for only releasing results they understand and have confidence are not disclosive
- Results should be reviewed in a timely manner to ensure optimal benefits from data
- Reviewers are responsible for clarifying issues to understand Results Review request
- Rejected Results Review requests require clear explanation
- Output Reviews will be conducted by a minimum of 2 reviewers
- Each reviewer is expected to conduct an independent review in keeping with guidance
- If reviewers disagree, a senior reviewer will review and aim to reach agreement. Results will be exported when all reviewers agree it is a 'safe output'.

Disclosure Review

Reviewers' standards & checklist

Analysis approach

- Is in line with project approval and data sharing agreements
- Performed within the ICODA Workbench – only results have been exported

Data Checking & Disclosure Control

- No data or Individual-level data exported
- Cells analysed shall not contain a value less than 5
- Zero is not permitted where there is potential for disclosure
- Maximum or minimum values are not permitted where there is potential for disclosure related to outliers associated with single individual
- Graphs and other visualisations are subject to the same criteria as numeric results, where exact values can be determined
- Nothing that could be used for performance tracking of individual organisations is permitted

Data Contributor requirements

- Ensure data contributor attributions and restrictions are met

Results Review

Reviewers' standards & checklist

As for Disclosure review with additional steps:

Results check

- Results inspection – check for obvious anomalies, unexplained or spurious results
- Re-run analysis on obvious anomalies, unexplained or spurious results
- Run spot check analysis
- Double check research question results are answered
- Ensure sensitive results are correct and robust

Facilitate PI engagement with data contributors

- Appraise data contributor of potential controversy or sensitivity on publication
- There is a sense check with and validation from the data contributor pre-publication

Checks should be aligned with [SDC Handbook \(securedatagroup.org\)](https://www.securedatagroup.org/)