

# Output Review Process v2.1

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	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

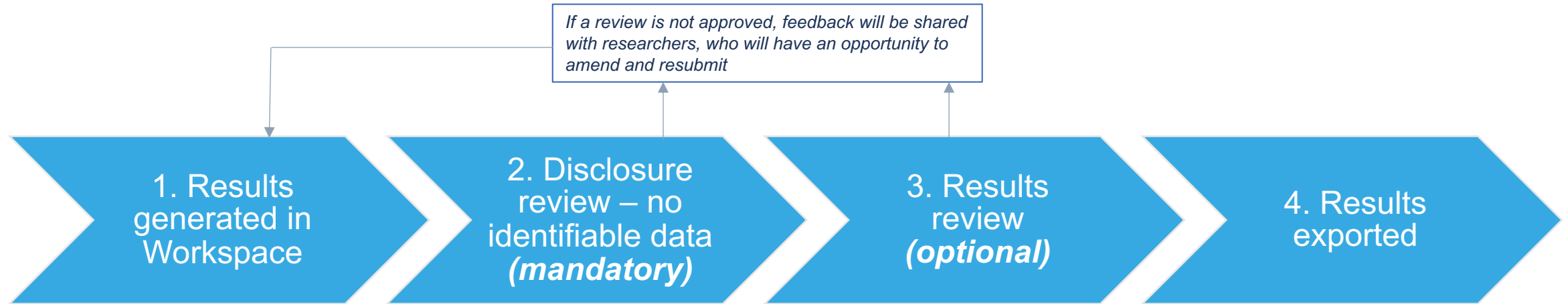
Purpose:

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 ICODA*

- 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](mailto: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/)