



Approvals Panel

Operating Procedures

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Scope

The Approvals Panel (AP) assesses if a project proposal meets the criteria to be granted access to administrative, linked, de-identified data. It will make sure the process of granting access to sensitive linked administrative data is seen to be fair and transparent.

This document outlines how the Approvals Panel operates to fulfil its Terms of Reference and how it interacts with other elements and stakeholders within the ADRN and outside. See also the Panel's Terms of Reference in the *ADRN014-AP Terms of Reference* document.

Definition of Terms

See ADRN018 Glossary for a list of definitions
(<http://www.adrn.ac.uk/get-data/documentation/>)

1. Background

1.1 The Approvals Panel (AP) is established to ensure that there is a transparent process for independently assessing and approving ADRN project proposals.

1.2 The AP helps ensure that academics and other researchers perceive ADRN as a level playing field with no privileged access, and provides data owners with expert assessment of projects to minimise their burden in processing applications for data access and linkage.

1.3 It also contributes towards minimising the perception of risk among members of the public by reassuring them that there is an expert, impartial, body overseeing projects applying to access sensitive administrative data to ensure that they are suitable, ethical and in the public interest.

1.4 All research projects wishing to use ADRN facilities and services to access data whether from academics, government researchers, or researchers from other accredited organisations, will have to be approved by the Approvals Panel.

1.5 The purpose of the group is to review all formal proposals for access to data through the Network and recommend whether they should be approved as ADRN projects and to report to the ADRN with their decision.

2. Procedure

2.1 After the initial contact, and the preliminary eligibility checks (e.g. that the project meets the definition of an ADRN project), ADRN will send the relevant application documents and procedures to researchers who are eligible to apply. ADS will also assign a unique number to each proposed project.

2.2 The researcher will submit their project proposal to ADRN including any relevant supporting documents such as the corresponding ethical review application and result.

2.3 ADS will maintain a central record copy of all project applications and documents relevant to the AP.

2.4 ADRN will consider the information on the project proposal form and, in consultation within the Network when necessary, will produce reports on the project's feasibility and any privacy impact.

2.5 ADS will compile the following information in an AP submission portfolio, ready to circulate to the AP:

- a. the project proposal document (including any relevant supporting documentation submitted by the applicant)
- b. Approvals Panel Submission Portfolio cover document
- c. feasibility report: ADRN will provide comments on the project's feasibility, based on the "Criteria for assessing feasibility" (see ADRN010, ADRN Feasibility Report Template).
- d. ethical review documentation: ADRN will report on whether the project proposal has already undergone ethical review and will append any supporting documentation to the Approvals Panel Submission Portfolio.

- e. privacy impact assessment: ADRN will provide information relevant to privacy issues related to the project.

2.6 ADS will act as a secretariat to the Panel and will circulate the submission portfolio at least 5 working days in advance of the panel's meeting, to be taken into account by the Panel when making decisions.

2.7 Arranging for ethical review of projects will be the responsibility of the lead researcher.

2.8 The initial assessment of the feasibility and privacy implications of a project will be the responsibility of the ADRN, drawing on advice and expertise from across the network and in consultation with data owners.

2.9 ADS may seek to add an item to the agenda as an emergency item. An emergency item can only be one which could not have been foreseen 10 working days in advance of the meeting and which must be resolved before the next scheduled meeting.

2.10 Occasionally, it may be appropriate to deal electronically with an urgent item which needs to be resolved before the next scheduled meeting. The permission of the Chair to do this must be sought in all cases. If permission is granted, ADS will circulate the documentation relating to the item by e-mail and will request responses by a specified date and time. After the deadline has passed, ADS will inform the Committee, by e-mail, of the outcome of the discussion. The outcome will be noted in the minutes of the next scheduled meeting.

2.11 The Approvals Panel's membership, frequency of meetings and meeting arrangements are noted in the Terms of Reference (ADRN014).

2.12 The Panel will consider each application and will review each ADRN project proposal on the following criteria:

- a. **ethical review:** the Panel will decide if they are satisfied with the evidence provided that a project proposal has undergone an appropriate ethical review, and that the researchers have satisfactorily addressed any issues arising from the review.

The Panel will consider projects which have not yet completed Ethical Review if the Lead Researcher has applied, or made reasonable arrangements, for their project to be reviewed by an appropriate institutional Research Ethics Committee (or equivalent alternative arrangement).

Any project proposals that are approved by the Panel which have not received ethical approval before they are submitted to the Panel, will be Approved – Subject to Satisfactory Completion of Ethical Review. It will be necessary for the Panel to confirm satisfactory completion of ethical review has occurred before the researcher(s) accesses data in an ADRC.

In cases where a project has been Approved – Subject to Satisfactory Completion of Ethical Review; when Ethical Review is complete, the Panel members will be sent a confirmation email, with the Ethical Review application and outcome documentation attached, to consider and respond within 7 days indicating that they either have 'No Concerns' or outlining any concerns they identify with the Ethical Review decision. If concerns are identified the researcher will be asked to provide clarification, once a response is received the project will be scheduled for discussion at the next Panel meeting. If no concerns are identified the project will be approved.

If a member of the Approval Panel does not offer a response they will be sent reminders by email and by telephone. If a response is still not forthcoming the project will be referred to the Approval Panel chair for a final decision on behalf of the Panel.

If the outcome of an Ethical Review results in significant change to the project proposal, the project application would need to be amended accordingly and may need to be reconsidered by the Panel.

- b. **privacy impact:** The Panel will decide if they are confident that any potential privacy issues has been assessed and reported appropriately and addressed satisfactorily and will consider whether the potential public benefit offered by the project outweighs the potential privacy impact.
- c. **feasibility:** the Panel will review the information presented and consider whether they feel that it is feasible for the project to proceed as an ADRN project
- d. **scientific merit:** the Panel will decide whether the project is of sufficient scientific merit to warrant the use of ADRN resources.
- e. **public benefit:** the Panel will decide if the project has potential to be of sufficient benefit to society to warrant the use of ADRN resources, and to outweigh any potential privacy impact.

2.13 The panel will consider each application submitted and, by considering the above criteria, will make a decision. The following decisions are available to the Panel:

- a. Approved
- b. Approved with comments
- c. Approved subject to adoption of minor changes
- d. Approved subject to discussion with nominated Panel member and (if relevant) adoption of minor changes
- e. Substantial changes required - resubmission to future meeting requested
- f. Rejected

The processes applying to each of the above decisions are detailed in Appendix 1.

The Panel may also agree to nominate the Chair to make decisions by Chairs Action.

2.14 To inform these decisions the AP may ask the ADS to approach anyone on a list of experts that will be administered by the ADS. After the initial consultation, the AP may also request further expert views before concluding their review.

2.15 Where resubmission is requested proposals will be reconsidered at the next available meeting, once changes have been made to the proposal.

2.16 ADS will record the decisions of the Approval Panel, and any comments made, and will circulate minutes to the Panel members for Approval. Minutes will be circulated to Panel members as soon as practicable after the Panel meeting, Panel members will have 48 hours within which to respond with any corrections or amendments, after which the minutes will be considered approved.

2.17 ADS will inform the researcher of the Approval Panel decision as soon as practicable.

2.18 If the project proposal has been **Approved**, ADS will notify the lead researcher of the Panel's decision, including any comments and inform them of the next steps. If significant changes to a project are requested by a researcher following Approval the Panel reserves the option to require reconsideration of the revised proposal by the Approval Panel.

2.19 If the AP **refers the project to an expert**, ADS will inform the lead researcher of the Panel's decision and the subsequent process. ADS will also notify the appropriate expert with information about the project proposal and the topic on which the AP would like further advice. The expert will have 3 working days to confirm if they can help and will then have up to 10 working days to provide the information the Panel has requested. The expert will then send the information to ADS who will make the information available to the Panel for their consideration.

2.20 If the project proposal has been **rejected**, ADS will notify the lead researcher about the Panel's decision and the reasons for rejection, as well as about how to appeal if they wish.

2.21 Grounds for appeal: An appeal can be considered, if the researcher has provided evidence that:

- the assessment was not conducted in accordance with the ADRN policies and procedures;
- some other material irregularity related to the assessment process has occurred.

Appeals against the academic or professional judgement of the Approvals Panel will not be considered.

2.22 Process for appeals: The researcher must notify the ADS that they intend to appeal within 10 working days of receipt of the Approval Panel's decision. The appeal must be submitted within 4 weeks of the receipt of the decision and should be acknowledged within 10 days of receiving the appeal.

2.23 A two-stage process for reviewing appeals will follow consisting of an initial scrutiny stage and then, if progressed, a formal appeals stage.

2.24 First, appeals will be subject to an initial scrutiny and additional background information might need to be gathered. This stage is to ensure that the appeal is made on the grounds indicated earlier with appropriate evidence in place. Appeals that are not made on grounds as specified (e.g. contesting the academic expertise of the panel), or not made within the time frame specified, they will be rejected at this stage and no further appeal can be made for this decision.

2.25 Appeals that are made on the grounds specified with evidence and within the specified time frame, will proceed to a formal appeal's stage.

- At this second stage, the appeal will be forwarded to an Appeals Panel. The ADS will inform the Chair of the ADRN Board who will convene an Appeals Panel consisting of 2 members of the Board, and a representative of the ESRC.
- The Appeals Panel will convene a meeting three weeks after the submission deadline for the appeal.
- In reaching a decision the Appeals Panel will have access to all documents seen and produced by the Approvals Panel. The Appeals Panel may also draw on any relevant expertise in reaching their decision.

2.26 The Appeals Panel will take its decision to the Board. The Board will aim to provide a full response within 5 working days after the first meeting of the Appeals Panel, provided that submission is no later than 21 days in advance of the meeting. Where a full response is not possible within this timeframe the researcher will be contacted with an update on progress and an estimate of the time it will take the Board to come to a decision.

2.27 The Board's judgement is final and cannot be subject to further appeal.

3. Appendix 1

Approval Panel decisions: Immediate actions and Next Steps

Panel decision	Immediate actions required	Next steps
<p>1. Approved (Panel discuss project, agree to approve, have no comments to make to the applicant)</p>	<p>ADS confirm to applicant that project is approved (written confirmation provided)</p> <p>Panel no action required</p> <p>Applicant no action required</p>	<p>Project proceeds through ADRN processes with no further reference to the Approval Panel</p>
<p>2. Approved with comments (Panel discuss project, agree to approve, agree they wish to make some comments to the applicant)</p>	<p>Panel agree specific comments which they wish to make to the applicant*</p> <p>ADS confirm to applicant that project is approved and provide the comments</p> <p>Applicant no action required</p>	<p>Project proceeds through ADRN processes with no further reference to the Approval Panel</p>
<p>3a. Approved subject to adoption of minor changes</p> <p>(Panel discuss project, agree there are minor issues that require minor amendment, agree these are sufficiently minor that they could be resolved by the applicant)</p>	<p>Panel agree specific minor changes which they wish the applicant to make to the project</p> <p>ADS confirm to applicant which changes are requested</p> <p>Applicant to consider changes and confirm their agreement.</p> <p>ADS confirm to applicant that project is approved</p>	<p>Project proceeds through ADRN processes with no further reference to the Approval Panel.</p>
<p>3b. Approved subject to discussion with nominated Panel member and (if relevant) adoption of minor changes</p> <p>(Panel discuss project, agree there are minor issues which require clarification and identify issues that <u>may</u> require minor amendment, agree these are sufficiently minor that they could be resolved by the applicant following a</p>	<p>Panel agree which member will conduct a phone call with the applicant</p> <p>Nominated Panel member to record relevant issues for discussion</p> <p>Nominated Panel member to make direct contact with the applicant (ADS to provide contact details if requested) within 5 working days to arrange phone call.</p> <p>Nominated Panel member to conduct phone call with lead applicant – discuss the points – decide whether to recommend approval, rejection or substantial changes.</p>	<p>Nominated Panel member circulates email update (with a subject line making clear a response is needed) to remaining Panel members within 1 working day of phone call – including recommendation (approve/reject/require a resubmission.)</p> <p>Remaining Panel members indicate within 1 working day whether they:</p> <ul style="list-style-type: none"> a) Agree with the recommendation made b) Do not agree and therefore require the project be scheduled for discussion at the next available meeting.

<p>discussion with a Panel member)</p>		<p>Non-response by a panel member will be considered as agreement.</p>
<p>4. Substantial changes required resubmission to future meeting requested</p> <p>(Panel discuss project, agree there are substantial changes required, without which the Panel cannot approve the project)</p>	<p>Panel agree, in writing, the specific reasons for the substantial changes required, if appropriate indicate the changes they believe need to be adopted</p> <p>ADS confirm to applicant that project requires resubmission and provide the written feedback</p> <p>Applicant revises application and resubmits to a future Panel meeting</p> <p>OR</p> <p>Applicant addresses the specific points which require changes and produces a response to the Panel</p>	<p>Panel reconsider the project.</p> <p>Panel consider whether the response addresses the reasons that substantial changes were required</p>
<p>5. Rejected</p> <p>(Panel discuss the project, agree that it should be rejected as it does not meet the approval criteria/cannot reasonably be amended to meet the approval criteria.</p>	<p>Panel agree, in writing, specific reasons for the rejection, identifying specifically which of the 5 criteria for Approval have not been met.</p> <p>ADS confirm to applicant that the project has been rejected and provide the written feedback</p>	<p>Applicant may utilise the Approval Panel appeal process.</p>

NB: If significant changes to a project are requested by a researcher the Panel reserves the option to require reconsideration of the revised proposal by the Approval Panel.